

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-775V

Filed: March 16, 2011

Unpublished

BRIGITTE MUELLER,

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Petitioner,

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Hepatitis A, Hep A; Witness testimony

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weighed against contemporaneous

v.

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medical records; No factual predicate for

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experts' medical opinion

SECRETARY OF HEALTH AND
HUMAN SERVICES,

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Respondent.

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Lisa Annette Roquemore, Broker & Associates, P.C., Irvine, C.A., for Petitioner.

Ryan Daniels Pyles, U.S. Department of Justice, Washington, D.C., for Respondent.

Entitlement Decision¹

GOLKIEWICZ, Special Master.

On November 16, 2006, Brigitte Mueller, petitioner, filed a Petition for compensation under the National Childhood Vaccine Injury Act of 1986, as amended (“the Act” or “Program”).² The Petition states that on February 11, 1999, petitioner received Hepatitis A, polio and tetanus vaccines and “subsequently suffered a cause in fact injury known as Guillain-Barre Syndrome.” Petition at unnumbered 1 (“Pet.”). While paragraphs two and three of the Petition discuss events following the Hepatitis A vaccine, the Petition does not explicitly state

¹ The undersigned intends to post this decision on the website for the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). **As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id. Any motion for redaction must be filed by no later than fourteen (14) days after filing date of this filing. Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision, order, ruling, etc.**

² This Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) (hereinafter “Program,” “Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. §§ 300aa of the Act.

which vaccine is being blamed for the injury; however, the Petition states that petitioner “sustained an injury in the form of a Guillain-Barré Syndrome [“GBS”] caused by vaccine [sic].” Pet. at 3; ¶12. The Petition continues by stating that petitioner has not collected any damages for “any vaccine related injury or death including without limitation the Tetanus Vaccination which is the subject of this Petition.” Id. at ¶ 13. Which vaccine is allegedly involved is critical in this case because of the Act’s statute of limitations. See §16.

A claim that the Hepatitis A vaccine caused petitioner’s injury is timely because the Hepatitis A vaccine was added to the Vaccine Injury Table effective December 1, 2004. See 69 Fed. Reg. 69945 (Dec. 1, 2004). A revision to the Vaccine Table opens the jurisdictional door for a new two year period for filing a claim relating to the affected vaccine. § 16(b). Accordingly, petitioner had until December 1, 2006, to file a claim alleging her February 11, 1999, Hepatitis A vaccine caused an injury. Id. Petitioner filed her claim on November 16, 2006, and thus a claim that the Hepatitis A vaccine caused her alleged injuries is timely. See Respondent’s Rule 4(c) Report at 1, n. 1 (stating that the Hepatitis A claim is timely.) However, any claim based upon the polio vaccine or tetanus vaccine, also given on February 11, 1999, is time-barred. Section 16(a)(2) of the Act provides a three-year period following the first symptom or manifestation of injury to file a claim. Since petitioner claims her injury manifested on April 5, 1999, see Pet.at 2, ¶ 5, any claim based upon the polio or tetanus vaccines had to be filed by April 5, 2002, to be timely. Again, the Petition was filed on November 16, 2006. While the Petition is not clear as to which vaccine is being targeted, petitioner’s prosecution of this case was based clearly and solely upon the Hepatitis A vaccine.

Petitioner’s Affidavit

According to petitioner’s affidavit filed with the Petition, petitioner was a very active, healthy individual. Pet. at Ex 1, ¶ 2. The one exception was sciatica pain that developed in 1985. Id. at ¶ 3. This was treated by chiropractic care. Id. Petitioner was vaccinated on February 11, 1999, in anticipation of a trip to the Far East. Id. at ¶ 5. Petitioner returned from the Far East on April 3, 1999. Id. at ¶ 6. Other than muscle aches and pains from her work on the Habitat for Humanity project, petitioner claimed she experienced “no problems of which I was aware in my back or otherwise.” Id. This changed on April 5 as petitioner experienced a drop in energy level, which she attributed to a “delayed reaction” to the trip. Id. at ¶ 7. However, the feeling persisted and was joined by “some discomfort and tingling in my left foot.” Id. Petitioner associated the tingling with her prior back problem and attempted to address it with yoga exercises. Id. During the months of May and June, petitioner continued to feel “drained and exhausted.” Id. at ¶ 8. In addition, petitioner reports becoming “irritable” and “argumentative,” and stated “it was difficult for me to socialize.” Id. Petitioner reported that in the first week of July she experienced a “numbness” in one of her toes on her left foot. Id. Petitioner recalls that the numbness and some leg weakness continued, prompting a visit with her chiropractor. Id. Her chiropractor stated that she “was having a sciatica flare up.” Id. These symptoms “slowly progressed” in the months of August and September whereby the numbness affected “all my left toes and [] the toes of my right foot.” Id. By mid-September, petitioner stated that in addition to the discomfort in her feet, she began to experience “stinging sensations.” Id. She attributed the symptoms to her lower back. Id. “By November

[petitioner's] feet began to swell and not only [her] ability to do yoga and walk was reduced, but [she] was having trouble with routine walking.” Id.

Petitioner avers that by December the symptoms of numbness, tingling and swelling in the feet worsened, in addition to “sensitivity to heat and pressure.” Id. at 9. Petitioner was seen by several doctors in January 2000, and it was in February that she was diagnosed with GBS. Id. at ¶ 10. Stated simply, the medical records do not record the history as set forth by petitioner.

The essence of this case is a factual dispute. As discussed later, *infra* at 10-11, the contemporaneous medical records do not record the symptoms of fatigue and tingling sensation until November of 1999 -- nine months following the February 11, 1999, immunizations and concededly far outside any medically acceptable time frame for vaccine causation. However, petitioner herself alleges an onset of fatigue in April of 1999 with a continual progression of symptoms thereafter. While there are many medical issues involved in this case, the interpretation and resolution of the factual issues is paramount.

Procedural History

A short description of the evolution of this case may be helpful to understanding the development of the record. Proceedings were initially before a previously assigned special master. Petitioner, represented by her original counsel, filed her Petition on November 16, 2006, which was accompanied by the limited medical records available and the affidavits of petitioner and her one-time boy friend, Mark Blatchford. Pet., attached Exs 1, 2. On June 11, 2007, a consented motion was granted substituting petitioner, *pro se*, for her terminated counsel. Over the ensuing six months a number of status conferences were conducted discussing the need for petitioner to submit a medical opinion in support of her case.

On December 17, 2007, an Order issued for petitioner to file pertinent portions of her calendar for the period from February 1997 through the Spring of 1999. These entries were filed on December 26, 2007. Petitioner's current counsel was substituted in on January 23, 2008. With the appearance of current counsel, the case development progressed. The previously filed medical records labeled exhibits A-I were re-filed as petitioner's exhibit 3 (hereinafter “P Ex ___ at ___”). The calendar entries were re-filed as petitioner's exhibit 6. The August 2007 visit to Dr. Jordan was re-filed as P Ex 4, and the September 2007 visit to Dr. Latov was re-filed as P Ex 5. The report and supplemental report of Dr. Latov were filed as exhibits 7 and 11 respectively. Dr. Byers report was filed as exhibit 13 and Dr. Steinman's report was filed as exhibit 14. Factual affidavits were filed as exhibits 15 and 16. Finally, after many status conferences, a fact hearing was scheduled for December 19, 2008. With my colleague's integral involvement with the pending autism litigation, the case was transferred to the undersigned on November 17, 2008.

The fact Hearing was conducted on December 19, 2008.³ Following the Hearing, the undersigned issued a brief Order setting forth the essential fact rulings. Due to information that

³ There are four transcripts filed in this case. They will be cited as follows: Transcript of December 19, 2008 Fact Hearing - “T1 at ___”; Transcript of September 1, 2009 Second Fact Hearing - “T2 at ___”; Transcript of April 23, 2009 Expert Hearing - “T3 at ___”; and Transcript of June 12, 2009 Second Expert Hearing - “T4 at ___”.

was produced at the Hearing, petitioner was ordered to file the remainder of her journal for the year 1999. Thereafter, a Hearing was conducted on April 23, 2009, to hear the testimony of the respective experts. To give the experts an opportunity to discuss medical literature that was submitted at the Hearing on April 23, 2009, a telephonic Hearing was conducted on July 14, 2009. Finally, additional fact testimony was taken on September 1, 2009, related to petitioner's exhibit 18; exhibit 18 was the remaining portion on the 1999 calendar filed following the first fact Hearing. Finally, the experts were given an opportunity to file supplemental reports discussing information adduced at this last Hearing. Those reports were filed. The parties declined an opportunity to examine the experts on those reports. The parties have copiously briefed the issues presented in this case. The case is now ripe for decision.

While it may appear that this case proceeded piecemeal and in a protracted fashion, that would not be accurate. This case presents difficult factual issues, minimal medical records (both because petitioner did not seek medical attention following immunization and because many of the records prior to immunization were no longer available) and a number of medical issues. Counsel for their respective clients conducted this litigation vigorously and with a high degree of professionalism. In short, it was a well-handled litigation.

Summary of Experts

The primary expert relied upon by petitioner is Dr. Lawrence Steinman. See P Ex 14. Dr. Steinman is a Board Certified neurologist practicing at Stanford University Medical Center. See P Ex 20 (Dr. Steinman's CV). Importantly, Dr. Steinman has conducted extensive research on how the immune system can attack a person's own nervous system. Dr. Steinman testified as an expert in neurology and immunology without objection. T3 at 16. He has testified before the undersigned on two occasions. The undersigned has found Dr. Steinman to be extremely knowledgeable and well-versed in the substantive areas of medicine involved in the cases. The only criticism is that Dr. Steinman at times "stretches" his testimony to fit the result he is supporting, as opposed to strictly presenting medical information to inform the court. See infra at 23, n. 18. That was seen herein with regard to Dr. Steinman's interpretation of the medical significance of factual information presented in this case. The undersigned finds that extremely unfortunate as it naturally undercuts the persuasiveness of Dr. Steinman's opinions.

Dr. Steinman opines that the Hepatitis A vaccine given to petitioner on February 11, 1999, was a substantial factor in petitioner's development of Guillain-Barré Syndrome,⁴ which subsequently evolved into chronic inflammatory polyneuropathy ("CIDP").⁵ P Ex 14 at 1.

⁴ GBS is "an acute, immune-mediated disorder of peripheral nerves, spinal roots, and cranial nerves, commonly presenting as a rapidly progressive, areflexive, relatively symmetric ascending weakness of the limb, truncal, respiratory, pharyngeal, and facial musculature, with variable sensory and autonomic dysfunction; typically reaches its nadir within 2-3 weeks, followed initially by a plateau period of similar duration, and then subsequently by gradual but complete recovery in most cases." *STEDMAN'S MEDICAL DICTIONARY* 1899 (28th ed. 2006).

⁵ CIDP is "an uncommon, acquired demyelinating sensorimotor polyneuropathy clinically characterized by insidious onset, slow evolution, (either steady progression or stepwise), and chronic course; symmetrical weakness is a predominant symptom, often involving proximal leg muscles, accompanied by paresthesias, but not pain." *STEDMAN'S MEDICAL DICTIONARY* 1537 (28th ed. 2006).

According to Dr. Steinman, the onset of petitioner's symptoms began approximately on April 5, 1999, with chronic fatigue and tingling dysesthesias in her left leg. Id. Relying upon a study of the Swine Flu epidemic showing an increased risk of GBS within 12 weeks of immunization,⁶ Dr. Steinman averred that the timing in the instant case is appropriate. Dr. Steinman's medical theory of causation is that the Hepatitis A vaccine shares chemical sequences with myelin proteins and the cross-reactivity between the vaccine and the myelin proteins is well established. Id. at 2-3. Dr. Steinman relies on literature documenting the Hepatitis B vaccine triggering immune reactions to support his thesis that the Hepatitis A vaccine can likewise cause an immune reaction. Id. Dr. Steinman concludes saying that in petitioner's case "an immune response to hepatitis A could have induced a cross reaction with myelin basic protein, which is present in the peripheral nervous system" and thus causing GBS. Id. at 4.

While petitioner appeared *pro se*, she saw Dr. Norman Latov for a supportive expert opinion. See P Status Report, filed January 11, 2008. Petitioner was referred to Dr. Latov by her original treating neurologist, Dr. Sheldon Jordan, who saw petitioner on August 13, 2007. Dr. Latov saw petitioner on September 27, 2007, and the report from this visit was re-filed as P Ex 5. Dr. Latov recounts Ms. Mueller's medical history, notably that "[h]er symptom[s] began with generalized fatigue and tingling in her left leg in early April 1999." Id. Since there is no contemporaneous medical record documenting this onset in April, it is presumed that the information came from petitioner. Dr. Latov's clinical impression was "most consistent with diagnosis of CIDP." Id. at 2. Regarding causation, Dr. Latov stated that "[h]er condition could have been triggered by the vaccinations, as fatigue can be the presenting symptom in CIDP (Boukhris et al.⁷)" Id. Dr. Latov subsequently filed an affidavit opining that Ms. Mueller's chronic form of GBS, or CIDP, was a direct consequence of being vaccinated "with the hepatitis A in combination with the tetanus and polio vaccines." P Ex 7 at 2. However, under the "Reasons for my opinion" section, Dr. Latov gives a slightly different opinion, stating that it was "more likely than not that the Hepatitis A vaccine was a substantial factor in the development of GBS as any of the other[vaccines]." Id. at 3. Dr. Latov was then asked to clarify his statements. See R Status Report, filed March 12, 2008. On May 20, 2008, Dr. Latov's responses were filed as P Ex 11. The informational basis for Dr. Latov's placement of Ms. Mueller's symptoms in April 1999 was most important to this case. Dr. Latov stated:

My statement is based on the following: a. My office visit note of September 27, 2007, as reported by Brigitte Mueller, b) Report of Sheldon E. Jordan M.D. office note of 8/13/07 based on his medical records.

⁶ Dr. Steinman later testified regarding the medically appropriate timing of onset that based upon the Schonberger article, P Ex 14, "I think I have no problem with eight weeks. If I lay more heavily on Schonberger I can go to 10 weeks so it depends, but definitely eight weeks." T4 at 264. Thus, Dr. Steinman opined to eight weeks, ten weeks and twelve weeks as medically appropriate timing for onset of GBS following immunization. The changing positions and inexactness in Dr. Steinman's testimony raise significant questions about its reliability.

⁷ This article is filed as an attachment to P Ex 7.

P Ex 11 at 1. The referenced office note of the visit to Dr. Sheldon Jordan on August 13, 2007, can be found at P Ex 4. Under “History of Present Illness,” the office note states that the “history was obtained from the patient and my following records were reviewed.” P Ex 4. Importantly to the issue of onset, Dr. Jordan records the receipt of vaccinations on February 11, 1999, and “by early April 99 she began to have numbness in the feet. Over the ensuing months, she began to have numbness in the hands as well.” *Id.* Since this information is not contained in Dr. Jordan’s contemporaneous notes from January 2000, P Ex 3 at 19 (“numbness in toes and finger tips since November”), the information “was obtained from the patient.” P Ex 4 at 1. Dr. Jordan does not give an opinion on causation, but records “[t]he only identified cause in this case was exposure to vaccinations about one month from the onset of symptoms.” *Id.* at 3.

Thus, Dr. Jordan’s factual information, which differs from the history contained in his contemporaneous office notes, was provided by Ms. Mueller more than eight years after the dates in question. Further, Dr. Latov’s factual information was provided by Ms. Mueller and by Dr. Jordan, who got his information from Ms. Mueller. Again, this information was provided by Ms. Mueller more than eight years after the dates in question. Since the undersigned finds the factual information attributed to Ms. Mueller flawed, the predicate for Dr. Latov’s and Dr. Jordan’s discussion of the alleged role of the vaccine is flawed.⁸ Additionally, neither Dr. Latov nor Dr. Jordan stated an opinion on a probability scale as to which vaccine was the causative culprit. Dr. Jordan merely stated that the “only identified cause in this case was exposure to vaccinations.” P Ex 4 at 3. Dr. Latov, while saying that the Hepatitis A vaccine was “more likely” than the other vaccines to be a substantial factor, he states further that “[i]t is not possible to ascribe Ms. Mueller’s illness to any one of the 3 vaccines.” P Ex 7 at 3. As discussed earlier, the issue of which vaccine may or may not be causative is critical because of §16, the limitation period for filing the Petition. *See supra* at 2. For these reasons, no further discussion of Drs. Latov and Jordan is necessary.⁹

⁸ Petitioner developed an argument that Drs. Latov and Jordan as Ms. Mueller’s treating neurologists should be given greater evidentiary weight. *See Capizzano v. Sec’y of the Dept. of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (“treating physicians are likely to be in the best position to determine whether ‘a logical sequence of cause and effect show[s] that the vaccine was the reason for the injury.’”). *See* P Post-Trial Brief at 36 -40. It cannot be emphasized enough that Dr. Jordan’s contemporaneous history records symptoms beginning in November 1999, not April as petitioner alleges. P Ex 3 at 19. In addition, there is no mention of the vaccinations. *Id.* Dr. Jordan’s August 2007 Report was based upon information supplied by Ms. Mueller - **eight years** after the time in question. P Ex 4. As noted in the Report, Ms. Mueller saw Dr. Jordan “for a review of her history, questions about prognosis and confirmation about the possibility of vaccination as a cause.” *Id.* Dr. Latov’s September 27, 2007 report relied upon information from Ms. Mueller and Dr. Jordan. P Exs 5, 7, 11. Thus, as is seen throughout this case, the factual information underpinning a continuous progression of symptoms beginning in April comes from Ms. Mueller at least **eight years** after the immunizations. While not explicitly stated in *Capizzano*, the undersigned believes it reasonable to find that the Circuit’s reference to “treating physicians” was regarding their **contemporaneous** medical findings, not findings based upon eight year old histories provided by the patient. The Court of Appeals for the Federal Circuit instructed the special masters that in weighing factual testimony, medical records “warrant consideration as trustworthy evidence.” *Cucuras v. Sec’y of the Dept. of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). These records are “generally contemporaneous to the medical events,” and “accuracy has an extra premium” because a patient’s proper treatment is “hanging in the balance.” *Id.* Dr. Latov’s and Dr. Jordan’s 2007 reports were not “contemporaneous to the medical events” and thus do not warrant greater evidentiary weight.

⁹ Petitioner also submitted the expert report of Dr. Vera Byers. P Ex 13. The undersigned reviewed the report and finds it most unhelpful in resolving the issues presented in this case. Petitioner has not advanced any argument to the contrary.

Respondent relied upon the reports and testimony of Dr. Thomas Leist. See Reports at R Ex A, D, E, and I. Dr. Leist's CV was filed at R Ex B. Like Dr. Steinman, Dr. Leist testified as an expert in neurology and immunology without objection. T3 at 173. Dr. Leist's fundamental unwavering opinion throughout this case is that "there is no association between [Ms. Mueller's] ultimate developing CIDP¹⁰ and the vaccinations given in early 1999." Id. at 175. Dr. Leist explores extensively the medical records and Ms. Mueller's first set of calendar entries covering January 30, 1977 to May 30, 1999. See P Ex 6. His basic position in the first report is that "there is no record of any side-effects in the days after administration of the vaccines." R Ex A at 5. He also notes that there is an absence of epidemiologic studies linking vaccines with GBS. Id. at 8. Dr. Leist's first Supplemental Report, R Ex D, addressed the supplemental report of Dr. Latov and Dr. Steinman's initial report. In addition to taking issue with specific points in Dr. Latov's and Dr. Steinman's report, Dr. Leist concludes that "[l]ack [of] ascertainable progression of symptoms over a period of more than 2 months after the alleged onset of disease is not congruent with a diagnosis of GBS on or about on April 5, 1999." Id. at 6. Dr. Leist's Second Supplemental Report, R Ex E, followed the initial fact hearing. The report addresses several medical issues that need not be resolved because of the decision to reject petitioner's factual contentions. Dr. Leist's Third Supplemental Report, R Ex I, addressed Dr. Steinman's Supplemental Report, P Ex 24, and the accompanying article by Forsberg. These reports are discussed in detail infra at 19-23. Dr. Leist testified consistent with his reports. Dr. Leist was found to be the more persuasive expert in this case and was relied upon by the undersigned to the extent that medical issues needed to be resolved.¹¹

Fact Determination

The primary focus, and correctly so, throughout the litigation of this case has been the factual information underpinning the experts' analysis of the case. There are minimal medical records. T1 at 9. Petitioner explained that she did not often go to the doctor and that her medical insurance affected her decisions of if and when to go. See T1 at 24. As stated earlier, the essence of petitioner's claim is that in early April of 1999, she experienced generalized fatigue accompanied by tingling in one leg that progressively worsened until she was diagnosed with GBS in January of 2000. See T1 at 38-41; see also Petitioner's Post-Trial Brief at 3. The

¹⁰ Ms. Mueller was diagnosed in 2000 with probable GBS, but was later diagnosed with CIDP. The medical and legal consequences of the differences between these disease entities have been and continue to be fought in vaccine cases. See Kelley v. Sec'y of the Dept. of Health & Human Servs., 68 Fed. Cl. 84 (Fed. Cl. 2005). According to Dyck's textbook of Peripheral Neuropathy, "CIDP is separated from AIDP [most commonly known as GBS, 2 PERIPHERAL NEUROPATHY 1437 (Peter James Dyck et al. eds., 3d ed. 1993),] mainly by having a different course. AIDP develops over a few days or weeks, plateaus, and then slowly improves. By contrast, CIDP evolves over many weeks, months or years, persists generally for years, and recovery usually is incomplete even years later." Id. at 1499. Dr. Latov stated that "[t]he only difference between GBS and CIDP is that of time course, with CIDP being a chronic form of GBS." P Ex 11 at 3. Dr. Leist did not take issue with Dr. Latov. R Ex D at 4; see also T3 at 217 ("if one uses the terms between CIDP and chronic GBS as interchangeable terms, then afterwards I don't have an objection."). However, he contended that neither CIDP nor chronic GBS has been reported in the context of the Hepatitis A vaccine. R Ex D at 4. It is unnecessary to discuss this issue further given the decision regarding the factual information provided in this case.

¹¹ Petitioner attacked the credibility of Dr. Leist on several bases. See Petitioner's Post-Trial Brief at 23-26. The undersigned reviewed closely petitioner's arguments and considered them in the context of Dr. Leist's testimony. As stated above, Dr. Leist's testimony was consistent with the medical literature, was based upon the facts as found by the undersigned and importantly was completely consistent with testimony the undersigned has heard in similar cases. No bias was detected by the undersigned.

contemporaneous medical records from petitioner's treating doctors do not support petitioner's claims. See P Ex 3 at 9, 13, 19. Given the obvious passage of time, to bolster her case, petitioner submitted a personal journal. P Ex 6. To address the factual issues, testimony was taken from petitioner, her boyfriend at the time, her sister and close friend. See generally T1. Following the December 19, 2008, Hearing, the undersigned orally ruled on the limited factual issues to be decided at that Hearing and followed with an Order that was prepared without benefit of the transcript.¹² The Fact Ruling was very limited, and will be quoted at length here because petitioner attempted to build her case on an unwarranted over-reading of the ruling in presenting subsequently her case.

As stated in the Order, the "central issues at the fact hearing were whether petitioner experienced an onset of fatigue following her vaccinations on February 11, 1999, and if yes, when did the onset occur and how severe were the symptoms." Order filed December 22, 2008 (hereinafter "Fact Ruling"). The undersigned found as follows:

The essence of the undersigned's findings was that petitioner's journal does not document or support the alleged exhaustion and fatigue. In addition, the witness testimony did not support, what the undersigned interpreted as, the debilitating¹³ fatigue petitioner alleged. Factual testimony and allegations of debilitating fatigue are therefore rejected.

However, the undersigned was impressed with the relative consistent (the undersigned recognizes that there were some discrepancies between the witness testimony) testimony that petitioner was "a different person" after her return in early April from the Far East. Petitioner's change in energy level was depicted in several different ways by the witnesses - drop-off in attending social functions, greatly reduced work-out efforts, fatigue in hiking, change in personality - and convinced the undersigned that petitioner did in fact experience a change in her energy levels in early April. However, as noted above, the undersigned was not persuaded by the fact testimony that the change in energy levels was extreme of debilitating.

¹² In retrospect, the issuance of the Order so quickly was not a good decision. Fact hearings are frequently conducted in the Vaccine Program prior to getting expert opinions. The factual issues are generally narrow, usually involving the proper timing of events. Thus, the rulings are narrow and quick turnaround is important to begin the expert phase of the case. However, given the subsequent submission of additional portions of petitioner's journal, P Ex 18, the better course would have been to complete the factual testimony prior to hearing from the experts. In this case, in retrospect, the factual issues were more complex and the undersigned's quick ruling probably prolonged the case by not discussing the issues more fully and by having issued the ruling prior to the expert Hearing and submission of the further journal entries, which required a second Hearing.

¹³ Petitioner argued throughout that the use of the word "debilitating" was incorrect. The undersigned notes that debilitating is defined as, "[t]o make feeble; enervate." THE AMERICAN HERITAGE DICTIONARY at 369. Enervate and feeble convey a loss of strength, weakness. Ms. Mueller's testimony clearly alleged debilitating fatigue. See e.g. T1 at 35.

However, the evidence did not support the extreme fatigue and exhaustion petitioner alleged. In fact, in evaluating petitioner's change in energy, the degree of change must be considered and evaluated in the context of petitioner continuing to work 12-14 hour days during this time period. Stated another way, while petitioner was not able to socialize as much as she had prior to returning home in April, petitioner was able to maintain her heavy work schedule, which included lengthy workdays.

Fact Ruling at 1-2.

While this case presented a myriad of medical issues, implicating all three prongs of the Althen¹⁴ test of causation, the initial critical difference between the experts is how they interpreted Petitioner's testimony and journal. Petitioner's expert, Dr. Steinman, interpreted petitioner's fatigue as "really impressive fatigability," T3 at 18, "as far out of proportion to what we all think fatigue is," id. at 21, or a "tremendous falloff in physical and motor activities," id. at 28. Dr. Steinman's interpretation of petitioner's fatigue is counter to the undersigned's factual findings (rejecting "debilitating" fatigue) and the undersigned finds it is not supported by the record. Utilizing this incorrect interpretation of the Record, Dr. Steinman relied upon a study by Boukhris, attached to P Ex 7, to opine that petitioner's fatigue was the onset of her GBS.

Respondent's expert, Dr. Leist, testified consistently with the undersigned's Fact Ruling. Dr. Leist conceded that vaccines "have the potential to cause demyelinating events in situations where the sequence is correct." T3 at 198. He explained that the "sequence of events" are the appropriate time frame, the ruling out of other causes, and whether "the course of events [are] reasonably congruent with what one would observe in other - - similar events in other patients under these conditions. . . ." Id. at 199. The problem Dr. Leist saw with this case is that the sequence of events is not congruent with the expectation. See id. at 176, 179, 221, 226, 247. As he explained:

I understand that it is to be accepted that on or about April 5th there was a decrement in - - a relatively sudden decrement in energy levels, but afterwards I don't see that there is a progressive change that you would underlie - - that you would expect from this disease process. I cannot find this change in what I have reviewed.

Id. at 226; see also id. at 180 (Dr. Leist explaining that fatigue would not be expected to be the solitary symptom but joined by muscle weakness and areflexia (absence of reflexes)).

¹⁴ To establish a prima facie case of actual causation, petitioner must "show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Thus, while a number of medical issues are presented in this case, such as the support for the Hepatitis A vaccine causing GBS, how is the Hepatitis A vaccine fingered as the causative culprit here, as opposed to the tetanus vaccine,¹⁵ what is the medically appropriate temporal relationship between immunization and the onset of a demyelinating condition, which implicate all three Prongs of the Althen standard, the critical issues for deciding this case are actually quite narrow. While the Fact Ruling found a drop in petitioner's energy levels in April of 1999, what was not discussed or found was the continuing course of petitioner's physical condition and whether petitioner's symptoms progressed beginning in April. Ms. Mueller testified that this process began in April 1999, T1 at 41, the medical records say otherwise. In essence, the question presented is whether petitioner's testimony regarding her progressively worsening condition is credible, see T1 at 41, or should the medical records be relied upon showing an onset date for her demyelinating condition sometime in November of 1999. Lastly, to the extent that medical issues need be decided, who was the more credible expert, Dr. Steinman for petitioner or Dr. Leist for respondent. As the undersigned communicated to the parties on numerous occasions, the undersigned was not impressed with petitioner's testimony regarding the progression of her symptoms and the undersigned found Dr. Leist far more persuasive on the medical issues presented in this case.

Medical Records

The first contemporaneous record of any medical treatment following her immunization on February 11, 1999, is a visit to her chiropractor on July 22 for "sciatic neuritis." P Ex 3 at 9. The treatment note indicates petitioner was treated for "sciatic neuritis." Id. Petitioner testified that she actually saw the chiropractor on July 2, but there is no record of this visit. T1 at 40. Petitioner testified that she had not seen the chiropractor for "close to two years," but was "getting weaker" and the tingling was "progressing, getting worse" and she thought it was time to get a "mechanical fix." Id. at 40-41. Petitioner stated that the adjustment did not work, and thus went back to the doctor on July 22. Petitioner did not report any of the symptoms of fatigue or tingling. See T1 at 106. In fact, Ms. Mueller agreed that tingling pain reported between July 22, 1999 and September 30 was consistent with sciatic pain that she stated in her affidavit she experienced since 1985. Id. at 111. While the notes are very difficult to read, petitioner returned to the chiropractor on July 24 and 30 for the same condition. Id. The note on July 24 indicates that the symptoms are "much better" and records "L/3 feels weak." Id. The next medical record was another visit to the chiropractor on November 23, 1999. P Ex 3 at 29. This is more than nine months post immunization. At this visit, Dr. Yanagita records a history of "[t]ingling in both feet." Id. at 43. He also notes, for the first time, decreased energies. Id. (noting decreased by a downward arrow sign). This is the first contemporaneous recordation of decreased energy.

Petitioner testified that this tingling, first reported on November 23, was different than the sciatica because she never experienced sciatica in the right side and "which means it's already progressed and done damage in the left side and moved over." T1 at 110. In fact, Ms. Mueller continues to suffer from sciatic problems. Id. at 113.

¹⁵ See Althen, 418 F.3d at 1281-82 (finding the tetanus vaccine to be causative and noting that there was no rebuttal to the testimony regarding a "lack of a known causal relationship between the hepatitis A vaccination and central nervous system demyelinating disorder.")

Ms. Mueller saw Dr. Nasir on January 5, 2000. P Ex 3 at 13. Petitioner gave a history to Dr. Nasir, T1 at 116-17, and filled out a medical questionnaire for the visit to Dr. Nasir. P Ex 3 at 16-17. Dr. Nasir records “[r]ight and left foot pain times three” months. P Ex 3 at 13. Petitioner returned to her chiropractor on January 11, 2000, with the complaint that numbness and tingling was in both feet and hands. Id. at 9.

On January 15, 2000, Ms. Mueller was evaluated by Sheldon Jordan, a neurologist, for “numbness in toes and finger tips since November.” P Ex 3 at 19. Dr. Jordan’s Consultation Report indicates that a “comprehensive examination” was performed, which included taking a history of the present illness, a past medical history and medical review of petitioner’s bodily systems. Id. Very meaningfully to this dispute, Dr. Jordan records under “Chief Complaints” the following, “[n]umbness in toes and finger tips since November; worsened heat exposure.” Id. Dr. Jordan noted decreased vibration and light touch sensation in both feet, and decreased deep tendon reflexes. Id. Dr. Jordan thought petitioner’s symptoms were consistent with a peripheral neuropathy. Id. at 19, 21. Ms. Mueller did not see another doctor until April 2004, when she saw Dr. Stephen Graham for unrelated ailments. Id. at 41-46.

The next relevant doctor’s visit was on February 15, 2006, when Ms. Mueller again saw Dr. Stephen Graham for reported recurrence of numbness in her lower extremities. Id. at 46. On March 8, she was evaluated by Dr. Colin Stokol, a neurologist, for increasing numbness and “subjective weakness.” Id. at 32, 48. Dr. Stokol suspected CIDP and ordered a nerve conduction study to confirm the diagnosis. Id. The study showed evidence consistent with CIDP. Id. at 33. Dr. Stokol again saw Ms. Mueller on March 27, 2006, complaining of increased weaknesses and loss of reflexes since the last visit. Id. at 32, 48. Dr. Stokol noted the concern that petitioner suffered from a progressive inflammatory condition such as chronic inflammatory demyelinating polyneuropathy (“CIDP”), or was experiencing “a flare of Guillain-Barre; she apparently had some of the features back in 2000.” Id. Petitioner was started on therapy with intravenous immunoglobulin (“IVIG”). Id. On April 13, 2006, Dr. Stokol confirmed the diagnosis of CIDP, and notes that petitioner has responded well to the IVIG treatments. Id. at 49.

Most importantly, for purposes of the discussion here, is that nowhere in the contemporaneous medical records is a history given that is remotely consistent with the timing of events Ms. Mueller is alleging in this lawsuit. Ms. Mueller claims to have told Drs. Jordan and Nasir of her fatigue; no such history is noted. T1 at 117.

Conflicts between contemporaneous records and testimony given several years later at a hearing are common in Vaccine Act cases, and this case is no exception. The Court of Appeals for the Federal Circuit has instructed the special masters that in weighing factual testimony medical records “warrant consideration as trustworthy evidence.” Cucuras v. Sec’y of the Dept. of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). These records are “generally contemporaneous to the medical events,” and “accuracy has an extra premium” because a patient’s proper treatment is “hanging in the balance.” Id. Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of

symptoms is more immediate. Reusser v. Sec’y of the Dept. of Health & Human Servs., 28 Fed. Cl. 516, 523 (1993). Thus, “[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.” Murphy, 23 Cl. Ct. at 733 (citation omitted). Inconsistencies between testimony and contemporaneous records may be overcome by “clear, cogent, and consistent testimony” explaining the discrepancies. Stevens v. Sec’y of the Dept. of Health & Human Servs., No. 90-221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr. Dec. 21, 1990). Generally, however, because of the trustworthiness of contemporaneous medical records, conflicting oral testimony “deserves little weight.” Id. Such is the case here. The facts set forth in this opinion were determined with these legal principles in mind.

Ms. Mueller’s attempted explanations as to why the doctors did not record a history of symptoms that mirror her contentions in this case despite her allegedly telling them rings hollow. What makes far more sense is that the passage of over eight years before seeing Dr. Jordan and nine years before testifying has affected Ms. Mueller’s memory of the timing of events. That is not to suggest that Ms. Mueller dissembled during her testimony, but to state the logical fact that memories fade with the passage of time, and eight to nine years is an extremely long time, for anyone, to remember events accurately. However, petitioner claims her memory was refreshed by her journal. The undersigned disagrees and states why.

Calendars

Following the filing of this case and after Ms. Mueller filed her affidavit in support thereof, the prior special master inquired into supporting materials. Ms. Mueller then recalled that she kept calendars. T1 at 82. During the course of the first Hearing, it was disclosed that only a portion of the calendar was filed necessitating the filing of the remainder, followed by a subsequent Hearing. Id. at 92. Ms. Mueller described the calendars as a “chronicle of where I’ve been, what I’ve done, various things that I’ve, you know, spent my time doing but not - - I don’t ever get into really anything other than the actual event of what I’ve done that day.” Id. at 58. She stated that you cannot determine the quality of the activity because it is not a diary. Id. at 122. The chronicles were not contemporaneous to the event; she never recorded them on a daily basis. Id. at 60. She would go back and fill in dates “once a week, once every two weeks.” Id. She kept calendars from 1996 to 2001 or 2002. Id. at 61. The calendars “refreshed” her memories of certain events. Id. at 82. She recognized that her refreshed memory conflicted with her affidavit filed in this case. See id. at 77-82. Ms. Mueller stated that going back through the books made “some things . . . really come back to life in terms of what was going on at that time.” Id. at 67. But, she recognized that it was “not a perfect memory, but I remember feeling incredibly exhausted and fatigued in those months. . . .” Id. When asked how she was able to give meaning to an “event” nine years later, Ms. Mueller stated that “these are months where I remember being dramatically different” and “reading these calendar books, it very much refreshed my time [sic] of what those months were and the fatigue that started” Id. at 99-100.

There are numerous issues with the calendar and Ms. Mueller’s “refreshed” memory based upon the calendar. The undersigned does not intend to go day by day in discussing the

calendar, but will point out through examples why the calendar, and thus Ms. Mueller's refreshed memory, is not reliable. To begin with, it cannot be overemphasized that Ms. Mueller was testifying nine years after the time in question. To think that even with the aid of a calendar one can remember how they feel on a given day, the quality of their relaxation, how well they exercised or any of a myriad of daily activities testified to defies any reasonable level of credibility. Yet that is what petitioner asks the court to accept. In addition, it must be remembered that Ms. Mueller did not see or report her symptoms to a doctor until November of 2000, and when she did the recorded histories were very different than what is now being alleged.

Petitioner maintains that prior to her immunizations she was a very active person - hiking, power walking, practicing yoga and being very social. See T1 at 17-19. Following immunizations, petitioner alleges that this all changed. Many examples were given of "exhaustion". See id. 33-37. Petitioner testified to hiking to see the Great Buddha during which she had to be pushed up the hill. Id. at 33. This was not in petitioner's calendar or affidavit. On cross, petitioner stated that she did not remember "specifically everything that day but her sister refreshed her memory. Id. at 123-4. Interestingly, when petitioner's sister, Astrid Golda, testified, she stated, "I don't recall anything specific with how Brigitte was doing with the hike." Id. at 159. When asked on cross as to whether specific memories have faded, Ms. Golda stated the obvious truth, "It was a long time ago." Id. Another example of fatigue was a visit to the Van Gogh exhibit on April 5. Ms. Mueller stated that this memory stood out. Id. at 124. She said she was "fatigued and exhausted." Id. at 37. Mr. Blatchford, Ms. Mueller's boyfriend, testified to her fatigue at this trip. Id. at 183. However, as evidence of the varying degrees of fatigue and the danger inherent in putting too much credence in memories, two days following this visit, Ms. Mueller testified that she worked "anywhere from 12 -14 hour days." Id. at 83; see also P Ex 6 at 98.

Petitioner felt a tingling in her shoe, described as a pebble, in May of 1999. Id. at 38-39.¹⁶ This tingling is not mentioned in her calendar and was not recalled by petitioner, but her memory was refreshed by her friend, Andrea Pilat. Id. at 127. The tingling and weakness progressed until Ms. Mueller sought a "fix" from the chiropractor in July. Id. at 40-41. This progression continued up through November at which time the medical records begin recording the symptoms. Between April and November, Ms. Mueller stated that she continued trying to practice her yoga, but it was not a "strong practice." Id. at 42. Her walking was not "as strong or as powerful." Id. She also began to suffer heat sensitivity. Id. The fatigue issues continued through this progression. Id. at 45. She stated:

I had - - just constantly battling being exhausted or tired or fatigued or - - became much more of a couch potato In the sense that I would look forward to being at home and relaxing as opposed to going out after working. . . .

¹⁶ Compare this testimony with Ms. Mueller's affidavit wherein she states that "[t]hen in the first week of July for the first time I experienced a numbness which was very subtle in one of my toes on my left foot." Pet., attached Ex 1, ¶ 8.

Id. However, on cross-examination, Ms. Mueller agreed that she probably worked 12-14 hours on April 7, T1 at 83, P Ex 6 at 98, and worked late on the 13th. Id. She was also doing production work from May 10 -19. T1 at 85-87; P Ex at 104-05. Production work entailed 12-14 hour days. See T1 at 11-14. Respondent's counsel led Ms. Mueller through the various social entries on her calendar. See id. at 87-92. Interestingly, Ms. Mueller's memory began to fail her. When asked about entries possibly relating to work on her apartment, Ms. Mueller was not able to recall. See Id. at 93-97. Respondent's counsel summarized the time period between April 5 and May 30, 1999, which was the end of the first diary, P Ex 6, and was part of the first fact hearing, as follows:

[W]e show that you had various jobs or were looking for work. You did a U-Ground project, you were looking for work after that, you did the Profyle video. You're looking for work again towards the end of May. The social occasions added up - - whether they're social or work-related . . . whether you called it a party or brunch . . . 15 or so time, and you were moving in at the time

T1 at 97. In response to counsel's observation that April and May were active months, Ms. Mueller responded that they were "a lot less active than the previous two years." Id. at 97. She observed that she was still doing things and work¹⁷ was a necessity, but that she was uncomfortable and fatigued doing them. Id. at 98-100.

It was following this first Hearing that the undersigned issued the limited Fact Ruling. Again, while crediting the witness testimony that Ms. Mueller experienced a "change in her energy levels in early April," "the undersigned was not persuaded by the fact testimony that the change in energy levels was extreme or debilitating." Fact Ruling at 1. In addition, the journal entries could only be relied upon for the fact that an event occurred, nothing further. Id. at 2. It must be remembered that during this time that Ms. Mueller was working 12-14 hour days, she testified that she was "constantly battling fatigue." Id. at 45. And while the calendar records "relaxing" and "chilling," there is no notation of fatigue or exhaustion. The undersigned expressed concerns about the factual portion of the case to counsel. Based upon those expressed concerns and the filing of the remainder of the journal, P Ex 18, a second Hearing was conducted. At the second Hearing, the undersigned was far less impressed with Ms. Mueller's testimony.

Following the first Hearing conducted on December 19, 2008, and the filing of the remainder of her journal, P Ex 18, Ms. Mueller did an analysis of the pre- and post- vaccination calendar entries. T2 at 317. She produced a spreadsheet reflecting her analysis. P Ex 22. She testified that her analysis indicated a "drop-off in activity" post-immunization, "specifically social activity, and an increase in the relaxing and chilling and sleeping and reading." Id. at 319.

¹⁷ On several occasions, Ms. Mueller explained how, despite her fatigue, she was able to participate in certain activities. She stated they were "work-related" and that work "is a necessity." T1 at 98. While true, the fact that you can work more than ten hours in a day speaks to some extent to your energy level. For example, reading all day is tiring, whether or not it is work-related. See T2 at 337. Social activities require energy whether or not they are work-related. See id. at 365, 385. Ms. Mueller's reliance on work as an explanation for why she was able to participate in certain events is not persuasive.

She recognized that her work became more consistent, but “in general, my overall activities was decreased.” Id.

Before relating the statistical results of Ms. Mueller’s analysis, it is important for the reader to keep in mind that the calendar entries were not contemporaneous, see T1 at 60, and the entries chronicled events without description of the activity, see id. at 58, 122. When Ms. Mueller was asked why there is no notation of her feeling sick and exhausted, she responded that she notated events that “took time out of my day.” Id. at 58, 132; see also id. at 128. However, on December 16, 1998, Ms. Mueller in fact noted that “I don’t feel well.” Id. at 102; P Ex 6 at 79. Ms. Mueller had no explanation for why she would note not feeling well on a singular day but make no notations for a two-month progressive illness. Id. at 102-03. Another notation that conflicted with Ms. Mueller’s explanation of not noting her medical symptoms on the calendar was an entry for December 27, 1999, where she recorded “my foot hurts very bad.” T2 at 373. And there were some entries that Ms. Mueller could not explain why they were recorded. See T2 at 343, 349 and 360. Also very importantly, the calendar proved to be incomplete. See T2 at 341-2 (calendar did not record the “event” of seeing her chiropractor on July 2 and November 23.) Thus, Ms. Mueller’s “refreshed” memory is based upon a calendar that is itself of dubious reliability.

Finally, words used in the calendar took on different meanings depending upon whether they occurred before or after the immunizations. Thus, what became critical to Ms. Mueller’s contentions was how many times she “relaxed” or “chilled out.” When asked what the words meant, she replied “[i]t just means I stayed home and did nothing as opposed to -- if I did stuff, I would notate things like ‘cleaned house’ or ‘errands.’” T1 at 46. The use of the words can also change depending upon whether they involve her boyfriend. See id. at 56-7. When asked specifically by the court as to the apparent different meanings, Ms. Mueller responded:

I’m remembering . . . in April and May . . . is when I’m relaxing so much because I am exhausted. I’m doing it much more frequently than I ever would have, especially in a row, whereas in other occasions I don’t do it too many days in a row if in a row at all. If I had a particularly active week and I decide to relax for an evening, that’s what I’m doing. But to do it almost every day in two months is a lot.

Id. at 139-40. At the second hearing, Ms. Mueller explained further that the distinction between the use of the words “chill” and “relax” before and after the immunizations - recognizing the ten years of time passage, Ms. Mueller phrased it as a difference between “want versus need.” T2 at 321-22. What Ms. Mueller was asking the undersigned to accept is that after understandably misremembering events, see T1 at 81, she has her memory refreshed by her calendar, see id. at 82, 99, even with the calendar it is “not a perfect memory,” id. at 67, but she was able to discern a different meaning for the exact same word depending upon whether it is used prior to the vaccination or after. Clearly, Ms. Mueller is not remembering the event, but it is giving it meaning based upon when it occurred relative to the vaccination. That is reasonable given the passage of so much time, but is extremely unhelpful in constructing a timeline of events.

Thus the meaning, if any, to be given to the calendar is based upon Ms. Mueller's interpretation of the "event" entries, an interpretation based upon a nine year old memory. This memory had to be "refreshed", T1 at 82, by the calendar, proved to be faulty, *id.* at 81, and is now giving life to the calendared events. It simply defies any sense of logic and credulity to credit Ms. Mueller's testimony based upon this calendar. Again, that was the essence of the December 22, 2008, Fact Ruling - "[t]he journal cannot be relied upon for any significance other than the fact that the event did or did not occur." The undersigned will give several additional examples of why the testimony based upon the journal is not credible.

Ms. Mueller reviewed the spreadsheet information, which covered the one year period from April 1998 through March 1999. T2 at 318. This information was compared to a nine month period from April 1999 through December 1999. *Id.* Her analysis showed a drop-off in activity. *Id.* at 319. For example, for the 12 month period prior to the alleged April 1999 onset, she counted 279 social activities or an average of 23.25 activities per month. *Id.* For the post-onset period the average was 10.11 activities per month. *Id.* The analysis for staying at home was a total of 45 times pre-onset and 79 for a nine month period post-onset. *Id.* at 320. Thus, by these measures, petitioner calculated a 50% decrease in socializing post-onset and a 50% increase staying home post-onset. *Id.* at 321. However, as shown on cross-examination, during this same period of time when petitioner is alleging a drop-off in activity due to fatigue, her work days increased by 50%. *Id.* at 377. Petitioner attempted to explain away this increase by saying it was a less strenuous job, but the fact remains that she was able to work and function in an eight hour per day job. *Id.* at 378, 380. This was during a time when petitioner was "constantly battling being exhausted" and "every moment, I got in, I would sleep. I would just want to be sleeping or lying down or just resting." T1 at 45, 48. Petitioner was also asked about her attendance at events during this period of time and she responded by minimizing her participation. For example, on June 4 she attended a wedding in Boston. P Ex 18 at 1; T2 at 324. She explains her attendance as an "obligation" and remembers her energy level as "experiencing fatigue." But the fact she was able to go to Boston, obligation or not (one can question whether attending the wedding of a "best friend" is an obligation), speaks to the quality of fatigue. It was also during this time that Ms. Mueller testified that she was "getting weaker and the tingling wasn't going away and then it's aggravating and it just keep progressing getting worse." T1 at 40-41.

Ms. Mueller testified to her boyfriend's family arriving on June 18. T2 at 327. She said her overall energy level was "very low and it was . . . just try and keep up with things that we had planned" previously. *Id.* However, despite all of this fatigue, Ms. Mueller was able to travel to Las Vegas on June 23. *Id.* at 329. Her effort to downplay the significance of her being able to travel to Las Vegas during this period of exhaustion, *see* T1 at 45, as a "planned event," T2 at 329, defies any level of reasonableness, logic or credulity.

While the fundamental premise that looking back at what is essentially a listing of events on a given day will somehow trigger an accurate memory of what those bare words mean nine years later is fundamentally flawed, *id.* at 402, Ms. Mueller's efforts to spin the events to support her allegations proved fruitless. For example, when asked about working until 4:30 a.m., Ms.

Mueller answers with an explanation of it being a job and she had not worked in two years and she did not want to “back out” or “mess up a contact.” Id. at 337, 339. It does not seem to occur to petitioner that working until 4:30 a.m. is very tiring, even for healthy individuals, and it is inconsistent with someone describing extreme fatigue. Likewise a party on July 31 was a “work-related” event. Id. at 346. She also was able to go to Disneyland on August 28. Id. at 348. This is explained by it being her birthday and she had never been to Disneyland. Id. On cross-examination, it was disclosed that on the day after, August 29, Ms. Mueller attended a brunch and got drunk. Id. at 387. On September 4, she entertained people at her house, and on the 5th she attended a neighborhood Hawaiian-themed party. Id. at 351. The explanation is that her boyfriend likes to entertain and so they had people over and as to the outdoor party “it’s hard to not, at least for home, not to be friendly and walk outside and say hello.” Id. at 351-52. Another head scratcher is the September 24 notation of staying up all night. P Ex 18 at 17. Ms. Mueller blithely explains that she “was baby-sitting” the attendees so they would not hurt themselves. T2 at 357. These explanations are simply inadequate when measured against Ms. Mueller’s description of progressive worsening of fatigue and weakness.

Ms. Mueller summed up the interrelationship of her testimony and the journal very nicely. She stated:

On one level, it’s a numerical analysis; on another level, looking at specific days, and things, actual events and time frames. That’s what helps me completely recollect what’s happening in my life at the time and the quality of it. This, again, is just a sheer numbers exercise. It doesn’t tell you the quality of my life after versus before.

T2 at 402. In the end, if one is to accept Ms. Mueller’s testimony, one would be accepting a nine year memory over contemporaneous records that state that the onset of events occurred seven months later. See T1 at 67. The calendar does not contain information that adds to or negates information contained in those medical records. As Ms. Mueller stated multiple times, the calendar lists events, it is not a diary containing descriptions of those events. Ms. Mueller gives the calendar life - nine years later. Contrary to her statement that the calendar “helps [her] completely” to recall, on cross-examination her memory failed her multiple times. See T1 at 82, 94, 95, 96, 97, 117. The calendar was not contemporaneous. The calendar did not contain all of her events and there was never any testimony or other evidence of its completeness. And there is good reason to question Ms. Mueller’s memory. In her affidavit, she stated she “could be around anyone that was sick and never catch a thing.” P Ex 1, ¶ 2. When questioned, she stated that “my memory is that I didn’t get sick often at all ‘cause I was a very healthy person.” T1 at 81. However, when shown her calendar entries, in fact she noted being sick “about 12 to 15 days” in 1998. Id. at 82. And as noted earlier, two significant pieces of petitioner’s alleged factual puzzle were not noted in the calendar, were not recalled by Ms. Mueller, but were “refreshed” by other witnesses years later. Ms. Mueller testified to her difficulties hiking the hill to see the Great Buddha, T1 at 33, but she did not recall this significant event until her sister reminded her years later. Id. at 123. And the very significant “pebble in the shoe” where petitioner’s toe was “going completely numb” in May of 1999, id. at 39, was raised by her friend, Ms. Pilat. Id. at 127. It is

noted that petitioner's affidavit recounts numbness in her toe occurring in the first week of July. Pet. at Ex 1, ¶ 8.

The other fact witnesses were of no assistance beyond what was found in the Fact Ruling. Ms. Pilat testified that right after her return to the states in April 1999, Ms. Mueller was lethargic and depressed, "she didn't want to leave the house because she was afraid she wasn't gonna make it because she would poop out." T1 at 144. It was during this period of time that Ms. Mueller was working 12 - 14 hour days. Id. at 83. Ms. Pilat's testimony constitutes witness exaggeration. In addition, Ms. Pilat's testimony does not extend beyond May 1999 and is thus unhelpful to the continued understanding of Ms. Mueller's factual presentation. Ms. Golda's testimony is also limited to the time frame immediately prior to the return to the states and is thus unhelpful to understanding subsequent events. See T1 at 153-167. Lastly was the testimony of Mark Blatchford. Id. at 167. Mr. Blatchford's testimony was too general and punctuated by frequent answers of "don't recall" to be relied upon, especially when measured against the contemporaneous medical records. Of note was that he discussed "a great deal" with petitioner prior to submitting his affidavit. Id. at 190. It is also interesting that each witness used the phrase "pebble in the shoe" to describe Ms. Mueller's feet hurting. See id. at 205, 145, 39. Usage of such a phrase indicates that the witnesses participated in prior discussions. While Ms. Mueller and Ms. Pilat time the pebble in the shoe in May, Mr. Blatchford timed it in June or July. Id. at 205. While the witness testimony was strong enough to make a finding that Ms. Mueller experienced a decreased energy level upon her return to the states in April 1999, there is no basis in fact to extrapolate from that finding a continued fatigue and progression of symptoms until her reporting of symptoms to the doctors in November 1999.

As noted above, supra at 10, the contemporaneous medical records begin noting Ms. Mueller's symptoms in November of 1999, approximately nine months following immunization. Dr. Yanagita records the decreased energies and tingling in both feet on November 23, 1999. P Ex 3 at 9. Dr. Nasir's note of January 5, 2000, records right and left foot pain for three months. Id. at 13. Ms. Mueller filled out a medical questionnaire for Dr. Nasir. Id. at 16-17. There is no mention of an earlier onset of her symptoms. Id. Dr. Sheldon Jordan records the history of "[n]umbness in toes and fingers since November." Id. at 19. There is no contemporaneous history of symptoms concordant with petitioner's allegations. Ms. Mueller was asked if she told the doctors of her fatigue. She stated that she told Drs. Nasir and Jordan. T1 at 117. There is no notation until January 2000. She was asked if she told Dr. Yanagita about the fatigue. Id. at 51. She stated no because at the time Dr. Yanagita was a chiropractor dealing with mechanical fixes, but now that he is an acupuncturist she would tell him about the fatigue. Id.; see also T2 at 369-70. However, this answer did not bear up on cross-examination. It was pointed out to Ms. Mueller that Dr. Yanagita did record the subjective history of "feels weak" at the July 24, 1999 visit indicating that Ms. Mueller did relate more than the mechanical problems. Ms. Mueller attempted to explain, ". . . I mean, sometimes I'll say, you know, what's going on? I'll ask him questions. But often it's pretty routine because he does the same thing almost every time." Id. at 106. Ms. Mueller was asked whether she reported tingling and numbness to Dr. Yanagita during the July visits. At first she responded that "I don't remember exactly what I said to him, but often if I felt I needed an adjustment, it's because I had a tingling." Id. at 107. However, Dr.

Yanagita does not note tingling until the November 23 visit. P Ex 3 at 9. Ms. Mueller insisted that she told Dr. Yanagita about the tingling prior to the November 23 visit. T1 at 110-11.

Ms. Mueller's efforts to explain why there are no recorded symptoms prior to November or why the medical records place the onset of the GBS symptoms in and around November are simply unpersuasive.

This case began with a Fact Hearing that found a "change in energy levels in early April." Fact Ruling at 1. It was also noted specifically that further allegations of extreme fatigue and exhaustion were not credited. The undersigned was particularly nonplussed about petitioner continuing to work 12-14 hour days and required the medical experts to "rely heavily" on the medical records and "the absence of mentioning of the energy loss to the doctors." Id. at 2. Now, considering the entire record, the undersigned finds that the contemporaneous medical records correctly state the timing of events related to petitioner's GBS. In the end this is a credibility call by the trier of fact. The undersigned does not find Ms. Mueller's testimony regarding the timing of events to be credible. While the undersigned did find the witness testimony regarding the "change in energy levels in early April" to be credible based upon testimony regarding events occurring in early April, the undersigned finds the testimony regarding progressive worsening, see T1 at 49, exhaustion, see id. at 45, and drop-off in activity based upon the interpretation of calendar entries to be not credible.

Medical Experts

It is accepted law that a doctor's "conclusions...are only as good as the reasons and evidence that support them." Davis v. Sec'y of the Dept. of Health & Human Servs., 20 Cl. Ct. 168, 173 (Cl. Ct. 1990); see also Perreira v. Sec'y of the Dept. of Health & Human Servs., 33 F.3d 1375, 1377 n.6 ("An expert opinion is no better than the soundness of the reasons supporting it.")(citations omitted). Petitioner's medical experts based their opinions on information provided by Ms. Mueller. Given the undersigned's factual rulings detailed above, the underpinnings of her experts' opinions are faulty, and thus the opinions themselves are faulty. The undersigned's decision rests upon the contemporaneous medical records. Those records place the onset of petitioner's disease process in November of 1999. See P Ex 3 at 9, 13, 19. As noted earlier, Ms. Mueller's treating chiropractor records a history on November 23, 1999, of "Tingling in both Feet." P Ex 3 at 9. Dr. Nasir saw Ms. Mueller on January 5, 2000 and records right and left foot pain "x 3 months." Id. at 13. Ms. Mueller saw Dr. Jordan on January 15, 2000. Id. at 19. Under "Procedure" it states that "A comprehensive examination was performed including history or present illness, past medical history. . ." Id. The "Chief Complaint" was listed as "Numbness in toes and finger tips since November." Id. The comparison of these histories to petitioner's current contentions is striking, not only regarding the timing of petitioner's injury but also for the absence of the "exhaustion" and progression of her complaints. Petitioner had every opportunity to relate the full extent of her complaints to her treating physicians, see id. at 16-17 (doctor's questionnaire filled out by petitioner), but the information is absent.

The undersigned found Dr. Leist's testimony in this case compelling, and far more persuasive than that of Dr. Steinman. Dr. Leist was asked by petitioner's counsel to consider the calendar, fact hearing and witness testimony in evaluating the case. Dr. Leist, in what the undersigned finds to be an unproven set of facts, looked at what can only be described as the best case scenario for petitioner's case and found it to be "incongruent" with the onset of a polyneuropathy. T3 at 226. There was no expected progression of the disease process. Id. Dr. Leist's testimony was consistent with the undersigned's findings of fact, was consistent with the medical literature, and was persuasive and credible. Amongst the experts, his testimony stood out as logical, reasoned and cogent. The undersigned will briefly examine the deficiencies in petitioner's expert's opinions.

The primary deficiency in all of petitioner's experts was the facts, the experts relied upon information supplied by Ms. Mueller years after the events in question. In doing so, there is an almost complete ignoring of the contemporaneous medical records. Dr. Steinman testified that he "put[s] a lot of weight on a treating physician's diagnosis because they have the most or the most ideal set of circumstances." T3 at 19. As shown above, the treating physicians note the onset of symptoms in about November 1999, not April. See P Ex 3 at 9, 13, 19. Dr. Steinman's initial report contains one paragraph of history and not one mention of the medical histories contained in the records. P Ex 14 at 2. His history notes chronic fatigue accompanied by tingling dysesthesias in the left leg that spread until a diagnosis of GBS in January 2000. Id. There is no citation for this information. His testimony was similar, where he recounts a history of "tingling in her feet" and "impressive fatigability" in early April. T3 at 18; see also id. at 22. He stated, without reference, that he "put the onset based on the history that she gave to numerous individuals that it began the first week of April." T3 at 28. Based upon this factual information, Dr. Steinman opined that Ms. Mueller developed GBS clinically sometime in April manifested by the tingling in her feet and "really impressive fatigability." T3 at 18. Dr. Steinman opined that Ms. Mueller's GBS was caused by her Hepatitis A vaccine. Id. at 66-67.

As stated above, the undersigned has found facts to the contrary of those relied upon by Dr. Steinman; with that ruling, petitioner's claim fails. However, for the sake of completeness, a discussion of two pieces of medical literature Dr. Steinman relies upon for his opinion will follow. The undersigned finds that neither is supportive.

Dr. Steinman testified that "the real change in her level of fatigue, level of liveliness" supported the April onset date. Id. at 160. He relied on a paper by Boukhris, attached to P Ex 7, to support his testimony that Ms. Mueller's fatigue can be the precursor of her demyelinating condition. The study examined 11 cases where the main cause of referral was fatigue. The abstract clearly states that the study "shows that fatigue is a possible cause of *referral* for patients with CIDP. . . ." Id. at 27. There is no indication in the article that fatigue was determined to be the first sign or symptom of CIDP. In fact, there is good reason in the article to think otherwise. The authors cautioned that "fatigue is a subjective symptom, and the fact that it could be used to describe a feeling of tiredness that can be experienced even at rest as well as a difficulty in sustaining an effort is confusing." Id. at 32. This subjectivity of the "fatigue" can be seen by the information gathered. A chart attached as an Appendix to the article shows nine statements to gauge the level of fatigue. Id. at 35. Examples include, "exercise brings on my fatigue" or

“fatigue interferes with my physical functioning.” Id. These gauges were then scored from 1 to 7, where 1 indicates strongly disagree and 7 is strongly agree. Id. The patients chose the appropriate number for each statement. The totals were presented on Table 2, as totals before and after treatment. Out of a potential score of 63, the mean was 49.9 before treatment and 39 after treatment. Id. at 30. The authors did not comment on the meaning to attach to the scores. But they did make the statement that the “fatigue in these patients prevented most of daily activities and had a major impact on quality of life.” Id. at 33. Dr. Steinman communicated with Ms. Mueller and “asked her to give me her answers in the context of April 1999.” T3 at 61. Her score was 62 out of 63. It is based upon this subjective scoring, relating to events that occurred ten years prior, that Dr. Steinman opines that Ms. Mueller’s fatigue is the onset of her GBS.¹⁸ Dr. Steinman’s testimony on this issue is shockingly superficial. There is no indication in either Ms. Mueller’s testimony or her journal that she was unable to perform most of her daily life activities. Thus, clearly she did not begin to match the test subjects in their level of fatigue, yet scored significantly higher than each. Dr. Steinman sidestepped this point on cross-examination by saying that “it’s a term that is imprecise enough that it would be hard to answer.” T3 at 149. But an answer is critical because the author’s observation of the impact of the subjects’ fatigue on their daily living gives context for their numerical scoring. Subjects scoring 54 being unable to perform daily tasks shows that Ms. Mueller’s score of 62 while she continued to work, travel perform other daily tasks of everyday living is grossly exaggerated. See T3 at 228-230.

Most telling in Dr. Steinman’s selective use of the information from Boukhris is while all 11 patients described fatigue “as their most disabling symptom,” all of the patients had other symptoms that “prompted us to investigate a possible polyneuropathy.” P Ex 7 at 32. The most common symptom was areflexia. Id. As Dr. Leist testified, “these patients had examinations so they had areflexia as a symptom. [So] they had established symptoms outside of just having fatigue.” T3 at 180-81. No areflexia was noted in Ms. Mueller. See id. at 182. It must also be noted that the relationship of fatigue to CIDP is not established. The Abstract of the article states that “[t]his study shows that fatigue is a possible cause of referral for patients with CIDP. . . .” Id. at 27. And the article notes further that the “[p]athophysiology of fatigue in CIDP remains unclear.” Id. at 33. In the final analysis, Dr. Steinman’s reliance upon Boukhris is rejected because it relies upon information provided by Ms. Mueller eight to ten years after the event in question. While the undersigned agrees with Dr. Steinman that “we must take the patient’s account of her own illness with the utmost respect,” P Ex 24 at 6, we also must use common sense in considering the reliability of the information and evaluate the information along with the medical records in determining its usefulness. Dr. Steinman’s reliance on Ms. Mueller without discussing other information that calls into question Ms. Mueller’s memory of events resulted in unconvincing testimony. In addition, as Dr. Leist points out, Ms. Mueller’s lack of other confirmed symptoms renders Boukhris inapposite.

Lastly, in response to the undersigned’s consistently noting to the parties that the lack of evidence of progression in Ms. Mueller’s symptoms, as detailed by Dr. Leist, was critical to the decision in this case, petitioner filed P Ex 24 - a supplemental report from Dr. Steinman

¹⁸ In fact, Dr. Steinman testified that Ms. Mueller’s calendar evidenced fatigue. T3 at 162. Ms. Mueller testified repeatedly and consistently that the calendar was not a diary and it could only be used to determine if an event took place, and not for the quality of the occurrence. See T1 at 121-22; T2 at 402; see also Fact Ruling at 2.

accompanied by an article by Forsberg. Respondent filed R Ex I, a third supplemental report from Dr. Leist, in response. While offered, neither party wanted an opportunity to take testimony. Dr. Steinman's arguments, at this point they are no longer expert explications, are unavailing because they rely upon snippets of Ms. Mueller's testimony while ignoring the Fact Ruling and other contrary aspects of Ms. Mueller's testimony, such as her ability to continue working. Also, Dr. Steinman's reading of the article, as pointed out by Dr. Leist, is simply incorrect. As summarized by Dr. Leist:

Forsberg et al. Performed a retrospective study based on patient interviews with the aim . . . "to describe experiences of falling ill with GBS, with the focus on the onset of disease, the diagnosis and the illness progress during hospital care." The authors write in their introduction: "There are typically three phases to the course of GBS. The acute phase begins with the onset of symptoms for an average of 8-12 days before the illness peaks. This is followed by a plateau phase of 2-4 weeks, and then a recovery phase."

R Ex I at 1. Dr. Steinman contends, based upon a very selective use of alleged factual information, that the prolonged onset described in Forsberg is 'congruent with many of Brigitte Mueller's experiences that evolved over a period of weeks and months, a finding that was stated in the paper authored by Forsberg and colleagues. . . ." P Ex 24 at 3. Dr. Steinman provides no citation to the paper for his conclusion, and none is apparent to the undersigned. Dr. Leist takes vigorous exception.

Dr. Leist first notes the data collection that culminated in Table 1. R Ex I at 2, citing P Ex 24 at 8. Table 1 contains "Descriptions of activities of daily living (ADL) and working status; before the onset of Guillain-Barre syndrome, at 2 weeks and at 2 years after the onset." Id. Based upon the Table, Dr. Leist notes that 97% of the patients were "Dependent in instrumental ADL" and none of the patients were working or studying at 2 weeks post-onset of their symptoms of GBS. Id. As Dr. Leist summarizes the meaning of the data, "[a]ll patients in the series of Forsberg et al. developed significant clinical symptoms over 2 weeks or less that interfered with gainful activities and rendered the majority dependent with respect to instrumental activities of daily living." R Ex I at 3. Applying Forsberg to the case at hand, Dr. Leist states:

None of the patients in the article of Forsberg et al. had a clinical course comparable to that alleged in petitioner's case. On the contrary, the case series underlines the point that in GBS the disease nadir is reached rather quickly and during single evolving episode.

Id. Regarding Dr. Steinman's contention that the Forsberg authors supported a "prolonged" onset of GBS, Dr. Leist states that it is "evident" that "prolonged refers to a time period of 2 weeks or less and not an extended multi-month process as suggested by Dr. Steinman. . . ." Id. Petitioner maintains that "[n]owhere did the papers say progression stopped after two weeks." Petitioner Post-Trial Brief at 47. This is literally true. However, fairly read the authors set out

the three phases of GBS: the acute phase lasting on average 8-12 days, followed by a plateau phase of 2-4 weeks and finally a recovery phase. P Ex 24 at 7. Under Results, after describing the prolonged onset of GBS, the authors quote a person describing losing their balance “within a couple of weeks.” Id. at 9. Later in the discussion of the prolonged onset, they discuss the experiences of others, describing “sensations increas[ing] over the following days **and in a few cases over weeks.**” Id. (emphasis added.) The undersigned agrees completely with Dr. Leist’s analysis of the Forsberg article and finds that the article provides absolutely no support for petitioner’s contentions. Dr. Steinman’s contention that “long onset” GBS was “described so articulately” in the Forsberg article is simply incorrect.¹⁹

Legal Standard

To establish a prima facie case of actual causation, petitioner must “show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Sec’y of the Dept. of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Based upon the entire record, the undersigned finds that Prong I of Althen was met. Dr. Leist testified that “vaccines have the potential to cause demyelinating events in situations where the sequence is correct.” T3 at 198. This concession by Dr. Leist obviates the need to discuss the evidence of a medical theory presented by Petitioner.

Prong II was not met in this case. Relying upon the persuasive testimony of Dr. Leist, the undersigned finds, by the preponderance of evidence, that the lack of evidence of a progression of symptoms following Ms. Mueller’s immunization, the lack of contemporaneous findings by the treating doctors implicating the immunizations and the lack of credible factual information regarding the symptoms following immunization make a connection between the immunizations and petitioner’s demyelinating disorder illogical.

Regarding Prong III, the issue of the medically appropriate period of onset of petitioner’s GBS was vigorously litigated. It was the subject of the fourth Hearing. See T4. If one accepted the early April date as the onset of petitioner’s condition, her latency period would be roughly seven and one half weeks. The Institute of Medicine, whose teachings the special masters routinely rely upon, found an acceptable time for an immune-mediated response to be five days to six weeks. R Ex F at 45. Dr. Steinman relied upon a study by Schonberger et al. of GBS

¹⁹ Dr. Steinman is incredibly well-credential and exceedingly knowledgeable on the medical issues confronted in the vaccine program. However, he needs to understand that as an expert his obligation is to educate the court on the issues confronted. Providing helpful medical information is how an expert helps the cause of the party represented, advocating a position is not credible and is easily detected by the decision-maker. Such efforts are extremely unhelpful to the party represented. A statement, such as “The opinion [of the government doctor] was wrong especially for the failure to listen to the patient, Brigitte Muller [sic], and to interpret her complaints, for the failure to take her written accounts in her diaries as compelling, and for the conclusion to discount her testimony before this court,” P Ex 24 at 6, is an argument that should be advanced by counsel. This is argument, not expert analysis. Dr. Steinman should take heed for future cases as his expertise if properly utilized will benefit greatly the parties and the court.

cases following the 1976 swine flu vaccine and contended that the study showed an increased risk within twelve weeks of immunization. T3 at 132-33; T4 at 264. However, without a meaningful explanation, Dr. Steinman stated in response to a question on cross-examination – “I have no problem with eight weeks. If I [rely] more heavily on Schonberger I can go to 10 weeks. So it depends, but definitely eight weeks.” T4 at 264.

Respondent produced a paper by Langmuir et al. that was an evaluation of the Schonberger data. R Ex H. The authors concluded that “[t]he effect attributed to the vaccine lasted for at least six weeks and possibly for eight weeks but not longer.” *Id.* at 841, 866. Timing of onset is oftentimes a deciding issue in vaccine demyelination cases. Considering that the case at hand is easily resolved based upon the deficient factual predicate, prudence dictates not resolving the critical timing issue at this time. It is best to leave such an important issue to a case devoting the requisite time and attention to its full development and thus proper resolution.

Conclusion

Petitioner’s allegations of vaccine-caused GBS were built upon factual information that was not contained in the contemporaneous medical records but was based upon a “refreshed” memory. The undersigned finds that memory faulty and not credible. It follows that the expert testimony relying on the rejected facts must also fail. Accordingly, petitioner’s case fails for lack of preponderant, supporting evidence and is denied. The Clerk of the Court is directed to enter judgment accordingly.²⁰

IT IS SO ORDERED.

s/ Gary J. Golkiewicz
Gary J. Golkiewicz
Special Master

²⁰ This document constitutes a final “decision” in this case pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Unless a motion for review of this decision is filed within 30 days, the Clerk of the Court shall enter judgment in accord with this decision. Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by each party filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.