OFFICE OF SPECIAL MASTERS

No. 01-0317V

(Filed: March 30, 2004)

SUZANNE C. M. FALKSEN Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED

Edward Serr, Esq., Boulder, Colorado, for Petitioner.

Lynn Ricciardella, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION

ABELL, Special Master:

I. ISSUE

The Court held an entitlement hearing in this case on 9 April 2003. Petitioner alleges that a tetanus toxoid - diphtheria ("Td") vaccination administered on 29 May 1998 was the cause-in-fact of her suffering "encephalitis[1] with a residual encephalopathy." Petition at 1. The case presents two issues before this Court. The first issue is whether Suzanne Falksen suffered from encephalitis with residual encephalopathy. The second issue of course is whether the Td vaccination she received on

[1] "Inflammation of the brain." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 548 (27th ed. 1988).

29 May 1998 caused her injury. The Court finds that it is more likely than not, by a preponderance of the evidence, that Dr. Falksen[2] did not suffer from encephalitis with residual encephalopathy. And, *arguendo*, even if Dr. Falksen did suffer from encephalitis with residual encephalopathy, Petitioner has not proven by a preponderance of the evidence that Td can or did cause such injury.

II. PROCEDURAL BACKGROUND

On 25 May 2001, Petitioner filed a claim under the National Childhood Vaccine Injury Compensation Act (Vaccine Act or Act)[3] alleging that she suffered a vaccine-related injury. Petitioner claims that as a result of receiving a Td vaccination on 29 May 1998, she suffered an encephalitis with residual encephalopathy. Petition at 1.

Petitioner has satisfied the requirements for a *prima facie* case pursuant to § 300aa-11(b) and (c) by showing that: (1) Petitioner is a valid legal representative; (2) the vaccine at issue, Td, is a vaccine set forth in the Vaccine Injury Table; (3) the Td vaccination was administered to Dr. Falksen in the United States; (4) no one has previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. Additionally, the § 300aa-16(a) requirement that the petition be timely filed has been met.

On 9 April 2003, the Court conducted an evidentiary hearing in this matter. The Court heard testimony from Petitioner's medical experts, Pierre Brunschwig, M.D.,[4] Mary Ann Keatley, Ph.D.,[5]

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[2] Suzanne Falksen holds a Ph.D. in Engineering from Kennedy-Western University. Pet. Ex. 16 at 2.

[3] The statutory provisions governing the Vaccine Act are found at 42 U.S.C. §§ 300aa-1 to 300aa-34 (1991 & Supp. 2002). Hereinafter, for ease of citation, all references will be to the relevant subsection of 42 U.S.C. § 300aa.

[4] Dr. Pierre Brunschwig is a board certified family doctor and is currently in private practice at the Helios Health Center, located in Boulder, Colorado. Dr. Brunschwig is a Diplomate of the American Board of Family medicine and a Founding Diplomate, American Board of Holistic Medicine. It is of note that family medicine is a member board of the American Board of Medical Specialties but holistic medicine is not. http://www.abms.org/member.asp.

[5] Dr. Mary Ann Keatley has a Ph.D. in Speech-Language Pathology and Audiology and specializes in cognitive rehabilitation and rehabilitation for speech and language for people who have neurological problems.

and William J. Rea, M.D,[6] and Respondent's medical expert, Dr. Arthur Safran.[7] The hearing transcript was filed on 12 May 2003.

Thereafter, the parties filed post-hearing briefs. On 26 September 2003, Petitioner filed her post-hearing brief. On 24 October 2003, Respondent filed a post-hearing brief. Petitioner filed her *sur-response* on 12 November 2003. Thus, the record is complete and ripe for decision.

III. FACTS

Suzanne Falksen was born on 3 November 1947. Petition at 1. Dr. Falksen underwent bilateral tubal ligation when she was twenty five years old, unilateral salpingo-oophorectomy[8] for endometrial infection when she was thirty five, and a hysterectomy when she was thirty nine. Petitioner's Exhibit (hereinafter "Pet. Ex.") 1 at 10. She suffered a concussion when she was twenty five and again when she was thirty one. Pet. Ex. 12 at 2. Dr. Falksen has stated that she has "always seen double" but has been able to perform visual tasks reasonably well especially since being prescribed prism glasses in October 1996. Pet. Ex. 10 at 1. Dr. Falksen suffered two fractures of her right foot and five fractures of her left foot. Pet. Ex. 3 at 15.

Prior to the 29 May 1998 Td vaccination at issue, Dr. Falksen complained of pain and swelling in her right little finger in April and August 1996, Pet. Ex. 6 at 7; left foot pain in June 1996, Pet. Ex. 6 at 8; viral symptoms in January 1997, Pet. Ex. 6 at 9; and neck pain that radiated down her left arm in January 1998, Pet. Ex. 6 at 9. Dr. Falksen began taking Premarin[9] when she was forty, Pet. Ex. 3 at 12, and reported allergies to epinephrin, oral adrenalin, chlortrimeton, cortisone, sodium penathol, antihistimines, and saline preservative solution. Pet. Ex. 2 at 2; Pet. Ex. 6 at 7. On 3 May 1998, Dr. Falksen ran the Vancouver Marathon. Pet. Ex. 15 at 32.

On 29 May 1998, Dr. Falksen received a tetanus-diphtheria ("Td") booster at the recommendation of her gynecologist due to the fact that she mountain bikes. Pet. Ex. 2 at 1; Pet. Ex.

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[6] Dr. William J. Rae is certified by the American Board of Surgery, the American Board of Thoracic Surgery, and the American Board of Environmental Medicine. Dr. Rae is the Director of the Environmental Health Center, located in Dallas, Texas, where he specializes in environmental medicine. He is a Diplomate of the Board, American Board of Environmental Medicine and is the chief of surgery, Brookhaven Medical Center. It is of note that environmental medicine is not a member board of the American Board of Medical Specialties. Trans. at 166; http://www.abms.org/member.asp.

[7] Dr. Arthus Safran is board-certified in both internal medicine and neurology. Currently, he serves as an Associate Clinical Professor at Boston University School of Medicine, an Instructor at Tufts University School of Medicine, and a Lecturer at Harvard Medical School. The topic of his academic instruction is neurology. Dr. Safran also serves as an Attending Neurologist and Associate Physician at various Boston hospitals. Dr. Safran's clinical practice includes patients with various neurological disorders of the peripheral and CNS, primarily multiple sclerosis patients. In addition, Dr. Safran has published journals and other reference materials on multiple sclerosis.

[8] Surgery to remove the ovary and fallopian tube on one side of the body. www.health-dictionary.com.

[9] Premarin is an estrogen replacement drug.

1 at 1. On 2 June1998, Dr. Falksen went to her employer's medical clinic and reported that she had not felt well since receiving the vaccination. Pet. Ex. 2 at 1-2. According to the notes of the visit, on the day following the vaccination "she woke up with fever, aches and pains, and feeling as if her throat were a little swollen." *Id*. Dr. Falksen said she did not take her temperature at that time, however, she reported that she "felt very hot and feverish." *Id*. at 1. Dr. Falksen complained that "nasal congestion is what is bothering her the most," *Id*., and requested something to relieve her symptoms before she left for vacation. *Id*. Dr. Falksen informed the doctor that "the [symptoms] that she has experienced since having the Tetanus shot are slowly decreasing." *Id*. A strep screen was negative. *Id*. at 4. Dr. Falksen was assessed as having experienced a probable allergic reaction to tetanus. *Id.* at 2. The doctor was "hesitant" to prescribe anything other than Ibuprofen because of the fact that Dr. Falksen is "sensitive to so many medications." *Id*. The doctor discussed with Dr. Falksen that Cortisone would help but Dr. Falksen was allergic to it. *Id.*

On 11 June 1998, Dr. Falksen had a CT scan of her spine in order to rule out osteoporosis. Pet. Ex. 4 at 1. On 16 June 1998, Dr. Falksen saw Valerie Lipetz, M.D., and reported on the morning following the vaccination at issue she "couldn't move," "stayed in bed all weekend" and was "truly paralyzed but did not call for help because she figured she would 'ride it out.'" Pet. Ex. 1 at 1. Dr. Lipetz assessed Dr. Falksen as follows

> Patient with symptoms of severe URI which she is relating to diphtheria toxoid. Unclear whether there really is a causal relationship here. Interesting that the patient had a rather "belle indifference" response to her "paralysis" at the onset of this illness. Suspect this may have been viral upper respiratory infection, but cannot completely rule out bacterial infection. She seems to be resolving and I would like to try treating this with decongestants alone for now.

Id. Dr. Lipetz prescribed Liquibid D, a decongestant. *Id*. On 18 June 1998, Dr. Falksen telephoned Dr. Lipetz's office and indicated that she"feels dizzy," "has had a 'fuzzy feeling' [for] 3 weeks," and "lightheaded still - very foggy, her 'head is [not] right'." *Id*. at 2. Dr. Falksen stated she was less congested and Dr. Lipetz suggested that Dr. Falksen drink lots of fluids and decrease taking the Liquibid D because that "could be making her feel lightheaded." *Id*.

On 10 July 1998, Dr. Falksen called Dr. Lipetz's office regarding laboratory results. *Id*. Dr. Lipetz indicated the tests showed that Dr. Falksen's lymphocyte[10] levels above normal and that such levels did not normalize, she would refer her to a hematologist. *Id*. On 18 July 1998, Dr. Falksen's blood count was still abnormal and she was referred to an oncologist for "unexplained leukocytes." Pet. Ex. 4. at 5-6.

On 16 July 1998, Dr. Falksen began seeing David DePaolo, M.D. of Boulder Endocrinology Associates and Flatirons Osteoporosis Center. Pet. Ex. 3. Dr. DePaolo assessed "normal bone

[10] "A type of white blood cell. Lymphocytes have a number of roles in the immune system, including the production of antibodies and other substances that fight infection and diseases." www.health-dictionary.com.

density of the left femoral neck with the minimal osteopenia[11] of the lumbar spine." Pet. Ex. 3 at 19. Dr. DePaolo recommended that Dr. Falksen continue taking estrogen replacement medication and calcium supplements. *Id.* Dr. Falksen had appointments in August, October and December 1998. *Id*. at 4, 5, and 28.

On 29 July 1998, Dr. Falksen saw Michael Johnson, M.D., to obtain CBC,[12] LDH,[13] reticulocyte count,[14] serum, serum TSH[15] and serum quantitative immunoglobulins,[16] and an expeditious CT scan of the head to rule out strike versus mass effect. *Id*. at 5. Dr. Johnson ran some of the tests to assess Dr. Falksen's "mental status issues (memory difficulty)" and found her TSH was normal at 1.72 and her CT scan of her head was normal. *Id*. at 11. The blood tests did show "significant peripheral blood lymphocytes totaling over 6,000 of mature appearing lymphocytes." *Id.* On 5 August 1998, Dr. Johnson performed a bone marrow biopsy with aspirate. *Id*. Shortly thereafter, Dr. Falksen was informed that the bone marrow biopsy showed "monoclonal kappa B cell[17] population consistent with chronic lymphocytic leukemia[18]" and that she had "stage 0 disease." *Id*. at 18.

Between August 1998 and December 1998, Dr. Falksen trained for and completed the Honolulu Marathon, raised funds for the Leukemia Society's team in training, volunteered frequently at church, and corresponded with friends frequently via e-mail. She also vacationed in North Dakota, South Dakota, New Orleans, and Hawaii.

On 28 October 1998, Dr. Falksen had a follow-up appointment with Dr. Johnson. Pet. ex. 4 at 19. During the visit, Dr. Falksen informed the doctor that "[s]ometimes I have energy, sometimes

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[11] "Diminished amount of bone tissue or decreased bone density." www.health-dictionary.com.

[12] Complete blood count: "a measurement of size, number, and maturity of different blood cells in a specific volume of blood." www.health-dictionary.com.

[13] "An enzyme important to the process of glucose combustion in the body, and an important mechanism for cellular energy production." www.health-dictionary.com.

[14] The count of a specific type of young red blood cell. DORLAND'S *supra* at 1454.

[15] "Thyroid stimulating hormone." Neil M. Davis, MEDICAL ABBREVIATIONS: 8600 CONVENIENCES AT THE EXPENSE OF COMMUNICATIONS AND SAFETY (6th Ed. 1993)

[16] "Antibodies or proteins found in blood and tissue fluids produced by cells of the immune system to bind to substances in the body that are recognized as foreign antigens. Immunoglobulins sometimes bind to antigens that are not necessarily a threat to health." www.health-dictionary.com.

[17] "Substances that can locate and bind to cancer cells wherever they are in the body." www.health-dictionary.com.

[18] "A type of cancer in which the bone marrow makes too many lymphocytes (white blood cells)." www.health.dictionary.com.

I don't." *Id*. According to Dr. Johnson's progress notes Dr. Falksen "continue [sic] to be active with her marathon running. She denies any recent increased fatigue, fevers, chills, night sweats, adenopathy, early satiety or weight loss." *Id*. Dr. Johnson assessed her with chronic lymphocytic leukemia and that "she continues to do well on observation." *Id*.

On 6 January 1999, Dr. Falksen saw Dr. Johnson and complained of chronic fatigue and that over the "last month she has had a frontal headache with yellow to green postnasal drip." Pet. Ex. 4 at 22. According to Dr. Johnson's progress notes, Dr. Falksen "has continued to be active with her running; in fact she ran a 26.5 mile marathon in Honolulu just last month in under 5 hours." *Id*. Dr. Falksen was assessed with acute sinusitis and "[c]hronic lymphocytic leukemia - still with blood only disease." *Id*. On 11and 12 January 1999, Petitioner phoned Dr. Johnson who noted that congestion was better but she was "not well, " she was "fog headed special difficulty unable to figure out things." Pet. Ex 4 at 24, 25. Dr. Johnson's assessment after the 12 January 1999 call was "depression? Absolutely!" *Id*.

In January 1999, Dr. Falksen sought a second opinion at the Mayo Clinic in Scottsdale, Arizona. During January and February 1999, Dr. Falksen received a comprehensive evaluation that included examinations from numerous departments within the Mayo Clinic. Pet. Ex. 5. On 27 January 1999, David Osborne, Ph.D., performed several neuropsychological tests on her and found no cognitive decline or intellectual deficits:

> In summary, this is a woman of high-average intelligence who performs at this same general level on all tests administered. I see no signs of either specific intellectual deficits or of generalized cognitive decline. It may be that she is experiencing very subtle changes in cognitive abilities which are not detected by the tests. It is also possible that she has become overly concerned with cognitive abilities and is placing excessive emphasis on normal cognitive inefficiencies. If she feels that cognitive abilities are deteriorating, we could use today's results as baseline information and test her again in six months to one year for purposes of comparison.

Id. at 33-34. On 8 February 1999, John Caviness, M.D., of the Mayo Clinic's Department of Neurology made the following assessment after testing Dr. Falksen:

> Her CSF is totally normal. Her psychological testing is basically normal and her EEG and head imaging was unremarkable as well. I had to tell her that unfortunately I have no neurological explanation for her symptoms. We have not [sic] evidence her [sic] for an encephalitis what - so- ever. I have nothing to base a neurological diagnosis on and therefore no recommendation specifically that I can really give. I share with her her frustration of not having a specific answer, but I just do not know how we can reliably diagnose anything, let alone encephalitis, from neurological point of view with her clinical history, examination, and all her normal tests. She also relayed for me that a couple of weeks back, she woke up in the middle of the night and could not move any of her muscles and could not breath. This was of concern to her of course. However, I have no neurological explanation for this as

> well. I told her that if things worsen for her, then tests could be repeated again, but I think that we have a low yield here of having an encephalitic process and that her diagnosis should be regarded as non-neurological ast this point.

Id. at 25.On 22 February 1999, Dr. Osborne administered additional neuropsychological testing to "further evaluate cognitive impairment and to observe the effects of additional cognitive stress on her performance." *Id*. at 35. Dr. Osborne found that Dr. Falksen's "cognitive abilities continue to appear intact. She may experience mild cognitive inefficiencies from time to time, but I do not see any signs of an organic brain syndrome in these test results." *Id*. at 36.

On 22 February 1999, Dr. Falksen also saw Thomas Nelson, M.D., of the Mayo Clinic's Department of Psychiatry, to get an evaluation on why she was having trouble concentrating. *Id*. at 37-38. Dr. Nelson's findings were not conclusive but in his impression he stated that Dr. Falksen's condition could be a "variation on a somatization[19] disorder" or "depression and/or anxiety." *Id*. at 38. Dr. Nelson discussed the possibility that Dr. Falksen begin a low dose treatment of an antidepressant to which Dr. Falksen was noncommital. *Id*. Daniel Wochos, M.D., provided a summary of the findings and recommendations of the Mayo Clinic in Scottsdale:

> She has been told that despite a very extensive evaluation here at the Mayo Clinic Scottsdale, we have not come up with any objective abnormalities to explain her symptoms. She does have chronic lymphocytic leukemia, but we do not feel that is causing any of her symptoms. She has been told that it is time to move on–work to get her feeling better even if there is not a precise diagnosis. I am quite confident that the use of an antidepressant medication, psychotherapy, and also getting her back to work, is the best way to approach this. My expectation is that she can feel considerably better within just weeks.

Id. at 9.

On 26 February 1999, Dr. Falksen had a follow-up appointment with Dr. Johnson at Rocky Mountain Cancer Centers. Pet. Ex. 4 at 28. Dr. Johnson's assessment stated stage 0 chronic lymphocytic leukemia and that "her underlying fatigue is quite remarkable." *Id*. Dr. Falksen reported to Dr. Johnson that she "has extreme fatigue and difficulty concentrating to where she is unable to work even half of her normal day." *Id*. Dr. Johnson wrote a note to Dr. Falksen's employer to allow her to drecrease her work day to four hours per day. *Id*.

On 20 April 1999, Dr. Falksen began to see Pierre Brunschwig, M.D. Pet. Ex. 6 at 11. Dr. Brunschwig had previously seen Dr. Falksen between 1996 and early 1998, the last appointment

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[19] "In psychiatry, the conversion of mental experiences or states into bodily symptoms." DORLAND'S *supra* at 1546.

being 7 January 1998. *Id*. at 7-11. Dr. Johnson administered a homeopathic[20] therapy which improved Dr. Falksen's symptoms. *Id*. at 12.

On 7 May 1999, Dr. Falksen had another follow-up with Dr. Johnson where he again assessed stage 0 chronic lymphocytic leukemia. Pet. Ex. 4 at 32. Dr. Falksen reported that she had received a "'homeopathic antidote' to her tetanus vaccine ten days prior and since she has had improved energy and no further equilibrium problems." *Id*.

On 10 May 1999, Dr. Falksen visited Dr. Brunschwig again and complained of feeling out of balance and extreme fatigue. Pet. Ex. 6 at 12. Dr. Brunschwig assessed "post vaccination encephalopathy with residual atypical sx including light headedness 'stuffy head – obstructed breathing' and severe fatigue post Tdlm." *Id*.

On 8 June 1999, at Dr. Brunschwig's suggestion, Dr. Falksen met with Mary Ann Keatley, Ph.D. Pet. Ex. 7 at 2-7. Dr. Keatley found that Petitioner had a "full scale cognitive score in the 98th percentile for her age." *Id*. at 4, 20-21. However, Dr. Keatley also noted "problems in visual perception and reasoning." *Id*. Dr. Keatley, *inter alia*, made the recommendation that Dr. Falksen undergo a complete neuropsychological evaluation. *Id*. at 6. On 26 June 1999, Dr. Keatley completed a long term disability claim for Dr. Falksen in which she diagnosed her with an encephalitis. *Id*. at 12-13.

On 23 August 1999, at Dr. Keatley's recommendation, Dr. Falksen was evaluated by Rebecca Hutchins, O.D.[21] Pert. Ex. 10 at 1. Dr. Hutchins fitted Dr. Falksen with a new set of prism glasses. *Id*.

On 7 September 1999, Dr. Keatley stated that "I do not feel that she has received adequate diagnostic testing in the neurocognitive arena to rule out subtle brain-related symptomology." *Id*. at 20. Dr. Keatley recommended that Petitioner "undergo another comparative neuropsychological test battery as well as a vision evaluation to determine the relative contribution of symptoms to her difficulties. *Id*. at 21. Dr. Keatley noted that Dr. Falksen's "medical history of two concussions secondary to motor vehicle accidents, chronic lymphocytic leukemia and possible encephalitis secondary to tetanus shot seem like possible contributing factors to her current physical and cognitive symptoms." *Id*. On 1, 3, 8, and 10 November 1999, Dr. Falksen underwent neuropsychological testing by Jan Lemmon, Ph.D. Pet. Ex. 8 at 2-12. Dr. Lemmon opined that the neurological tests administered at the Mayo Clinic were not as sensitive as theycould be to "higher level information processing deficits." *Id*. at 1, 4. Dr. Lemmon found numerous areas of impairment from a battery of tests she administered over the course of several days:

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[20] "An alternative approach to medicine based on the belief that natural substances, prepared in a special way and used most often in very small amounts, restore health. According to these beliefs, in order for a remedy to be effective, it must cause in a healthy person the same symptoms being treated in the patient. Also called homeopathy." www.health-dictionary.com.

[21] "Doctor of optometry." MEDICAL ABBREVIATIONS *supra* at 123.

> Impairment was found in the areas of auditory and visual attention/concentration, multitrack thinking, mental control/organization, verbal fluency, encoding and registration of new information, short-term nonverbal memory and working memory. Motor ability impairment occurred for both hands on motor speed, grip strength, and fine motor coordination. Below average performance was also documented for reasoning.

Id. at 2-12, 15.

After completing a "neuromuscular and biofeedback evaluation" of Dr. Falksen in May 2000, Dr. Keatley recommended that she "engage in a neuromuscular and biofeedback program in order to improve her voluntary ability to relax her muscles, control temperature and electrodermal response." Pet. Ex. 7 at 38-39. On 27 June 2000, Dr. Falksen began receiving regular biofeedback sessions with Jaqueline Adolph of NeuroHealth Associates, L.L.C. Pet. Ex. 9 at 1. These treatments were performed under the supervision of Dr. Keatley. Pet. Ex. 10 at 1; Pet. Ex. 9 at 32. On 3 August 2000, Miss Adolph recommended that Dr. Falksen be seen again by Rebecca Hutchins, O.D. Pet. Ex. 10. Dr. Hutchins advised against additional neuropsychological testing. *Id*.; Pet. Ex. 22 at 5.

On 22 August 2000, at the request of UNUM Life Insurance Company, Dr. Falksen visited William D. Boyd, M.D., of Advanced Neuropsychology, Inc. Pet. Ex. 49, for further neuropsychologic evaluation.[22] Edward Serr, Esq., Dr. Falksen's attorney in this matter, accompanied her to the appointment with Dr. Boyd. *Id*. Mr. Serr urged Dr. Boyd not to test Dr. Falksen because such testing might be detrimental. *Id*. at 1. Dr. Boyd informed Mr. Serr that Petitioner could decline the evaluation but Mr. Serr countered by stating that this would cause more distress than the testing because her benefits might be cut. *Id*. After conferring with Mr. Serr, Dr. Falksen agreed to the evaluation. *Id*. Mr. Serr insisted that he be allowed to remain in the room while the tests were administered, however, Dr. Boyd declined asserting that the testing environment would be detrimentally changed and that the tests were confidential. *Id*. Mr. Serr continued to object to the testing at which point Dr. Boyd stated that the decision was up to Petitioner. *Id*. Mr. Serr again stated that refusing the tests could lead to a reduction in Petitioner's benefits and that could be more stressful than being tested. *Id*. Dr. Boyd suggested the if Dr. Falksen lost her benefits she could seek the counsel of an attorney, which led Mr. Serr to identify himself as Dr. Falksen's attorney. *Id*. Dr. Boyd assured Mr. Serr that he would make Dr. Falksen as comfortable as possible during the evaluation, at which point Mr. Serr relented. *Id*. In his review, Dr. Boyd found the "absence of objective evidence of abnormalities." *Id*. at 2. In concluding his incident report concerning the evaluation, Dr. Boyd stated that he "believe[s] that Mr. Serr's behaviors are creating and/or exacerbating Ms. Falksen's emotional reaction to the evaluation." *Id*. at 3.

On 27 December 2000, Petitioner visited Steven Stockdale, Ph.D., and received a

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[22] Dr. Brunschwig had written to UNAM Life Insurance Company protesting the request for further neuropsychological testing claiming such would severely aggravate Dr. Falksen's underlying symptoms and that UNUM should "[p]lease stop this testing." Pet. Ex. 5 at 5.

quantitative EEG evaluation. Pet. Ex. 11 at 1-4. After sharing his data with Robert Thatcher, Ph.D., he opined:

> The current quantitative EEG evaluation, including the review of this patient's past history and an independent interpretation of the data by Dr. Robert Thatcher, suggests that these quantitative EEG results are consistent with moderately abnormal quantitative EEG analysis. Dr. Thatcher felt that this patient has occasional sharp waves in the EEG in the frontal, central and parietal region and abnormalities in coherence, amplitude asymmetry and measures of relative power.

Pet. Ex. 11 at 5-6. On 6 March 2001, Dr. Stockdale wrote to Petitioner's attorney and recommended "EEG neurofeedback training, as part of her cognitive rehabilitation program." *Id*. at 1. Dr. Stockdale found that it was not "realistic for [Dr. Falksen] to maintain a job in the regular workforce . . . [w]ithout some significant changes from further treatment . . . ." *Id*. at 2.

On 13 February 2001, at the request of Dr. Brunschwig, Petitioner saw Janice Miller, M.D., a board certified neurologist, and received a neurologic evaluation. Dr. Miller found "very little data to suggest an epileptiform disorder" and noted the possibility that Dr. Falksen's head discomfort and visual disturbances could represent atypical acephalic migraines.[23] Pet. Ex. 12 at 3. Dr. Miller found no need to perform an additional MRI because Dr. Falksen already had two within the past two years, both of which were normal. *Id*. Dr. Miller recommended referral to a multi-disciplinary Swedish sleep center for Dr. Falksen's sleep disturbances. *Id*. at 4. Dr. Miller opined in her report to Dr. Brunschwig that she was "not sure that I have given you a great deal of help with this challenging patient . . . ." *Id*.

On 23 April 2001, at the recommendation of Dr. Brunschwig, Petitioner visited Christopher M. Filley, M.D., a board certified neurologist and an instructor-professor, Department of Neurology, University of Colorado Health Sciences Center. Pet. Ex. 13. Upon reviewing the Petitioner's history and her previous evaluations, Dr. Filley assessed:

> In summary, the problem for which the patient was referred today has largely resolved under Dr. Brunschwig's care. She has much improved cognition today by her history, and I can find no deficits on the examination today. I am also impressed that she had neuropsychological testing at a very prestigious institution on two occasions, and both of these she scored well. Indeed, her entire workup at the Mayo clinic in Scottsdale was essentially normal, and this is a very useful database from which to begin my evaluation of the case.

Pet. ex. 13 at 4. Dr. Filley was unable to conclude that the Petitioner experienced a neurological syndrome as a result of the vaccine she received on 28 May 1998:

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[23] A migraine with typical symptoms but without the headache. http://www.books.md/A/dic/acephalicmigraine.php.

> I told her that the vaccine that she received may well have caused a neurological syndrome, but without documentation at the time, it is impossible to verify that this in fact occurred. Therefore, we must remain careful to conclude that a viral encephalitis or postvaccinal encephalitis syndrome can only be speculated about at this time.

Id. Dr. Filley opined that treating the Petitioner's insomnia would be the best course:

> In trying to think of what I could do to help her feel better and achieve a higher level of function, I thought that treating insomnia would probably be the best course, given that we do not have a primary diagnosis about this cognitive syndrome. Clearly insomnia can worsen mental status functioning, and restoration of normal sleep can be very beneficial in anyone. Therefore, I would suggest that trazodone[24] 50 mg g.h.s. be considered in this patient. This medication also has antidepressant effects, and if the psychiatrist at the Mayo Clinic was correct in speculating on this matter, perhaps the trazodone will help her with that problem as well.

Pet. Ex. 13 at 5.

On 11 May 2001, Dr. Falksen returned to see her oncologist, Dr. Johnson, for chief complaint listed as "They found out what is wrong with me, Herpes Simplex 6." Pet. Ex 25 at 1. Dr. Johnson noted that Dr. Falksen's primary care physician "found her to have elevated levels of Herpes Simplex Virus Type 6."[25] *Id*. During the appointment, Dr. Falksen noted subsequent to the course of Valtrex[26] she was prescribed for her Herpes, she had a "'clearing of the head and increased mobility,' but still not to her baseline from 3-4 years ago." *Id*. Dr. Johnson's impression was that Dr. Falksen was "doing well without constitutional symptoms nor signs of disease progression [(lymphocytic leukemia)] as yet on observation alone." *Id*.

In the Fall of 2001, Dr. Falksen went to Dallas, Texas, for further testing. Petitioner saw William J. Rae, M.D., of the Environmental Health Center, and David C. Hickey, of North Texas Imaging Center. Dr. Falksen was evaluated for "toxic encephalopathy, fibromyalgia, chronic fatigue, syncope, altered mental status, seizures and vertigo." Pet. Ex. 31 at 20. Dr. Hickey noted that after undergoing a brain protocol, Dr. Falksen's mini-mental score was 30 out of a possible 30. Pet. Ex. 31 at 20. Dr. Hickey's impression was that Dr. Falksen had "1. Marked temporal asymmetry as discussed above. 2. Left parietal focal cortical defect with a correlation for history of trauma to this

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[24] Trazodone is an antidepressant.

[25] "A virus of the herpesvirus beta-subfamily, discovered in 1985, that infects more than 95% of people by the age of 2 years. It has been causally associated with roseola, mononucleosis-like illness, inflammation of lymph glands. There is also suggestive evidence for a role in multiple sclerosis." www.health-dictionary.com.

[26] Valtrex is a "drug for the treatment or suppression of genital herpes for adults." www.herpeshelp.com.

area suggested. 3. Activation of the deep gray matter, specifically the thalami."[27] *Id*. Dr. Rae noted in a letter to Dr. Brunschwig that Dr. Falksen underwent:

> [E]xtensive diagnostic work-up. Autonomic Nervous System Dysfunction was revealed by a Heart Rate Variability Test, which showed predominant sympathetic response and a decrease in parasympathetic response. An abnormal Pupillography[28] test revealed a cholinergic[29] response. Skin testing for Diphtheria-Tetanus provoked symptoms. A SPECT Brain scan showed severe temporal lobe asymmetry and her neurotoxic pattern was categorized as mild.

Pet. Ex. 31 at 1.

Dr. Falksen continues to receive treatment from Dr. Brunschwig, Jacqueline Adolph, Dr. Rae and follow-up with Dr. Johnson, her oncologist. She continues to this day to experience the symptomology set forth throughout her medical records

III. DISCUSSION AND ANALYSIS

1. Dr. Falksen did not suffer from an encephalitis with residual encephalopathy.

Every board certified neurologist that examined Dr. Falksen or reviewed her medical records either made the determination that there was no evidence of encephalitis or failed to diagnose encephalitis. John Caviness, M.D., of the Mayo Clinic Department of Neurology, found Dr. Falksen's neurological examination to be normal, Pet. Ex. 5 at 5, 31, and stated in his neurologic record of the examination that "We have not [sic] evidence her [sic] for an encephalitis what-so-ever. I have nothing to base a neurological diagnosis on . . . . I just do not know how we can reliably diagnose anything, let alone encephalitis, from a neurological point of view with her clinical history, examination, and all her normal tests. . . . [H]er diagnosis should be regarded as non-neurological at this point." Pet. Ex. 5 at 25. Christopher M. Filley, M.D., a board certified neurologist and an Instructor-Professor, Department of Neurology, University of Colorado Health Sciences Center, found no neurological deficits during his exam. Pet. Ex. 13 at 4. Dr. Filley stated that it was impossible to determine whether an encephalitis had occurred. *Id*. Janice A. Miller, M.D., a board certified neurologist, did not diagnose an encephalitis. Pet. Ex 12 at 1-4. Finally, Arthur P. Safran, M.D., Respondent's expert and a board certified neurologist, stated after his review of Dr. Falksen's

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[27] "genitive and plural of thalamus." DORLAND'S *supra* at 1703. Thalamus: "An area of the brain that helps process information from the senses and transmit it to other parts of the brain." www.health-dictionary.com.

[28] Pupillography is a "test that measures the response of the pupils to a standardized brief light stimulus." http://webeye.ophth.uiowa.edu/dept/service/pupilogr/.

[29] "Stimulated, activated or transmitted by choline (acetycholine): a tern applied to those nerve fibers which liberate acetylcholine at a synapse, when a nerve pulse passes, i.e., the parasympathetic nerve endings." DORLAND'S *supra* at 324.

medical records that "There is no evidence whatever of encephalitis." Res. Ex. A at 4. Additionally, Dr. Safran noted that standard electroencephalograms and a MRI showed no abnormality. *Id*.

A number of doctors, both medical doctors and Ph.D.s, did diagnose Dr. Falksen with having suffered an encephalitis. However, none of these doctors were board certified neurologists nor did they have any documented expertise in the field of neurology. Pierre Brunschwig, M.D., a board certified family practice physician, stated his "unwavering opinion that [Dr. Falksen] has suffered from a post vaccination encephalitis." Pet. Ex. 44 at 1. Nancy A. Didriksen, who has a Ph.D. in Psychology and a private practice in evaluation and treatment of environmentally ill and other chronically ill patients, opined that Dr. Falksen had a "possible resulting encephalitis" from her exposure to Td. Pet. Ex. 39 at 12. William J. Rea, M.D., who specializes in environmental medicine, made a specific diagnosis of "toxic encephalopathy secondary to a hypersensitivity reaction to the diphtheria-tetanus shot." Trans. at 176. Mary Ann Keatley, Ph.D., who specializes in cognitive rehabilitation and rehabilitation for speech and language for people who have neurological problems, admitted that she was not qualified to make a neurologic diagnosis of Dr. Falksen's alleged injuries. *Id*. at 143.

When determining the more credible medical expert witness, the Court must take into account the expert's area of expertise and training in such area. The expert's opinion should have a "reliable basis in the knowledge and experience of his discipline." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 (1993). Additionally, the AMA "Code of Medical Ethics" states at 9.07 Medical Testimony: "Medical experts should have recent and substantive experience in the area in which they testify and should limit testimony to their sphere of medical expertise . . . ."

The sphere of medical expertise at issue in this case is neurology, yet Petitioner does not present one board certified neurologist to opine in her favor. To the contrary, every board certified neurologist whose opinion is contained in the Court's record either finds no evidence of an encephalitis or fails to diagnose such. The Court has no other reasonable option but to find the opinions and testimony of those with an expertise in the medical sphere of neurology more credible and, therefore, more compelling than those who do not.

The tests performed on Dr. Falksen by the board certified neurologists resulted in no objective abnormalities indicating an encephalitis with residual encephalopathy. A head MRI on Dr. Falksen performed on 27 January 1999 was normal. Pet. Ex. 5 at 5, 18. An electroencephalogram ("EEG") done on 27 January 1999 was normal. Pet. Ex. 5 at 5, 19. Psychometric studies performed at the Mayo Clinic were "basically normal." Pet. Ex. 5 at 5. A spinal fluid examination on 11 February 1999 was "extremely normal." Pet. Ex. 5 at 8, and her cerebral spinal fluid ("CSF") was "totally normal." Pet. Ex. 5 at 26. The additional psychometric testing performed on 22 February 1999 was again basically normal and the EEG done immediately afterwards was "perfectly normal." Pet. Ex. 5 at 9.

On 27 December 2000, Dr. Falksen underwent a quantitative EEG ("QEEG").[30] Robert W. Thatcher, Ph.D., who is certified in EEG and QEEG Neurophysiology,[31] summarized his analysis of the QEEG by stating it "shows sub-optimal neural function in widespread cortical regions, which is likely indicative of reduced capacity for information processing and reduced cortical resource allocation." Pet. Ex. 11 at 7. Dr. Thatcher did not offer a causation for his findings.

In an assessment of QEEG sponsored by the American Academy of Neurology and the American Clinical Neurophysiology Society, the authors indicated that QEEG analysis techniques "remain controversial." Res. Ex. A at 5. The authors concluded from their assessment that "[b]ecause of substantial risk of erroneous interpretations, it is unacceptable for any . . . QEEG techniques to be used clinically by those that are not physicians highly skilled in clinical EEG interpretation." *Id*. at 14. Additionally, the authors stated that "[o]n the basis of clinical and scientific evidence, opinions of most experts, and the technical and methodologic shortcomings, QEEG is not recommended for use in civil or criminal judicial proceedings." *Id* at 13.

Dr. Rea stated that a brain SPECT scan[32] conducted on Dr. Falksen showed "marked temporal asymmetry," with the left being larger than the right, and "revealed neurotoxicity which substantiates significantly the neurological effects of the Diptheria-Tetanus vaccination." Pet. Ex. 32 at 2. Dr. Safran testified that the American Academy of Neurology does not accept brain SPECT scans "for use in diagnosing encephalopathy or encephalitis except for AIDS." Trans. at 375.

Not one board certified neurologist who examined or tested Dr. Falksen or reviewed her medical records made a diagnosis of encephalitis. The tests performed by board certified neurologists resulted in no objective abnormalities indicating an encephalitis with residual encephalopathy. Any tests that were interpreted to indicate such were not the result of a board certified neurologist's analysis nor were such tests generally accepted within the medical sphere of neurology. Accordingly, the Court finds that Petitioner has not met her burden of showing by a preponderance of the evidence that Dr. Falksen ever suffered an encephalitis.

2. Petitioner has not proven by a preponderance of the evidence that Td can cause such injury or did cause such injury in this case.

Having found that, by a preponderance of the evidence, Dr. Falksen did not suffer from an encephalitis with residual encephalopathy, the Court could end its discussion here. However, *arguendo*, even if Dr. Falksen did suffer the injury alleged, Petitioner has not proven by a

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[30] QEEG "is the mathematical processing of digitally recorded EEG in order to highlight specific waveform components, transform the EEG into a format or domain that elucidates relevant information, or associate numerical results with the EEG data for subsequent review or comparison." Res. Ex. A at 7.

[31] Dr. Thatcher's *curriculum vitae* can be found at www.appliedneuroscience.com/VITAE-Robert.htm.

[32] A "brain SPECT scan is a way for a physician to see how blood is flowing through different areas of [the] brain." http://www.amershamhealth-us.com/patient/diaguide/spect.html.

preponderance of the evidence that Td can or did cause such injury.

Petitioner can prove entitlement to compensation under the Program in one of two ways. They can prove entitlement through a statutorily prescribed presumption of causation or, by proving causation-in-fact. First, Petitioner may prove that she suffered an injury or condition listed in the Vaccine Injury Table within the statutorily prescribed time period. § 11(c)(1)(C)(i). If Petitioner establishes that she suffered such injury by a preponderance of the evidence, Petitioner is entitled to a presumption of causation. § 13(a)(1)(A). If Petitioner qualifies under this presumption, she will be said to have suffered a "Table injury." The burden would then shift to the Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B).

If Petitioner fails to satisfy the requirements under the Act for demonstrating a Table injury, Petitioner may prove by a preponderance of the evidence that the vaccination in question, more likely than not, caused the alleged injury. §§ 11(c)(1)(C)(ii)(I) and (II). This causation-in-fact standard, according to the Federal Circuit, requires proof of a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Once again, if Petitioner is successful in that showing, the burden shifts to Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B).

In the present case, Petitioner does not allege that she suffered a Table injury. Petitioner alleges that the onset of her encephalitis and resulting residual encephalopathy was the result of the Td vaccine she received on 29 May 1998. The Table does not list encephalitis as a recognized adverse event in conjunction with tetanus toxoid and diphtheria toxoid containing vaccines that warrants presumption, thus, Petitioner's claim is one of causation-in-fact.[33]

a. Causation-In-Fact

In order to demonstrate entitlement to compensation in a causation-in-fact claim, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question *more likely than not* caused the injury alleged. *See* 11(c)(1)(C)(ii)(I) and (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit, which summarized the legal criteria required to prove causation-in-fact under the Vaccine Act, requires that every petitioner:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires 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.

[33] 42 C.F.R. § 100.3(a).

Grant, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

This Court has organized the legal criteria in *Grant* by means of a two-part test. *First*, a petitioner must provide a reputable medical theory causally connecting the vaccination and the injury. In fine, *can* vaccine at issue cause the type of injury alleged? *Second*, a petitioner must also prove that the vaccine at issue *did* cause the alleged symptoms in her particular case.

Under the first prong, a petitioner must demonstrate the biologic plausibility of their theory. This may be accomplished in a number of ways. First, a petitioner must proffer a scientific pathogenesis underlying the alleged causal relationship. Reliability and plausibility are found by providing evidence that at least a sufficient minority of physicians have accepted the theory. In addition, epidemiological studies and an expert's experience, while not dispositive,[34] lend significant credence to the claim of plausibility. Articles published in respected medical journals, which have been subjected to peer review, are also persuasive.

The second prong of the causation-in-fact test is difficult but not impossible. A petitioner must show, by a preponderance of the evidence--as this special master is wont to say, a test based on fifty percent and a feather--that the vaccine caused the symptoms that manifested in this case. A petitioner does not meet this affirmative obligation by merely showing a temporal association between the vaccination and the injury. Rather, a petitioner must explain *how* and *why* the injury occurred. *Strother*, 21 Cl. Ct. at 370; *see also Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1993), *cert. denied*, 469 U.S. 817 (1984) (inoculation is not the cause of every event that occurs within a ten day period following it).

b. Applicability of the Two Part test in Miss Falken's Case

In Dr. Falksen's case, the Court follows the two pronged causation in fact analysis tailored as: (i) Is it biologically plausible a tetanus toxoid and diphtheria toxoid containing vaccine can cause encephalitis?; and, (ii) Did Dr. Falksen's Td vaccination result in her encephalitis with residual encephalopathy?

(i) Can the tetanus toxoid and diphtheria toxoid containing vaccines cause encephalitis?

"The evidence favors rejection of a causal relation between DT, Td, or tetanus toxoid and encephalopathy (acute or chronic)." INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH

[34] This first prong of the Court's test meets easily with cases where epidemiological or case study reports are already available. Beginning with this prong is practical when there is epidemiological evidence, for it avoids the tautalogical reasoning that would result when one attempts to answer *Can It?* without having reports and studies that previously would have answered *Did It?*

CHILDHOOD VACCINES: EVIDENCE BEARING CAUSALITY, 78 (1994) (hereinafter "IOM").[35] Although not dispositive, the Court gives great deference to the findings of the Institute of Medicine on the issue of cause and effect between vaccines and discrete injuries. Additionally, either party to a vaccine-related injury case, when in their favor, are quick to reference the findings of the Institute of Medicine.

Dr. Rea states that it is well documented in medical literature that encephalopathy can be precipitated by Diptheria-Tetanus vaccination. Pet. Ex. 38 at 2. In his supplemental report dated 8 April 2002, Dr. Rea references five articles that he states links "neurological dysfunction or encephalopathy secondary to Diphtheria-tetanus vaccine." *Id.* at 1. However, each article to which Dr. Rea references pertains to the diphtheria-tetanus-pertussis vaccine. *Id.* at 1-2. Pertussis containing vaccines are known to cause encephalopathy[36] on rare occasions, however, Dr. Falksen was not administered such. Therefore, Dr. Rea's reference to articles concerning pertussis containing vaccines is not compelling.

Petitioner has filed nine additional pieces of medical literature to advance her argument that Td can cause encephalitis. Pet. Ex. 33 through Pet. Ex. 37. Two of the nine filings report on alleged adverse events from the diphtheria-tetanus-pertussis vaccine.[37] As stated throughout this decision, the vaccine at issue did not contain pertussis, thus, the two articles add nothing to Petitioner's general causation argument.

Petitioner's Exhibit 33 contains the Physician's Desk Reference ("PDR") entry regarding tetanus toxoid adsorbed. Under the warnings section, the PDR states "neurological complications

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[35] The National Childhood Vaccine Injury Compensation Act established a committee at the Institute of Medicine (IOM) — a prestigious medical research organization funded by Congress to provide objective, timely, authoritative information and advice concerning health to government, the corporate sector, the professions, and the public — to review the medical literature on health problems or injuries occurring after vaccination. This Court, created by the same legislation, gives great deference to the committee's findings. "The principal purpose of the committee's work was to describe as precisely as possible, on the basis of all available evidence, the relationship between vaccines under study and specific adverse events. This led the committee to ask with each vaccine-adverse event pair, 'Can administration of the vaccine cause the adverse event.' All available sources of information were analyzed, from epidemiologic studies to unpublished case reports. Final decisions on causality were made by consensus after group discussion of all of the available evidence. In pursuing its conclusions, the committee adopted a neutral stance and maintained that stance consistently through each step in the process, assuming neither presence nor the absence of causal relation between the vaccines and the adverse events until the evidence indicated otherwise." INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING CAUSALITY (1994).

[36] The Vaccine Injury table lists encephalopathy as an adverse event for pertussis antigen containing vaccines. 42 C.F.R. § 100.3(a).

[37] Petitioner's Exhibit 35 includes a 27 December 1996 Filing by Lederle with the FDA regarding its diphtheria, tetanus, and acellular pertussis vaccine adsorbed. Petitioner's Exhibit 37 includes a 30 December 1996 Letter from the Department of Health and Human Services to Ledele Laboratories regarding the diphtheria, tetanus, and acellular pertussis vaccine adsorbed.

such as . . . encephalopathy . . . have been reported following administration of preparations containing tetanus antigen." Pet. Ex. 33 at 2. Since childhood vaccines that contain tetanus antigen may also contain the pertussis antigen, the PDR warning must be taken *cum grano salis*. Additionally, the PDR lists all possible reported complications without determining whether there is any causal link. Trans. at 382.

Petitioner's Exhibit 34 contains six articles. The first article concerned a 33 year-old Nigerian male that suffered from polyneuritis[38] twenty four hours after administration of tetanus toxoid. Pet. Ex. 34 at 1. The article is about a peripheral nerve disorder and is not relevant to Petitioner's claim of encephalitis. The second article is a case study concerning a thirty six year-old female who "had a rapidly progressing neuropathy with involvement of cranial nerves, myelopathy with hyperactive proprioceptive reflexes and Babinski sign, and encephalopathy with drowsiness and EEG disturbances," *Id*. at 4, 5, onset of which was five days after receiving a tetanus toxoid vaccination. *Id*. Although the author of the case study attributes the woman's condition to the tetanus toxoid, he notes that neurological complications from tetanus toxoid are "extremely rare," *Id*. at 4. Additionally, the woman was diagnosed with polyradiculomyelitis, which is another name for Guillan-Barré syndrome ("GBS").[39] Dr. Falksen has not been diagnosed with GBS. Article three is a case study concerning a 43 year-old man that developed acute disseminated encephalomyelitis[40] ("ADEM") possibly associated with tetanus toxoid. *Id*. at 10. Although the focus of the article is ADEM, which Dr. Falksen does not have, it does assert that encephalopathy is a known neurological complication to tetanus toxoid. However, the article does not specify what encephalopathic process tetanus toxoid is associated with.[41] Article four is a case study of a thirty three year-old who inadvertently received three tetanus toxoid injections over a five month period and subsequently developed a "profound mixed sensorimotor polyneuropathy." *Id*. at 12. Again, this article deals with a peripheral nerve disorder and is not relevant to Petitioner's claim. The fifth article concerns another case study of GBS following an injection of tetanus toxoid. *Id*. at 15. Dr. Falksen does not have GBS. The sixth article is actually a letter to the editor that was published in the June 1983 Archives of Neurology. *Id*. at 28. The letter was authored by Gerald M. Fenichel, M.D.,[42] of Vanderbilt's School of Medicine Department of Neurology, and in the letter Dr. Fenichel states there is no basis, other than a temporal relationship, to accept a link between tetanus toxoid and certain neurological complications. *Id*. Far from helping Petitioner's argument that tetanus toxoid can cause encephalitis, Dr. Fenichel refutes such claims that are based only on temporal relationship. *Id*.

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[38] "Inflammation of many nerves at once; multiple, or disseminated, neuritis." DORLAND'S *supra* at 1333.

[39] DORLAND'S *supra* at 1335.

[40] "An acute inflammatory demyelinating disease of the central nervous system." DORLAND'S *supra* at 550.

[41] For instance, GBS is an encephalopathic process that this Court has found to be associated with tetanus toxoid. However, Dr. Falksen has never been diagnosed with GBS. Therefore, just asserting that encephalopathy is a known neurological complication of tetanus toxoid without being more specific is not compelling.

[42] Dr. Safran testified that Dr. Fenichel is "a world expert on complications of vaccines and writes reports for the American Academy of Neurology." Trans. at 384.

Petitioner has not proven by a preponderance of the evidence that the Td vaccination can cause encephalitis. The IOM favors a rejection of any causal relation. In order to bolster his opinion, Dr. Rea references articles about pertussis antigen containing vaccines. The pertussis antigen is not at issue in this case. The remaining articles that Petitioner has filed to further her argument either do not address an injury similar to that alleged by Petitioner, give no basis for a conclusion that Td can cause encephalitis, or actually refutes Petitioner's argument. Additionally, and as stated *supra*, the medical experts opining on behalf of Petitioner do not specialize in neurologic injury, which is the type of injury Petitioner alleges.

(i) Did the tetanus toxoid and diphtheria toxoid containing vaccines cause the alleged encephalitis?

Petitioner argues that the difficult standard to overcome in a causation-in-fact case does not exist "when testing shows that a particular individual, here Dr. Falksen, does in fact react in an unusual way to a widely used and otherwise extremely safe vaccine." Petitioner's Closing Argument (hereinafter "Pet. Clos. Arg.") at 11. Petitioner's argument is based on a skin sensitivity test of a very small amount of diphtheria-tetanus ("DT") vaccine administered to Dr. Falksen by Dr. Rea. Dr. Rea reported that the test "showed a positive skin response," Pet. Ex. 32 at 2, and "provoked her symptoms and the effect was verified by a SPECT scan." Pet. Clos. Arg. at 10. Petitioner states that the outcome of this test "cannot be overemphasized" and dispositively shows that Dr. Falksen, "as a unique individual was adversely affected [sic] by the TD vaccine." *Id.* at 11.

Dr. Safran stated that such a reaction should be expected. He testified "that the purpose of giving the person the toxoid is to make them get allergic to it in the sense of developing antibodies." Trans. at 379. Dr. Safran testified that Dr. Falksen's reaction is known as an "Arthus"[43] reaction, which "is a reaction that happens when you have very high circulating antibody levels and you challenge the person with a test dose and they get a severe local skin reaction." *Id*.

Dr. Safran went on to testify that Dr. Rea, by administering a small dose of DT, administered the "wrong stuff" because the vaccine at issue is Td. Trans. at 378. Dr. Safran criticized Dr. Rea for the mix up stating that "[t]he childhood vaccine [DT] has much higher concentrations of the diphtheria toxoid" and "[Dr. Rea] ought to know that if he's doing immunologic testing because you can do harm, and you can get skin necrosis." *Id.* Dr. Rea refuted this assertion stating that whether it was DT or Td is irrelevant because "[t]he skin test utilizes very small doses relying on minute antigenic material to elicit a response."[44] Pet. Ex. 56 at 5.

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[43] "The development of an inflammatory lesion, characterized by induraton, erythema, edema, hemorrhage, and necrosis, a few hours after intradermal injection of antigen into previously sensitized animal producing precipitating antibody." DORLAND'S *supra* at 1428.

[44] In his testimony, Dr. Rea testified that they used DT for the test because it "was the only vaccine that we had available commercially because they'd taken some off the market." Trans. at 178. In his written response to Dr. Safran's testimony, Dr. Rea stated that "[a] call to Lederle was made providing the Lot # of the vaccine that Ms. Falksen was given that resulted in a severe reaction. We were provided the same vaccine which was eventually used

The lack of qualifications of Dr. Rea to opine on neurologic injury has greatly impacted the Court's perception of this case. In the issue of the skin test and its probity, the Court finds Dr. Safran's testimony more compelling. However, this finding is influenced by another assertion that Dr. Rea made, which has troubled the Court. Dr. Rea states that a positive Romberg sign can be an indication of brain injury. Pet. Ex. 31 at 2. Dr. Safran testified that a positive Romberg test "can either be in the peripheral nerves or in the spinal cord, but it is never -- I want to emphasize never -- in the brain." Trans. at 380. In the Court's own research, it has found that Dr. Safran is correct.[45]

The Court is confident that Dr. Rea is well qualified and highly regarded within his specialty of environmental medicine. However, the Court is less than confident when it comes to his qualifications in neurology. Accordingly, Petitioner has not met her burden by proving by a preponderance of the evidence that the Td vaccine she received on 29 May 1998 did cause her encephalitis with residual encephalopathy.

IV. CONCLUSION

This Court is aware that Dr. Falksen has suffered some injury that continues to plague her until this day. However, the Court finds that the woof and warp of Petitioner's argument lacks sufficient evidence by a preponderance to prove that she suffered an encephalitis, or any other neurological disorder, or that the Td vaccine administered on 28 May 1998 can or did cause her injury. Regretfully, entitlement must be denied for the foregoing reasons.

Accordingly, this petition is **DISMISSED with prejudice**, pursuant to Vaccine Rule 21, for failure to prove a *prima facie* case for entitlement under the Vaccine Act. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

Richard B. Abell
Special Master

to skin test Ms. Falksen." Pet. Ex. 56 at 5. Dr. Rea's testimony and subsequent follow-up on this matter are contradictory.

[45] The Romberg test is used "[f]or differentiation between peripheral and cerebellar ataxia; increase in clumsiness in movements and in width and uncertainty of gait when patient's eyes are closed indicate peripheral ataxia; no change indicates cerebellar type." http://www.orthoteers.co.uk/Nrujp~ij33lm/Orthclinsigns.htm.