OFFICE OF SPECIAL MASTERS

No. 02-667V V

(Filed: July 30, 2004)

JAMES NICKELSON Petitioner(s), v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	*	**TO BE PUBLISHED**

Jack Gage, Richard Gage, Cheyenne, WY, for petitioner.
Julia W. McInerney, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION

On June 11, 2002, petitioner sued on his own behalf under the National Childhood Vaccine Injury Act of 1986[1] (hereinafter the "Vaccine Act" or the "Act"), alleging that a tetanus vaccination

[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.

significantly aggravated his preexisting psoriatic arthritis and osteoarthritis and caused his Parkinson's disease. Petitioner filed an amended petition on February 23, 2004, alleging that a diphtheria/tetanus booster caused him to have a Table brachial neuritis, scleroderma, and Parkinson's disease. His allegations changed once more to tetanus vaccine causing him to have a Table brachial neuritis and a Parkinson-like disease. He dropped scleroderma from his allegations and did not pursue the allegation that tetanus vaccine caused him to have sclerodactyly.

Petitioner has satisfied the requirements pursuant to 42 U.S.C. § 300aa-11(c) of showing that: (1) he has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine injury; and (2) he received tetanus vaccine in the United States.

A hearing was held on May 12, and 13, 2004. Testifying for petitioner were James Nicholson, Mona Roque, a nurse practitioner, Dr. Richard Sauer, petitioner's neurologist, and Dr. Kenneth B. Wiesner, petitioner's rheumatologist. Testifying for respondent were Dr. Alan I. Brenner, a rheumatologist, and Dr. Arthur P. Safran, a neurologist.

FACTS

Pre-vaccination records

James Nickelson was born on August 21, 1952.

On January 20, 1999, Mr. Nickelson visited **Dr. Roy M. Harris** with a complaint of chest congestion and cough. He had **stiffness in his joints for years**, and wanted to see a rheumatologist. Med. recs. at 48C.

Mr. Nickelson visited **Dr. Kenneth B. Wiesner**, a rheumatologist, on April 16, 1999, who noted that Mr. Nickelson had **psoriasis** for about 30 years, involving his elbows, back, legs, knees, buttocks, and genitals. He had noted some increasing thickness of his psoriasis over the years and

developed joint pain in his hands, hips, ankles, and knees primarily, with a little pain in his back and neck. Mr. Nickelson's joints got stiff and sore. He had stiffness in his neck, shoulders, and low back. He had **Raynaud's disease** and he fatigued easily. He had a history of ringing in his ears and numbness and tingling in his hands. On physical examination, Dr. Wiesner wrote that Mr. Nickelson had joint changes consistent with **osteoarthritis**. Med. recs. at Ex. 10, pp. 1, 2. Joint examination revealed crepitus with range-of-motion of his neck, osteoarthritis deformities of his hand joints, crepitus with range-of-motion of his knees, some decreased range-of-motion of his hips, and osteoarthritic changes of his feet. Med. recs. at Ex. 10, p. 2.

Also on April 16, 1999, Mr. Nickelson had x-rays of his lumbar spine, bilateral hands, cervical spine, bilateral knees, bilateral feet, and pelvis. His lumbar spine x-ray showed low-grade degenerative disc disease at the L4-5 and L5-S1 levels with mild retrolisthesis at L4-5 and mild spondylolisthesis at L5-S1. His hands showed minimal bony spurring of his joints. His cervical spine was negative. Med. recs. at Ex. 10, p. 3. His knees and pelvis were normal. His feet showed mild degenerative osteoarthritis of his joints. Med. recs. at Ex. 10, p. 4.

On July 1, 1999, Mr. Nickelson returned to Dr. Wiesner. He had small bilateral knee effusions. Med. recs. at Ex. 10, p. 5.

On August 25, 1999, Mr. Nickelson saw nurse practitioner Mona Roque (who works for Dr. Harris), with complaints of right leg pain and swelling. He said that, three weeks prior, he had right leg pain and pain in his joints which was worse when he sat. His right hip, knee, and ankle were the worst. He was diagnosed with **psoriatic arthropathy**. Med. recs. at 48B.

On September 16, 1999, Mr. Nickelson saw Dr. Wiesner again, complaining of increasing discomfort in his right hip. Med. recs. at Ex. 10, p. 6.

On September 22, 1999, Mr. Nickelson received a tetanus vaccination. Med. recs. at 47V. He had an x-ray done of his pelvis, knees, and lateral lumbar spine. The pelvis and knees were unremarkable. His L5-S1 showed **spondylitic spondylolisthesis** with mild disc space narrowing at L4-5 and L5-S1. Med. recs. at Ex. 11(b), p. 51.

Post-vaccination records

Mr. Nickelson returned to Dr. Wiesner one week later, on September 29, 1999, and told him that he developed increased pain in his right shoulder and anterior chest wall after his vaccination. On physical examination, Dr. Wiesner found that Mr. Nickelson had pretty good range of motion of his right shoulder. Med. recs. at Ex. 10, p. 7.

In October 1999, Mr. Nickelson had an x-ray of his right shoulder because of pain for two weeks. There was no acute osseous abnormality, and minimal arthrosis of the AC joint. Med. recs. at Ex. 11(b), p. 52.

On October 27, 1999, Mr. Nickelson saw nurse practitioner Roque, saying that he woke up a week before and his right shoulder hurt. He was driving on Saturday (Oct. 23rd) when it started to hurt. He had no history of injury, trauma, or past injury. He had no repetitive movement lately. He had a longstanding history of psoriatic arthritis.[2] On examination, Mr. Nickelson had a full range of motion with discomfort. His grips were symmetrical at 4/4. His DTRs (deep tendon reflexes)

[2] "Psoriatic arthritis, a chronic spondyloarthropathy, occurs in 7-42% of patients with active psoriasis,... with most recent investigations pegging this close to 30%. Clinical manifestations of psoriatic arthritis include joint inflammation, enthesitis, dactylitis, and psoriatic skin lesions. Common clinical features that distinguish psoriatic arthritis from rheumatoid arthritis include asymmetry of joint involvement, initial oligoarticular involvement, enthesial inflammation, iritis, and infrequent elevation of rheumatoid factor." Recent Advances in the Management of Psoriatic Arthritis (7/22/2004) by Philip J. Mease, http://www.medscape.com/viewarticle/482791?src=mp

were symmetrical. In the last two days, he had some tingling in the second and third fingers of his right hand. However, with his history of Raynaud's, this was difficult to tell. Med. recs. at 47S.

On November 8, 1999, Mr. Nickelson saw nurse practitioner Roque, complaining of pain in his right shoulder. He stated that he had a tetanus shot in that arm[3] three days prior to waking with pain. On examination, his range of motion was full but uncomfortable. Med. recs. at 47Q.

On November 24, 1999, Mr. Nickelson saw nurse practitioner Roque, complaining of right shoulder pain. On examination, he had full range of motion which was uncomfortable. His right grip was slightly less than his left. Med. recs. at 47O.

On November 29, 1999, Mr. Nickelson returned to Dr. Wiesner, stating he had a tetanus shot and developed increased pain in his right shoulder and anterior chest wall. On examination, Mr. Nickelson had pretty good range of motion in his right shoulder. He complained of some pain in his chest wall, anterior chest, and back. He said his ribs on the right are more prominent than on the left. There was no evidence of active synovitis in the upper or lower extremity joints. His problem might be due to some rotatory scoliosis. Med. recs. at Ex. 10, p. 7.

On December 9, 1999 (two and one-half months post-vaccination), Mr. Nickelson saw **Dr. Scott G. Smith**, an orthopedist, who noted Mr. Nickelson had right shoulder pain for the past several month and believed its onset could have been due to a tetanus shot he received in September. The pain had been intermittent since then and caused difficulty with lifting, overhead activities, and sleeping. In addition to his right shoulder pain, Mr. Nickelson complained of pain in his right elbow, right wrist, right hand, right hip, right knee, and right ankle. He also complained of swelling and

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[3] Mr. Nickelson actually received diphtheria/tetanus vaccine in his **left** deltoid, not his right as he told nurse Roque on November 8, 1999. P. Ex. 35, p. 4.

tenderness over his right anterior chest wall near his ribs. He stated he has **psoriatic arthritis** and had intermittent aching pains in all his joints for many years. Med. recs. at Ex. 2, p. 1.

Dr. Smith physically examined Mr. Nickelson and found skin dryness consistent with psoriasis. His right shoulder had no obvious muscular atrophy or deformity. It had a good range of motion. Mr. Nickelson had normal rotator cuff muscle strength and a mild amount of tenderness. There was a full and pain-free range of motion of the right elbow, wrist, and hand with a normal distal neurovascular examination. Dr. Smith assessed that Mr. Nickelson had right shoulder pain with probable **impingement syndrome**. Med. recs. at Ex. 2, p. 2. He felt Mr. Nickelson's pain came from **irritation of his rotator cuff** and an impingement-like syndrome. Id.

Also on December 9, 1999, Dr. Carrie Harvey did an x-ray (four views) of Mr. Nickelson's right shoulder and found it unremarkable. She did however find a lung nodule in the periphery of his right lung. Med. recs. at Ex. 2, p. 4.

On December 22, 1999, Dr. Richard W. Myers interpreted a bone scan of Mr. Nickelson's shoulders and thorax as normal. P. Ex. 36.

On December 31, 1999, Mr. Nickelson saw nurse practitioner Roque. He said his shoulder and hip pain were intensifying. The scan of his shoulder and thoracic region revealed no abnormalities. Med. recs. at 47L.

On January 13, 2000, Mr. Nickelson returned to see Dr. Smith. Mr. Nickelson described the pain in his right shoulder as migratory and he said he was starting to develop similar pain in his left shoulder. He also had aching pains in his hip joints. These types of pains had been on and off for several years. Med. recs. at Ex. 2, p. 5. Dr. Smith physically examined Mr. Nickelson's right shoulder and found no obvious muscular atrophy, deformity, or swelling. The range of motion

remained good. The rotator cuff muscle had normal strength. The impingement sign was mildly positive. Id. Dr. Smith's assessment was that Mr. Nickelson likely had some pain from irritation of his rotator cuff and some element of impingement. "His symptoms are not classic for impingement syndrome, however, and I think that they may also be related in large part due to his diagnosis of psoriatic arthritis." Med. recs. at Ex. 2, p. 6.

Also on January 13, 2000, Mr. Nickelson returned to Dr. Wiesner, complaining he was still in a lot of pain. His most painful areas were his chest, shoulders, neck, ribs, right hip, right and left knees, feet, ankles, and right hand. On physical examination, he had some chest wall tenderness to pressure, and asymmetry of his right shoulder compared to the left. His hips had decreased range of motion and his knees had crepitus with range of motion, but there was no synovitis in any joint. Med. recs. at Ex. 10, p. 9.

On January 14, 2000, Mr. Nickelson had a CT scan of his chest which showed a calcified granuloma in his right mid-lung with associated right hilar lymph node calcification. Med. recs. at Ex. 2, p. 7.

Also on January 14, 2000, Mr. Nickelson saw nurse practitioner Roque complaining of pain across his shoulders and a sore chest. He had no fever or fatigue but everything hurt. There was a significant amount of atrophy to the left[4] chest wall, arm, and shoulder. Med. recs. at 47K.

On January 22, 2000, Mr. Nickelson had an MRI of his right shoulder. Dr. Charles H. McDonnell found **acromioclavicular joint osteoarthrosis with some inferior osteophyte**

[4] By affidavit, dated June 7, 2003, Mona Roque said she typed "left" in error and meant "right." P. Ex. 29.

formation which may contribute to impingement. There was no muscle atrophy about the shoulder. Med. recs. at Ex. 2, p. 11.

On January 25, 2000, Mr. Nickelson saw Dr. Harris, complaining of his shoulders hurting and sometimes his right shoulder feeling out of joint. He had decreased range of motion on the right. He had a lump on his right lower rib margin which was 3 x 5 cm. Dr. Harris diagnosed him with psoriatic arthritis. He felt the skin lesion was a lipoma. Med. recs. at 47I.

On February 4, 2000, Mr. Nickelson saw Dr. Smith again who noted that Mr. Nickelson's shoulder was feeling pretty well. He continued to have some vague and migratory complaints referred to the chest wall over his ribs and now also over his flank. On examination, Mr. Nickelson's shoulder had a full range of motion. Rotator cuff strength was normal. Dr. Smith recommended physical therapy, but Mr. Nickelson was not interested in this. Med. recs. at Ex. 2, p. 12.

On February 8, 2000, Mr. Nickelson saw **Dr. David L. Haugen**, a surgeon, for evaluation of a nodule in his right lateral chest wall which was 1.5 x 2 cm. He recommended it be biopsied. Med. recs. at Ex. 3, pp. 1-2. Dr. Haugen excised the nodule on February 23, 2000. Med. recs. at Ex. 3, p. 3. It was diagnosed as a lipoma. Med. recs. at Ex. 3, p. 4.

On May 2, 2000, Mr. Nickelson saw Dr. Wiesner and said his shoulder pain was getting better. He had more pain in his right ankle. On physical examination, he had limited range of motion of his neck, fairly good range of motion of his shoulders, some osteoarthritic changes in his shoulders, decreased range of motion in his left hip, crepitus with range of motion of his knees, and a small bulge through the fascia on his right ankle's lateral aspect. Dr. Wiesner noted that he did not have much active inflammatory joint disease and most of his findings were of osteoarthritis. Med. recs. at Ex. 10, p. 10.

On May 10, 2000, Mr. Nickelson saw nurse practitioner Roque, complaining of a lump on his right ankle, a cyst on his left wrist, and numbness and tingling in his 4th and 5th fingers. He had gone back to being a mechanic and was using his hands and wrists more. His chest wall muscle mass definitely improved since he returned to more active work. He complained of continuing thoracic and rib pain predominantly on the right side as before but migrating down. A thoracic and shoulder bone scan was normal. There was pain to palpation of the right shoulder anteriorly and the anterior upper chest. His upper extremity reflexes were intact. His grips were equal in both extremities and much better than prior visits. Med. recs. at 47E.

On May 23, 2000, Mr. Nickelson saw **Dr. David W. Tai**, an orthopedist, who noted the his upper extremities had full range of motion. Med. recs. at Ex. 1, p. 2. Mr. Nickelson was complaining of a left wrist dorsal mass and a mass about the lateral aspect of his right ankle. Dr. Tai aspirated the left dorsal wrist mass. Med. recs. at Ex. 1, p. 3.

On June 8, 2000, Mr. Nickelson saw nurse practitioner Roque, complaining of chest pain due to tetanus vaccination. He had probable lipomas in his chest and a removal of a lipoma from his chest recently. His arthralgias were constant and impairing his work. His ankle swelling was due to herniations of the muscle, according to Dr. Tai. Med. recs. at 47C.

On July 18, 2000, Mr. Nickelson saw Dr. Haugen again because of several new nodules over his right anterolateral chest wall. Dr. Haugen felt they were small lipomata without clinical significance. Med. recs. at Ex. 3, p. 9.

On August 15, 2000, Mr. Nickelson saw **Dr. David B. Wampold**, a cardiologist, who noted that Mr. Nickelson complained of chest discomfort which he dated to September when he had a tetanus shot. Mr. Nickelson stated his entire chest around to the back is uncomfortable all the time.

Besides the constant aching, Mr. Nickelson had localized pains in various parts of his chest, particularly to palpation. He complained of his ankles and generalized arthritis. Med. recs. at Ex. 4, p. 4.

On examination, Mr. Nickelson was neurologically within normal limits grossly. Dr. Wampold decided to do a stress echocardiogram because Mr. Nickelson's father died at age 56 of a myocardial infarction, although Mr. Nickelson's chest discomfort sounded very atypical for coronary ischemia. Med. recs. at Ex. 4, p. 5. Mr. Nickelson had a normal stress echocardiogram on August 28, 2000. Med. recs. at Ex. 4, p. 9.

On September 5, 2000, Mr. Nickelson saw Dr. Wiesner, complaining that he was doing poorly. He was too sore and stiff when he finished working. On examination, Dr. Wiesner found trigger point tenderness at certain areas, but no obvious evidence of synovitis. He concluded that Mr. Nickelson did not have inflammatory joint disease, but had a lot of soft tissue pain. Dr. Wiesner said Mr. Nickelson was more disabled by **fibromyalgia** than anything else. Med. recs. at Ex. 10, p. 11.

On September 8, 2000, Mr. Nickelson returned to Dr. Wampold, stating that his chest pain was constant and unchanged. Dr. Wampold did not think these chest pains were cardiac. Med. recs. at Ex. 4, p. 15.

On September 29, 2000, Mr. Nickelson had a CT of the soft tissue in his neck. The impression was unremarkable. Med. recs at Ex. 5, p. 1.

On October 9, 2000, Mr. Nickelson submitted a claim for disability insurance benefits, claiming that his disability began on October 7, 2000. Med. recs. at Ex. 14, p. 1.

On October 20, 2000, Mr. Nickelson had a fluoroscopic and radiographic examination of his esophagus, which was unremarkable. Med. recs. at Ex. 5, p. 3.

On October 23, 2000, **Dr. John R. Macri**, an ear, nose and throat specialist, wrote to Dr. Roy Harris that he was unsure of the etiology of Mr. Nickelson's one-month history of trouble swallowing and hoarseness with left-sided neck symptoms. Head and neck examination, including careful examination of his hypopharynx and larynx, was unremarkable. A barium swallow and CT scan of his neck were normal. Med. recs. at Ex. 5, p. 4.

On December 7, 2000, Mr. Nickelson went to **Dr. James C. Stoody**, a neurologist, who noted that for the past three to four months, Mr. Nickelson had increasing problems swallowing and with weakness of his voice. Med. recs. at Ex. 5, p. 11. Mr. Nickelson also noted questionable cramping or abnormalities in muscle tone at night in his legs. His legs were somewhat shaky. His fourth and fifth digits of both hands were occasionally numb.

On neurological examination, Mr. Nickelson's gait and station were normal. There was a slight arthritic stance on heel and toe. He had no abnormalities of tone or drift on motor examination. His strength was intact throughout. There were no fasciculations or atrophy. His sensory examination was intact. His reflexes were 3+ and symmetric. His coordination was intact. In his assessment, Dr. Stoody wrote that it was unclear whether Mr. Nickelson's dysphonia and dysphagia were myogenic (related to muscle tissue) or neuropathic, and he recommended a brain MRI. Med. recs. at Ex. 5, p. 12.

On December 12, 2000, Mr. Nickelson had an MRI done on his brain. He had a history of dysphonia, dysphagia, and hoarseness for two months. His MRI was unremarkable. Med. recs. at Ex. 6, p.1.

On December 13, 2000, Mr. Nickelson saw **Dr. Scott T. Anderson**, a rheumatologist, as part of a workmen's compensation independent medical examination. Dr. Anderson wrote that Mr. Nickelson has longstanding osteoarthritis, not psoriatic arthritis, and his tetanus shot was unrelated to his complaints. Med. recs. at Ex. 12, p. 1, 11. Mr. Nickelson first became symptomatic with osteoarthritis in his 20s. Dr. Anderson noted that Mr. Nickelson worked as a heavy equipment operator and mechanic, which predisposed him to osteoarthritis. Med. recs. at Ex. 12, p. 11. Mr. Nickelson's shoulders had full, painless range of motion bilaterally. Med. recs. at Ex. 12, p. 7. His deep tendon reflexes were 2+ and symmetric in his upper and lower extremities. Strength and sensation were intact. Med. recs. at Ex. 12, p. 9.

Dr. Anderson noted that Mr. Nickelson had a two-year history of gradually worsening joint pain. Med. recs. at Ex. 12, p. 2. Mr. Nickelson did not report any specific acute traumatic injury which occurred in the past several years, but rather described a gradual worsening of pain. Id. He frequently worked in cramped quarters over a period of 30 years, underneath vehicles, with cumulative stresses to his back, ankles, wrists, and hands. Med. recs. at Ex. 12, pp. 2-3. Dr. Anderson diagnosed Mr. Nickelson with osteoarthritis (degenerative joint disease) in his hands, right shoulder, and lumbosacral spine, and to a lesser extent, the first metatarsophalangeal joints of his feet. Med. recs. at Ex. 12, pp. 10-11. Tetanus vaccine was unrelated to any of his current problems. Med. recs. at Ex. 12, p. 11. Mr. Nickelson's repetitive trauma as a heavy equipment operator and mechanic probably contributed to the arthritis of his hands, right shoulder, low back, and feet. Id. Dr. Anderson stated that tetanus vaccine does not cause degenerative arthritis. Med. recs. at Ex. 12, p. 12.

On December 21, 2000, Mr. Nickelson returned to Dr. Stoody who noted Mr. Nickelson had developed some new symptoms: some type of head tremor. Dr. Stoody could not identify any lower motor neuron findings either on cranial nerve exam or physical exam. Dr. Stoody was perplexed and regarded this as a very peculiar problem. Med. recs. at Ex. 5, p. 19.

On December 28, 2000, Mr. Nickelson returned to Dr. Wiesner, complaining about a lot more musculoskeletal discomfort. He was being worked up for multiple sclerosis. On physical examination, Dr. Wiesner did not see evidence of active synovitis in upper or lower extremity joints. Mr. Nickelson had deformities of his hands, knees, and feet, all compatible with osteoarthritis and perhaps some inflammatory component from psoriatic arthritis. He had limited range of motion in his neck. Mec. recs. at Ex. 10, p. 12.

On January 4, 2001, Mr. Nickelson returned to Dr. Stoody for an EMG and nerve conduction studies. Med. recs. at Ex. 8, p. 5. Mr. Nickelson had a normal EMG of his right upper and lower extremities. Nerve conduction studies were normal on the right median, ulnar, and tibial motor nerves. There were absent sensory action potentials for the right upper extremity of unclear clinical significance. Med. recs. at Ex. 8, p. 6.

On January 9, 2001, Mr. Nickelson saw Dr. Tai again, complaining of inability to bear weight due to ankle pain and coordination problems. Dr. Tai's impression was psoriatic arthritis and involuntary tremor. Med. recs. at Ex. 1, p. 4.

On January 11, 2001, Mr. Nickelson saw Dr. Stoody again with continuing significant hoarseness and dysphonia. All his diagnostic studies have been normal. Med. recs. at Ex. 8, p. 10.

On February 6, 2001, Mr. Nickelson saw **Dr. Ginger M. McMullen**, an endocrinologist, for further evaluation of his tremors. She was not sure if Mr. Nickelson's symptoms were a reaction

to his tetanus shot or just coincidence. Med. recs. at Ex. 4, p. 17. He was diagnosed with psoriatic arthritis in April 1999. In September 1999, he had a tetanus shot. He has had intermittent arthralgias in multiple joints, mostly in the shoulders, arms, wrists, and elbows. He has tenderness in his rib cage. He developed multiple nodules which were lipomatous. Last summer, he developed some malaise and fatigue. From September to October 2000, he developed hoarseness and throat pain. It became difficult to swallow. He developed tremors in his hands and neck. He lost 35 pounds from October through December. He has difficulty with balance. He has seen a neurologist, an ear, nose, and throat specialist, an orthopedic surgeon, a rheumatologist, and a cardiologist. Med. recs. at Ex. 4, pp. 17-18. Intermittently, his ears ring and he has trouble sleeping.

On physical examination, Mr. Nickelson's neurological examination was nonfocal. Dr. McMullen's impression was tremors, unexplained weight loss, dysphagia, dysphonia, and a history of hyperlipidemia. Med. recs. at Ex. 4, p. 20. His skin is dark with ichthyosis. She did not know of an endocrine disorder that would tie all this up. Med. recs. at Ex. 4, p. 21.

On February 16, 2001, Mr. Nickelson saw **Dr. Richard N. Sauer**, a neurologist, who noted that he had a history since October 2000 of a decrease in the force of his voice as well as a monotone character, difficulty swallowing, bradykinesia, and tremor. Mr. Nickelson believed some of his symptoms may have begun three weeks after a September 1999 tetanus booster injection. This was primarily chest pain and right shoulder pain. Med. recs. at Ex. 6, p. 2. He believed some of his symptoms of psoriatic arthritis may have worsened at that time. Mr. Nickelson also noted that his singing voice had changed since October 2000. He lost 35 pounds last fall.

Motor examination showed Mr. Nickelson to have a mild to moderate amount of upper extremity rigidity which was symmetrical and noted to a lesser extent in the lower extremities,

cogwheel in nature. Deep tendon reflexes were 1+ and symmetrical. Sensory examination showed no deficit to touch or pain. Cerebellar examination was normal to finger-to-nose testing. Ankle and hip pain affected his gait. He had very minimal intention tremor. Dr. Sauer assessed Mr. Nickelson with a **Parkinson syndrome**. Dr. Sauer wrote, "The time course is somewhat atypical for this to be a reaction to the tetanus injection that was given in September 1999." Med. recs. at Ex. 6, p. 3. He also assessed Mr. Nickelson as having psoriatic arthritis, producing moderately severe symptoms and causing some gait changes. Id.

On February 20, 2001, Mr. Nickelson returned to Dr. McMullen. His lab results were not remarkable. He did not have a thyroid disorder. Med. recs. at Ex. 6, p. 13.

An EEG was done on February 22, 2001 which proved to be normal. Med. recs. at Ex. 6, p. 7.

On March 26, 2001, Mr. Nickelson returned to Dr. McMullen. She doubted he had a pituitary tumor. He had multiple testosterone levels which were borderline low. She diagnosed **hypogonadotropic hypogonadism** and put him on a Testoderm patch daily. Med. recs. at Ex. 7, p. 18.

On April 26, 2001, Mr. Nicholson saw **Dr. Andrew K. Burt**, an orthopedist, for an insurance evaluation. Med. recs. at Ex. 13, p. 1. Dr. Burt noted that at some time in the summer of 1999, without any specific inciting injury, Mr. Nickelson became aware of increasing joint pain. Id. He was employed at Western Traction Company from April 20, 1998 to October 6, 2000. Over the last year or so of his employment, the pain in Mr. Nickelson's wrists, hands, and shoulders became worse and he developed pain in his lower extremities. A doctor removed a ganglion cyst from one wrist. Med. recs. at Ex. 13, p. 2.

As time passed, Mr. Nickelson's symptoms gradually increased. He stopped working because of his lower extremity pain (i.e., pain in his feet, legs, hips, and ankles). Id. Mr. Nickelson complained to Dr. Burt of diffuse joint pain, involving his shoulders, elbows, wrists, hands, and the small joints of his hands and feet, as well as his hips, knees, ankles, and low back. Id. As for past history, Mr. Nickelson told Dr. Burt there was no history of non-industrial orthopedic injury to his spine or extremities. Med. recs. at Ex. 13, p. 3. Mr. Nickelson said he had life-long psoriasis, psoriatic arthritis involving his upper extremities, and "some undiagnosed immune disorders with a flare-up of symptoms following a tetanus toxoid injection." Id.

Dr. Burt examined Mr. Nickelson and found normal range of motion of both shoulders. Mr. Nickelson complained of pain and there was some crepitus in the subacromial region. Med. recs. at Ex. 13, pp. 4-5. Deep tendon reflexes were normal and equal bilaterally in the biceps, triceps, and brachioradialis tendons. On sensory examination of the upper extremities, there was no dermatome pattern deficit or sensory loss to sharp stimulation with a pinwheel. Med. recs. at Ex. 13, p. 5. On measuring the arms, Dr. Burt found no atrophy. Id.

Dr. Burt's diagnoses were chronic diffuse joint pain due to psoriatic arthritis, chronic musculoligamentous back pain, and anterior tibial fascial herniations at the lower extremities bilaterally. Med. recs. at Ex. 13, p. 7. Dr. Burt wrote, "It is medically plausible that the heavy physical demands of his job as a heavy equipment mechanic aggravated and accelerated the arthritic process in the lower extremities." Med. recs. at Ex. 13, pp. 8-9.

On May 1, 2001, Dr. Sauer did a nerve conduction study and electromyography on Mr. Nickelson. Med. recs. at Ex. 6, p. 9. EMG in all muscles in the extremities was normal. The EMG study showed no evidence of radiculopathy or other abnormality that might be related to motor

neuron disease or other disease. He had a minor right median nerve lesion at his wrist which may or may not be clinically significant. Med. recs. at Ex. 6, p. 11.

On May 14, 2001, **Dr. Alan G. McNabb** removed surgically two subcutaneous nodules from Mr. Nickelson's right chest wall. Med. recs. at Ex. 9, p. 2. The pathology report dated May 15, 2001 states the tissue is compatible with **lipoma**. Med. recs. at Ex. 9, p. 7.

On June 15, 2001, Dr. Sauer did visual evoked responses on Mr. Nickelson which showed normal left and right latencies with a non-significant high normal right latency. Med. recs. at Ex. 6, p. 21.

On June 19, 2001, Mr. Nickelson returned to Dr. Wiesner who noted he saw no evidence of active synovitis to suggest active psoriatic arthritis. He had **sclerodactyly**,[5] a tremor, and Raynaud's-like findings. Med. recs. at Ex. 10, p. 13.

On July 2, 2001, Mr. Nickelson returned to Dr. McMullen. The testosterone patches did not work well and he was on testosterone 100 mg. per week. He felt much better in terms of his energy. His recent testosterone level was normal. Med. recs. at Ex. 7, p. 22.

On July 12, 2001, Mr. Nickelson returned to Dr. McMullen for a followup. She diagnosed him as having hypogonadism and doing well on testosterone; hyperlipidemia for which he was stable; questionable Parkinson's disease; and tremor. Med. recs. at Ex. 10, p. 11.

On September 8, 2001, Mr. Nickelson saw **Dr. Douglas M. Haselwood**, a rheumatologist. P. Ex. 18. On examination, Dr. Haselwood found no frank sclerodactyly. Dr. Haselwood found "the

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[5] "Sclerodactyly: Localized thickening and tightness of the skin of the fingers or toes. Sclerodactyly is commonly associated with atrophy of the underlying soft tissues. The term "sclerodactyly" is made up of "sclero-" from the Greek "skleros" meaning hard and "-dactyly" from the Greek "daktylos" meaning finger or toe = hard fingers or toes." http://www.medterms.com/script/main/art.asp?articlekey=13572

objective database still too incomplete or nonspecific for a definitive unifying diagnosis from a rheumatologic standpoint particularly in light of the implications for a reaction to the tetanus vaccination." P. Ex. 18, p. 2.

On November 29, 2002, Mr. Nickelson saw Dr. Wiesner. He complained of scalp tightness, pressure sensation in his throat, tight chest, pain in his palms and hands, osteoarthritis of his thumbs, trigger finger, generalized joint pain, tight feet, and his head feeling as if it were being pulled down. His assessment was Raynaud's, history of psoriatic arthritis and osteoarthrosis, probably radiculitis involving the right upper extremity and Parkinson's disease. P. Ex. 38, p. 11.

On January 28, 2003, Mr. Nickelson saw Dr. Sauer, complaining of right upper extremity pain described as a soreness. Neurological evaluation showed no neurologic abnormality. P. Ex. 23. A review of the nerves on May 1, 2001 showed no abnormality of the cervical nerve roots, proximal upper extremity nerves or distal upper extremity nerves. Id. at p. 1.

Petitioner filed a report dated February 4, 2003 from **Dr. Bradley E. Chipps**, a specialist in pediatrics, pulmonary diseases, allergy and immunology. Dr. Chipps examined Mr. Nicholson on December 19, 2002. He wrote, based on the information he obtained, "it appears to me that Mr. Nickelson's problems are the result of an **autoimmune reaction** he experienced as the result of his September 22, 1999 D/T booster vaccination." P. Ex. 24, p. 2.

The first basis for Dr. Chipps' opinion is that Dr. Wiesner (Mr. Nickelson's rheumatologist who had never seen a brachial neuritis before) "was probably correct when he stated that Mr. Nickelson's symptoms were compatible with a neuritis. In addition, Mr. Nickelson's symptoms are all consistent with an autoimmune reaction." Id. Dr. Chipps refers to anecdotal articles and letters

by "various authors" (not giving any references to them) in which the letters' authors believe that people have reacted to tetanus vaccine. Id.

A second basis Dr. Chipps gives for his opinion is that Mr. Nickelson has suffered from psoriasis for 30 years but he does not have classic psoriatic arthritis. He states Mr. Nickelson's arthritis is more compatible with osteoarthritis. He also has a Parkinson-like tremor and Raynaud's disease. Dr. Chipps does not explain why this medical history is consistent with an opinion that tetanus vaccine caused an autoimmune disease reaction in Mr. Nickelson.

A third basis Dr. Chipps gives for his opinion is the temporal relationship (three days) which is consistent with the range of response times for tetanus vaccine to activate tetanus antibody memory B cells and T1 cells.

A fourth basis Dr. Chipps gives for his opinion is that Lederle, the manufacturer, in its product information, warns of neurological complications such as convulsions, encephalopathy, mononeuropathy, polyneuropathy, including Guillain-Barre Syndrome, in addition to Arthus-type hypersensitivity reactions or temperatures greater than 103° Fahrenheit if the vaccinee has a very high serum tetanus antibody level. Dr. Chipps concludes that persons who have received prior tetanus vaccinations have "some level of antibody titer which may cause an adverse reaction. The adverse reactions appear to be autoimmune in nature which supports the thesis that Mr. Nickelson had an autoimmune reaction." P. Ex. 24, p. 3. He finds causation from the tetanus vaccine "the most logical explanation" and says "the possibility" that this happened is supported by the manufacturer's product information and unspecified (and undiscussed) many anecdotal articles on the subject. Id.

Dr. Chipps concludes that Mr. Nickelson had an initial response of inflammation of his brachial plexus "which was not investigated until 4 years after vaccination." P. Ex. 24, p. 4. He also states that, since Mr. Nickelson's Parkinson's is improving, what Mr. Nickelson experienced was not actually Parkinson's (which does not typically improve), but an autoimmune reaction manifesting itself in a Parkinson-like syndrome. Id.

On July 1, 2003, Dr. Sauer found that electromyographic examination of Mr. Nickelson's lumbar-sacral spine showed evidence of a mild L5-S1 distribution nerve root lesion on the right. His nerve conduction studies however showed no evidence of peripheral neuropathy in his lower extremities. Med. recs. submitted by the undersigned's leave, July 8, 2004, p. 4.

On July 15, 2003, Mr. Nickelson saw **Dr. David H. Lehman**, an internist and rheumatologist, as part of an independent medical examination. In a letter dated July 16, 2003, Dr. Lehman states Mr. Nickelson had longstanding psoriasis without any evidence of psoriatic arthritis. He had mild symptoms of right carpal tunnel syndrome. His right arm continued to be mildly painful in an unclear pattern. He had skin thickening over his body except for his face and anterior neck, and diffuse stiffness. On examination, there was no weakness or wasting of his right arm and all his DTRs were normal. Dr. Lehman diagnosed Mr. Nickelson with **scleroderma** and minimal osteoarthritis. He had no evidence of Parkinsonism and nothing to suggest sequelae of brachial plexopathy, He concluded that Mr. Nickelson had acute pain and weakness after tetanus vaccine with no evidence for neurologic sequelae. He suspected Mr. Nickelson had a traumatic, localized nervy injury rather than a true plexopathy. "I would postulate that the patient's scleroderma is attributable to tetanus toxoid injection. Its onset several years after the injection would seem an

appropriate interval to me." R. Ex. J, p. 2. Dr. Lehman did not believe that Mr. Nickelson had Parkinsonism. He merely had titubation (reeling) which was idiopathic.

Dr. Lehman followed this letter with another one, dated September 15, 2003, in which he states that Mr. Nickelson's ANA was negative on August 25, 2003, but 5 to 10% of patients with scleroderma have negative ANA. Both Dr. Wiesner and he believe Mr. Nickelson had characteristic skin changes of scleroderma. Since, according to Dr. Lehman, Mr. Nickelson had an autoimmune response to his tetanus toxoid, as evidenced by his brachial plexitis,[6] he continued to feel that the scleroderma was directly related to the tetanus vaccine as well. R. Ex. L.

Dr. Chipps wrote a letter, dated October 27, 2003, to petitioner's counsel, having read Dr. Lehman's initial opinion. Dr. Chipps states he concurs that tetanus vaccine probably caused sclerodactyly first and now overt scleroderma. The imputed mechanism is one of specific stimulation of T cells with a similar cross-reacting antigen (tetanus toxoid).[7] This then predisposed him to a generalized inflammatory reaction. He felt the time frame was consistent with the process. P. Ex. 30.

Dr. Wiesner sent in a letter responding to these reports by stating that he is not satisfied that Mr. Nickelson has scleroderma, although he has sclerodactyly and Raynaud's. P. Ex. 31.

On April 13, 2004, Mr. Nickelson saw Dr. Wiesner, complaining that the left side of his face went numb and was cold to the touch. His feet felt wrapped tight. He was nauseated and his

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[6] Dr. Lehman obviously did not reread his prior letter in which he stated Mr. Nickelson did not have brachial plexopathy.

[7] Mr. Nickelson received tetanus diphtheria vaccine. Med. recs. at 47Q.

forearms felt wrapped. The assessment was Raynaud's, sclerodactyly, psoriatic arthritis, osteoarthritis, and Parkinson's disease. P. Ex. 38, pp. 19, 20.

Other submitted materials

Petitioner submitted, attached to Ex. 19, an on-line letter to the editor, entitled "Severe but transient parkinsonism after tetanus vaccination," by J.C. Reijneveld, et al., 63 *J Neurol Neurosurg Psychiatry* 258-59 (1997). The letter discusses a 38-year-old metal worker who, within hours of a tetanus toxoid vaccine, had fluctuating fever and sweating, palpitations, tremor of the upper parts of both legs, and diplopia. The symptoms were present for five days. Within a week, he progressed to severe hypokinetic dysarthria, a mask-like face, a resting tremor of both hands, bradykinesia, generalized rigidity, and a cogwheel phenomenon in his arms. His creatinine phosphokinase activity was elevated as were his lymphocytes. SPECT (single photon emission computed tomography) showed a decreased ganglia to cortex ratio, indicating a postsynaptic disorder. He had gradual but impressive clinical improvement within several weeks. The authors state, "The sequence of events strongly suggests a relation between the vaccine and the neurological syndrome, although the causal nature is difficult to prove." Id. at 258. They theorized that, since this was the last of three vaccinations for tetanus, repeated injections with the tetanus toxoid might have caused hypersensitivity. Id.

Dr. Sauer, Mr. Nickelson's neurologist, whose report of November 4, 2002 in this case mentions the above letter, notes that he had two personal observations a number of years ago where the individuals had symptoms a bit more global than Mr. Nickelson's, but they had Parkinson syndrome following tetanus vaccination. Mr. Nickelson had no sign of primary Parkinsonism, and his past Parkinson syndrome had resolved somewhat. P. Ex. 19, p. 2.

Dr. Wiesner, Mr. Nickelson's rheumatologist, submitted a report dated July 22, 2002 in this case, stating that he saw Mr. Nickelson two months post-vaccination (on November 29, 1999) and, on examination, Mr. Nickelson did not have any inflammatory disease of his right shoulder. He had good range of motion and the shoulder joint was not swollen. "Whether or not this is a direct result of the tetanus toxoid injection, it is unknown to me." P. Ex. 21, p. 3. In addition, Dr. Wiesner wrote, "I can not place cause and effect on the tetanus toxoid injection." Id.

In a letter dated November 7, 2002 to petitioner's counsel, Dr. Wiesner wrote that his expertise in neurology is limited. P. Ex. 22, p. 2. He also wrote, "I have not personally ever diagnosed a brachial neuritis." Id. at p. 3. He continued that he is not familiar with EMG and nerve conduction studies in brachial neuritis and cannot comment on the results of these tests on Mr. Nickelson. Id.

Petitioner filed an article entitled "Parkinson Disease," by J. Blackmer from the website emedicine (Jan. 25, 2002). P. Ex. 34.

On May 14, 2004, the undersigned filed P's Ex. 32 by my leave. It is entitled "Acute Brachial Plexus Neuritis: An Uncommon Cause of Shoulder Pain," by J.D. Miller, et al., from the American Family Physician, Nov. 1, 2000.

Dr. Roy Harris and nurse practitioner Mona Roque sent a letter, dated September 18, 2002, stating that, on September 22, 1999, their office administered a tetanus diphtheria injection into Mr. Nickelson's **left deltoid**. On October 27, 1999, he complained of one week's right shoulder pain without trauma or exacerbation history. They did an x-ray of the shoulder. On November 8, 1999, Mr. Nickelson complained of one month of right shoulder pain that was no better. X-rays showed arthrosis and osteophytes. On November 24, 1999, Mr. Nickelson complained of shoulder pain and

right anterior chest wall pain for three days. On December 3, 1999, Mrs. Nickelson telephoned and said that her husband's shoulder and chest wall pain was severe. Chest x-ray showed calcified granuloma/arthritis. On December 31, 1999, a bone scan showed no abnormalities. Physical therapy caused more pain. On January 14, 2000, a shoulder scan showed a pulmonary nodule. Mr. Nickelson had atrophy of his right upper chest wall and shoulder. On February 10, 2000, an MRI of the shoulder region was normal. The diagnosis was just osteoarthrosis and impingement syndrome of the right shoulder. On May 10, 2000, Mr. Nickelson had nodules in his chest wall. His chest pain and shoulder arthralgia continued. The nodules were felt to be lipomas. On June 29, 2000, Mr. Nickelson had increasing overall joint pain and felt dizzy and weak. His lab results were normal. On September 6, 2000, he felt his skin tightening and had myalgia and chest pains. A cardiologist tested him on a treadmill which was normal. The doctor felt it was not cardiologically related. On October 10, 2000, Mr. Nickelson noted hoarseness, occasional choking, and he was referred to an ear, nose, and throat doctor who found him normal except for hoarseness. On October 31, 2000, Mr. Nickelson had trouble swallowing. An ENT work-up was negative. A surgeon felt the tumors on the chest were lipomas. On December 8, 2000, Mr. Nickelson said he lost 10 pounds in two months. He had insomnia and pain. On December 29, 2000, Mr. Nickelson had tremor mostly in the head. He lost another 6 pounds in one month and was feeling dizzy. On January 3, 2001, his head and upper arms were tremulous and he had a 35-pound weight loss the prior year. On January 17, 2001, Mr. Nickelson had sharp pains to his left arm intermittently. He had tremor and felt his blood pressure was low. An MRI of the brain was negative. The pain to his shoulders and chest was the same. On January 31, 2001, a slow widening of his gait and head tremor were noted. On February 21, 2001, Mr. Nickelson saw Dr. Sauer who felt he had Parkinson's. Mr.

Nickelson felt more unstable. On March 20, 2001, he continued with the same pains, tremor, and dizziness. On May 21, 2001, he had an EMG which showed no evidence of radiculopathy or other abnormality that might be related to motor neuron disease or other disease. He had evidence of a minor right median nerve lesion at the wrist which might or might not be clinically significant. On May 22, 2001, his dizziness continued but his weight was more stable. On May 31, 2001, he developed symptoms of Raynaud's phenomenon. On August 1, 2001, he had memory problems, tremor, possible Raynaud's, and sclerodactyly. On August 14, 2001, they confirmed Parkinson's disease, psoriatic arthritis, sclerodactyly, and Raynaud's symptoms. The orthopedist did not diagnose brachial neuritis but impingement. On September 11, 2001, Dr. Haselwood thought the chest pain was due to arthritis and scleroderma. Mr. Nickelson had muscle spasms, impaired balance, and generalized myalgia. On January 24, 2002, his tremors were less. Dr. Harris and nurse practitioner Roque conclude "we can not confirm nor dispute that Mr. Nickelson's symptoms and decline were due to the Tetanus injection." Based on literature from the Physician's Desk Reference, they thought there was a relationship due to his rapid decline after the injection. P. Ex. 35, pp. 4-6.

Petitioner filed an affidavit of Dennis Goss who trained under Mr. Nickelson. He remembered that during the two days he trained with Mr. Nickelson (September 28th and 29th, 1999), Mr. Nickelson had pain and discomfort in his shoulder and would periodically grab his shoulder with one hand and rotate the other hand in the air to reduce his discomfort. Filing of August 14, 2002.

Petitioner filed 40 articles or letters and respondent filed nearly 100 articles, doubtless because the allegations in this case kept shifting.

TESTIMONY

James Nickelson testified first. He stated he received a tetanus vaccination in his left arm on Wednesday, September 22, 1999, and, on Saturday morning, he had sudden pain in his right shoulder. Three to four months later, he developed pain in his left shoulder going across his chest. Weakness started in January 2000. After four months, his shoulder pain subsided. He is still sore today. The onset of his Parkinson's was October 2000. He used to lift transmissions at work. He did overhead lifting as a heavy equipment mechanic.

Nurse practitioner Mona Roque testified next for petitioner. She works for Dr. Roy Harris as a family nurse practitioner. During Mr. Nickelson's January 14, 2000 visit, she detected atrophy to his left chest wall, arm and shoulder, but that was a mistake in her notes. It really was atrophy on the right. She filled out a VAERS form for Mr. Nickelson. She agreed that a neurologist is the appropriate doctor to diagnose brachial neuritis in the first three months. Mr. Nickelson's first shoulder complaints were on October 27, 1999. Nurse Roque stated she has never seen a case of brachial neuritis, but she is reading articles on brachial neuritis.

Dr. Richard N. Sauer, petitioner's treating neurologist, testified next for petitioner. Mr. Nickelson has a lesion at the L5-S1 distribution which causes back pain, numbness, and weakness, based on an EMG done July 1, 2003. By Mr. Nickelson's history primarily and ruling out a cervical radiculopathy, Mr. Nickelson had a brachial neuritis three days after his vaccination which the vaccination caused. If Mr. Nickelson did not have atrophy or weakness, he could have had mild inflammation of his sensory nerves. Dr. Sauer sees two brachial neuritis cases a year. This is his only case where the vaccine induced it. His explanation for why Mr. Nickelson's EMG and nerve conduction studies were normal is that they were not done early enough. He cannot interpret the

conflicting reports of Dr. Smith, an orthopedist who examined Mr. Nickelson on January 13, 2000 and found no atrophy, and Mona Roque, the nurse practitioner who examined Mr. Nickelson one day later and found atrophy. Dr. Sauer said his opinion that Mr. Nickelson had brachial neuritis is based on Mr. Nickelson's history and nurse Roque's examination.

In addition, a reaction to the tetanus vaccine caused his Parkinson syndrome. Dr. Sauer was unsure of the onset of his Parkinson syndrome and stated that if it were a number of months later, it would be too far out for causation. Days or weeks would be an appropriate interval.

He saw a similar case 20 years ago. He thinks the vaccination was diphtheria/tetanus and the onset was a week or two. The patient had cerebritis (mental status changes) and a motor deficit. It seemed to him that the tetanus vaccine caused it. He assumes it is an autoimmune reaction.

Dr. Kenneth B. Wiesner, petitioner's treating rheumatologist, testified next for petitioner. He has treated him since 1999. He thought it a tough question whether or not Mr. Nickelson had brachial neuritis. He saw him seven days after vaccination when he complained of pain in his right shoulder and anterior chest wall (including the rib cage, lung area, and breast). Mr. Nickelson had pretty good range of motion of his right shoulder. Petitioner has some cervical disc disease. He has never diagnosed brachial neuritis. He attributes Mr. Nickelson's asymmetric shoulders to guarding. A bone scan showed osteoarthritis and inflammation of his sternomanibrial joint. The acromioclavicular joint can cause pain which is localized on the top of the shoulder. Mr. Nickelson's pain is more diffuse: over the shoulder to the back and front. He never found a diagnosis for it. He also never diagnosed Mr. Nickelson with an autoimmune disease. Solvents used in industry can cause sclerodactyly. He does not think Mr. Nickelson has scleroderma. An MRI showed that Mr. Nickelson has spinal stenosis at the L3-4 and L4-5 levels. The normal course of

osteoarthritis is chronically progressive with wear and tear on the joints. Dr. Wiesner never described muscle atrophy. Dr. Wiesner testified that he is not diagnosing Mr. Nickelson with brachial neuritis because it is out of his area of specialty.

Dr. Alan I. Brenner, a rheumatologist, testified for respondent. He consulted with the Centers for Disease Control to analyze shoulder complaints after receiving anthrax vaccine. His opinion is that there is no association between diphtheria/tetanus vaccine and Mr. Nickelson's shoulder condition based on his review of the medical records, the medical literature, and his own experience. Dr. Wiesner's first report, dated April 16, 1999 (five months before vaccination) showed Mr. Nickelson to have a 30-year history of psoriasis, and polyarticular pain (stiffness in the neck and shoulders, numbness and tingling).

Mr. Nickelson did not have brachial neuritis after vaccination. He had clear-cut symptoms and signs of shoulder impingement syndrome, as Dr. Smith concluded. Mr. Nickelson did not have muscle weakness or atrophy of his brachial plexus (which runs behind the clavicle and into the armpit or axilla). Rotator cuff impingement (supraspinatus) caused Mr. Nickelson's shoulder pain. He has osteoarthritis in multiple joints and a genetic abnormality in his cartilege that caused him to develop osteoarthritis at a young age (his symptoms began in his 20s). In addition, Mr. Nickelson was a heavy equipment mechanic. This put extreme stress on the articular and periarticular structures of his shoulder.

Dr. Brenner said that nothing about Mr. Nickelson's complaint is typical of neuropathic pain which would be burning, numbness, tingling, and demonstrable muscle weakness. His deep tendon reflexes were normal. His strength was normal. His sensory examination was normal. Dr. Brenner

said that the nurse practitioner did not do a proper neurological examination in January 2000. An MRI confirmed osteoarthritis with spur formation, constituting impingement syndrome.

Dr. Brenner testified that 100% of Mr. Nickelson's joint problems were due to his osteoarthritis. His sclerodactyly and Raynaud's may be due to his occupation. He had rapid development of lipomas in his chest, which may be the cause of his pain there. When Mr. Nickelson would grab his shoulder with one hand and rotate the other hand in the air to ease his pain, that was consistent with impingement syndrome but not with brachial neuritis. A high percentage of impingement syndrome patients have full range of motion.

Brachial neuritis is nerve pathology, not shoulder pathology. The tingling in Mr. Nickelson's second and third fingers is due to a peripheral nerve, not to brachial neuritis paresthesias. Mr. Nickelson also has carpal tunnel syndrome, and the medial nerve enervates the second and third digits. Dr. Brenner does not know the cause of Mr. Nickelson's diffuse pain but neither does Dr. Wiesner. It does not come from brachial neuritis.

Dr. Arthur P. Safran, a neurologist, testified next for respondent. His opinion is that Mr. Nickelson did not have brachial neuritis because he did not have atrophy in his shoulder, abnormal or lost reflexes, or weakness. When someone has brachial neuritis, the pain is usually gone in a few weeks or a month. The hallmark of brachial neuritis is profound weakness. Grip weakness is the worst test for strength. One does not get intermittent tingling.

Mr. Nickelson has Parkinson's disease. He has been on the drug Serzone for years and that drug causes Parkinson's. Tetanus vaccine is not the cause of his Parkinson's. If Mr. Nickelson still has symptoms of shoulder problems, his EMG and nerve conduction studies should be abnormal. There must be lower motor neuron weakness in order to diagnose brachial neuritis. The limb will

be weak and limp with the absence of deep tendon reflexes. Arthritis and impingement syndrome are not neurological. Mr. Nickelson had pain in the opposite arm which received the vaccination. He did not have weakness, atrophy, or reflex change. His shortness of breath is unrelated to brachial neuritis or impingement syndrome.

We do not know what causes Parkinson's disease. Onset is important. Beyond a month after a presumed cause means no causation. Serzone causes shaking, stiffness, and trouble swallowing and articulating.

DISCUSSION

With 16 doctors and at least 15 diagnoses in this case, it would be an overwhelming task to determine just what diseases or conditions Mr. Nickelson has. The simpler task is the one petitioner set forth at trial when he finally determined what allegations he would attempt to prove: (1) that he had a Table brachial neuritis within Table time of his diphtheria/tetanus vaccination; and (2) that diphtheria/tetanus vaccine caused in fact his Parkinson's syndrome.

The regulations at 42 C.F.R. § 100.3(b)(7) define a Table brachial neuritis as follows:

> (i) This term is defined as 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.
> (ii) 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 mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

On January 20, 1999, before he received the tetanus vaccination on September 22, 1999, he complained to Dr. Harris of stiffness in his joints for years. On April 16, 1999, Dr. Wiesner diagnosed Mr. Nickelson with psoriasis for 30 years, stiff and sore joints, including stiff neck, shoulders, and lower back, Raynaud's disease, and easy fatigueability. He also had ringing in his ears, and numbness and tingling in his hands. Dr. Wiesner wrote that Mr. Nickelson's joint changes were consistent with osteoarthritis. X-rays of his lumbar spine showed low-grade degenerative disc disease. After the tetanus vaccination in his left deltoid on September 22, 1999, Mr. Nickelson saw Dr. Wiesner seven days later, complaining of increased pain in his right shoulder and anterior chest wall. Dr. Wiesner noted pretty good range of motion of the shoulder.

When nurse Roque examined Mr. Nickelson a month later, on October 27, 1999, he had **symmetrical grips** and **symmetrical deep tendon reflexes**. On December 7, 2000, Mr. Nickelson saw Dr. James C. Stoody, a neurologist, who noted **intact strength, no atrophy, and symmetric reflexes of 3+**. His first thorough examination was on December 9, 1999 when Dr. Scott G. Smith, an orthopedist, noted that Mr. Nickelson complained of intermitted right shoulder pain, and pain in his right elbow, right wrist, right hand, right hip, right knee, and right ankle. He also complained of swelling and tenderness over his right anterior chest wall. **Dr. Smith examined Mr. Nickelson and found no obvious muscular atrophy or deformity.** He diagnosed him with probable impingement syndrome.

On December 13, 2000, Mr. Nickelson saw Dr. Scott T. Anderson, a rheumatologist, who said he did not have psoriatic arthritis, but longstanding osteoarthritis, and his tetanus vaccine was unrelated to his complaints. Mr. Nickelson had EMG and nerve conduction studies under Dr. Stoody on January 4, 2001. The EMG was normal of the right upper and lower extremities. The nerve conduction studies were normal on the right median, ulnar, and tibial motor nerves.

On January 13, 2000, Mr. Nickelson returned to Dr. Smith who again examined his right shoulder **and found no obvious muscular atrophy, deformity or swelling.** On the same day, Dr. Wiesner examined him and found asymmetry of his shoulders, which he attributed (at the hearing) to guarding against pain. One day later, Mr. Nickelson saw nurse practitioner Roque who found significant atrophy to his right chest wall, arm, and shoulder. This examination stands alone among all of Mr. Nickelson's records for finding muscle atrophy. One week later, on January 22, 2000, Mr. Nickelson had an MRI which Dr. Charles H. McDonnell interpreted as acromioclavicular joint osteoarthrosis with some inferior osteophyte formation which may contribute to impingement. **Dr. McDonnell did not find any muscle atrophy about the shoulder.**

On February 16, 2001, Mr. Nickelson saw Dr. Sauer, the neurologist, for the first time. Dr. Sauer examined him and diagnosed him with a Parkinson syndrome, stating the time course was atypical for a reaction to tetanus vaccine. He also diagnosed him as having psoriatic arthritis, but he did not diagnose him as having brachial neuritis.

On April 26, 2001, Mr. Nickelson saw Dr. Andrew K. Burt, an orthopedist, who examined him and found **normal deep tendon reflexes and no atrophy**. Mr. Nickelson had another EMG and nerve conduction study on May 1, 2001, under Dr. Sauer. The EMG was normal and showed no evidence of anything related to motor neuron disease or other disease.

On January 28, 2003, Mr. Nickelson returned to Dr. Sauer, complaining of right upper extremity pain described as soreness. **Neurological evaluation showed no neurologic abnormality.** On July 15, 2003, Mr. Nickelson saw Dr. David H. Lehman, a rheumatologist, complaining of mildly painful right arm. **On examination, there was no weakness or wasting of his right arm and all his DTRs were normal.**

In every examination recounted above, there is no proof that Mr. Nickelson had brachial neuritis, except for the examination nurse practitioner Roque did in January 2000, finding atrophy, just a day after an actual medical doctor found he did not have atrophy. Nurse Roque's examination is not credible in the light of the overwhelming evidence before and after her January 2000 examination.

Dr. Sauer testified that Mr. Nickelson had brachial neuritis based on Mr. Nickelson's history and nurse practitioner Roque's examination of Mr. Nickelson four months after vaccination during which she found atrophy. Since the court has rejected the credibility of nurse practitioner Roque's examination, Dr. Sauer's conclusion in the context of litigation (but not reflected in any of his notes which are contemporaneous with his examinations of Mr. Nickelson and which do not diagnose brachial neuritis) must fall.

Dr. Wiesner testified he has never diagnosed brachial neuritis and he was not diagnosing brachial neuritis in this case because it was out of his specialty. Dr. Wiesner saw Mr. Nickelson on January 13, 2000, the day before his examination by nurse Roque, and Dr. Wiesner noted asymmetry of his right shoulder compared to his left, which Dr. Wiesner attributed to guarding, i.e., because of discomfort, Mr. Nickelson held his shoulder in a particular way that caused asymmetry.

The regulation quoted above, the medical literature, and the testimony of respondent's experts are consistent that, in order to diagnose brachial neuritis, the patient must have atrophy, weakness, and absent or abnormal reflexes. Time after time, every examination of Mr. Nickelson showed no atrophy, no weakness, and no areflexia, except for nurse Roque's January 2000 examination, which the court holds suspect. Dr. Sauer's opinion is no better than its basis and where, as here, the basis is faulty, the opinion is not credible. Any note that Dr. Harris may have made that Mr. Nickelson had brachial neuritis was unexplained and in the context of litigation. Dr. Lehman contradicts himself by saying, in his first report, that Mr. Nickelson did not have brachial plexopathy, and, in his second report, that he did. Dr. Chipps' supposition that Mr. Nickelson had a nerve injury is speculative and is based on Dr. Wiesner's speculation, which is not grounded in his knowledge, experience, or examinations of Mr. Nickelson.

Mona Roque's assumption that Mr. Nickelson had brachial neuritis is not probative. She admits that she has never seen a brachial neuritis. The undersigned does not accept into evidence testimony about medical diagnoses from persons who are not medical doctors. 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).

Respondent's expert neurologist, Dr. Safran, makes the salient point that, since petitioner continued to complain over years of right shoulder symptoms, his EMG and nerve conduction studies should have confirmed a neurologic abnormality in his right brachial plexus if there had been one, and they did not. Dr. Brenner as well concluded that Mr. Nickelson did not have brachial neuritis based on the absence of appropriate signs and symptoms. He said that nothing about Mr.

Nickelson's complaint is typical of neuropathic pain, which would be burning, numbness, tingling, and demonstrable weakness.

Petitioner has failed to prove a prima facie case that he had a Table brachial neuritis.

Mr. Nickelson's second allegation is that diphtheria/tetanus vaccine caused in fact his Parkinson-like syndrome. To satisfy his burden of proving causation in fact, petitioner 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. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must not only show that but for the diphtheria/tetanus vaccine, he would not have had a Parkinson-like syndrome, but also that the vaccine was a substantial factor in bringing about his Parkinson-like syndrome. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

Dr. Sauer's only basis for testifying that diphtheria/tetanus vaccine caused in fact Mr. Nickelson's Parkinson-like syndrome is that he had another patient with psoriatic arthritis who had cerebritis and a motor deficit after perhaps receiving tetanus vaccine, and a letter to a medical journal recounts a transient Parkinsonism in someone who received tetanus vaccine. This is insufficient to

persuade the undersigned that diphtheria/tetanus vaccine caused in fact Mr. Nickelson's Parkinson-like syndrome for the following reasons:

1. The onset of Mr. Nickelson's Parkinson-like syndrome was over one year after he received diphtheria/tetanus vaccine. Dr. Sauer said an appropriate time interval between vaccination and onset would be weeks or months. Dr. Safran would not go beyond one month..

2. The undersigned has absolutely no documentation of the other patient to whom Dr. Wiesner referred who presumably had a tetanus vaccination and experienced cerebritis a week later.

3. The experience of transient Parkinsonism of a recipient of tetanus vaccine described in a letter to a medical journal happened within hours of vaccination, and included fever, sweating, and diplopia. This does not describe Mr. Nickelson's symptomatology at all. And Mr. Nickelson's onset was one year later, not within hours.

Dr. Safran gave an interesting alternate explanation for the cause of Mr. Nickelson's Parkinson's. The Serzone he has been taking for years causes the symptoms Mr. Nickelson has. But, it is not respondent's burden to prove the cause of Mr. Nickelson's Parkinson's.

Petitioner has failed to prove a prima facie case that diphtheria/tetanus vaccine caused in fact his Parkinson-like syndrome.

This case has been deeply unsatisfactory in determining what exactly is wrong with Mr. Nickelson and when certain events happened. The records conflict with each other based on inconsistent histories that Mr. Nickelson gave. To two doctors who examined him for insurance purposes, Mr. Nickelson stated that there was no trauma or dramatic injury he could recall–just years of arthritis. His doctors are quite puzzled as to his condition and the reasons for his problems. The undersigned is in no better position than his doctors.

CONCLUSION

Petitioner's petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.[8]

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master

[8] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.