In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-898V
Filed: October 9, 2020

THEODORE A. BRYAN,	*	
	*	TO BE PUBLISHED
Petitioner,	*	
v.	*	Special Master Katherine E. Oler
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Chronic Fatigue Syndrome (CFS); Influenza vaccine; Th2 immunity
Respondent.	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for Petitioner
Camille Collett, U.S. Department of Justice, Washington, DC, for Respondent

RULING ON ENTITLEMENT[1]

Oler, Special Master:

On September 23, 2014, Theodore Bryan ("Mr. Bryan" or "Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program"). The petition alleges that Mr. Bryan developed chronic fatigue syndrome ("CFS") as a result of the influenza ("flu") vaccination he received on October 10, 2011. Amended Pet. at 1-2.

[1] This Ruling will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Ruling will be available to anyone with access to the internet**. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Ruling's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, 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, this Ruling will be available to the public in its present form. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Upon review of the evidence in this case, I find that Petitioner has met his burden in showing that the flu vaccination he received on October 11, 2011 caused him to develop CFS. He is therefore entitled to compensation under the Vaccine Act.

I. Procedural History

Petitioner filed his petition on September 23, 2014 and filed an amended petition on January 9, 2015. ECF Nos. 1, 15. On February 26, 2015, Respondent filed a Rule 4(c) Report stating that compensation was not appropriate in this case and the petition should be dismissed. Resp't's Rep. at 15., ECF No. 18.

Petitioner filed several affidavits on April 20 and 28, 2015. Exs. 21-24. On June 15, 2015, Petitioner filed an updated medical report from his treating physician, Regina Smith, D.O. Ex. 27. Dr. Smith filed a supplemental report on September 9, 2015 that answered additional questions about Petitioner's CFS diagnosis. Ex. 28.

On May 17, 2017, Petitioner filed an expert report from Dr. Susan Levine. Ex. 36, ECF No. 78. On September 21, 2017, Respondent filed an expert report from Dr. Kenneth Fife, along with his curriculum vitae. Exs. A, B, ECF No. 87. On July 9, 2018, Petitioner filed an expert report from Dr. Charles Lapp. Ex. 52, ECF No. 97.

I held an entitlement hearing on January 9 and 10, 2019. *See* Minute Entry on 1/23/19. On January 30, 2019, this case was referred to Special Master Dorsey for Alternative Dispute Resolution (ADR). ECF No. 116. This case was removed from ADR on March 6, 2019. ECF No. 121. Petitioner filed a post-hearing brief on August 13, 2019. ECF No. 124. Respondent filed his post-hearing brief on December 18, 2019, and Petitioner filed a post-hearing brief reply on February 18, 2020. ECF Nos. 127, 128. Petitioner filed Dr. Smith's CV on September 23, 2020. Ex. 60, ECF 131. The parties have indicated that the record is complete. Accordingly, this matter is ripe for adjudication.

II. Medical Records

A. Petitioner's Health Prior to the Allegedly Causal Vaccination

Mr. Bryan had a history of depression, hyperlipidemia, and fatigue prior to vaccination. Petitioner had numerous visits with his primary care physician (PCP), Dr. William Albright at Pinnacle Health in 2009 regarding these health issues; the medical records are unclear as to the precise onset of these symptoms.[3]

B. Petitioner's Health after the Allegedly Causal Vaccination

[3] With the medical records provided, Petitioner's symptoms of depression, sleeping difficulties, and concentration difficulties date back to July 2, 2009, the earliest medical record provided. Ex. 16 at 5. Respondent does not assert that Petitioner had CFS prior to his vaccination. I agree and have not analyzed this issue.

Petitioner was 42-years old when he presented to Dr. Albright at Pinnacle Health on October 10, 2011. Ex. 2 at 2. Mr. Bryan had left and right elbow lateral epicondylitis release procedures performed in 2011 and had a history of neck, back, and forearm pain. *See id.* at 25-28. As of October 10, 2011, Petitioner was on the following medication: promethazine, sertraline, Wellbutrin, simvastatin, Zithromax, zolpidem, AndroGel, and Abilify. *Id.* at 3.

Petitioner received the flu vaccine at his appointment with Dr. Albright on October 10, 2011. Ex. 2 at 3. On October 20, 2011, Petitioner returned to Dr. Albright with joint pain. *Id.* at 5. Dr. Albright prescribed Medrol and noted "medrol is helping most likely rxn to flue [sic] injection." *Id.* Petitioner returned to Dr. Albright on October 24, 2011 presenting with fatigue and depression. *Id.* at 8. Dr. Albright noted that Petitioner "feels much better most likley [sic] a reaction to the flue [sic] injection. abilify is working well at this point." *Id.*

On November 14, 2011, Petitioner presented to Dr. Natalie Dubchek for a rheumatology consultation. Ex. 3 at 1. Dr. Dubchek noted that Petitioner "was in a good general state of health until October 12th of this year when he developed diffuse arthralgias and joint swelling two days after he received his flu shot….. Also he noticed early onset fatigue." *Id.* She also noted that "he may have had a reaction to the flu vaccine that presented with arthralgias and now is greatly improved. Another possibility could be underlying psoriatic arthritis with enthesitis with the onset of his symptoms after the flu shot may be coincidental." *Id.* at 2.

Petitioner returned to Dr. Dubchek on November 29, 2011. Ex. 3 at 3. The doctor noted that "[h]e continues to experience the same symptoms of generalized fatigue, generalized pain, now mostly localized to the lower legs, knees, and calves." *Id.* Dr. Dubchek noted that Petitioner denied worsening depression but continued to have significant trouble with insomnia. *Id.* at 4.

On December 5, 2011, Petitioner returned to Dr. Albright. The reason for this visit was noted to be depression. Ex. 2 at 14. More specifically, Dr. Albright noted:

> The patient presents with difficulty concentrating, fatigue and muscle weakness. The fatigue is associated with generalized weakness. The patient denies any change in appetite, chills, change in sleep cycle, constipation, diaphoresis, diarrhea, dyspnea, flank pain, heartburn, hematemesis, hematochezia, hoarseness, increased abdominal girth, jaundice, lightheadedness, loss of interest, malaise, melena, myalgia, pallor, pruitus [sic] and weight gain; Additional information: saw reumatologist [sic], most likley [sic] rxn to TVF [sic], had extensive work up.

Id. Petitioner was prescribed tryprednisone to treat his fatigue. *Id.* at 16.

Petitioner returned to Dr. Albright on December 19, 2011 for depression and fatigue. *Id.* at 18. Under depression, Dr. Albright noted "still does not feel right? rxn to flue [sic] shot. ? rxn to zocor.? ms saw rheumatologist. No dx." *Id.* Petitioner was taken off Zocor and was directed to follow up in two weeks. *Id.* at 19.

On January 5, 2012, Mr. Bryan returned to Dr. Albright. Ex. 2 at 21. Dr. Albright noted that Petitioner's depression and fatigue had not improved after stopping Zocor. *Id.* Dr. Albright assessed Petitioner with chronic fatigue syndrome and referred him to a neurologist. *Id.* at 22.

On February 6, 2012, Petitioner saw Dr. Salim Qazizadeh at the Pennsylvania Neurosurgery & Neuroscience Institute, Inc. (hereinafter "PNNI"). Ex. 4 at 13, 17. Petitioner presented with memory loss. *Id.* at 13. Dr. Qazizadeh noted:

> 43-year old man who has been having a variety of complaints since October of last year when he had a flu shot. These include difficulty focusing, unable to multitask, blurriness of vision, extreme fatigue, muscle weakness, tremor, numbness, tingling, cramps in the legs, joint pain, interrupted sleep, memory problems, low back pain, stiffness, and vertigo. The patient also does have a history of depression and is being treated for that. He has seen different physicians, including his primary care physician as well as a rheumatologist. The thought is that probably it is a serum sickness reaction to the flu shot that he had. Due to persistence of his symptoms he is being referred to me for further evaluation and management.

Id. Dr. Qazizadeh ordered MRIs with and without contrast of Mr. Bryan's brain, an EEG, a full-night sleep study, and a wide assortment of lab tests. *Id.* Dr. Qazizadeh also noted that he is "not sure if indeed his problems are neurological." *Id.*

On March 8, 2012, Mr. Bryan returned to Dr. Qazizadeh for follow-up. Ex. 4 at 18. Dr. Qazizadeh noted that Petitioner's MRI and EEG were "unremarkable" and other lab tests were also unremarkable, but his vitamin D level was low and that he should continue a multi-week course of high-dose vitamin D. *Id.* The summary for the visit noted that "[t]he possibility of serum sickness is being entertained." *Id.* Petitioner's wife stated they were interested in getting a second opinion at Johns Hopkins and were encouraged to do so by Dr. Qazizadeh. *Id.*

On January 15, 2014, Petitioner saw Dr. Maria Michalek at Pinnacle Health Sleep Center for a comprehensive polysomnography. Ex. 17 at 4. The results of the polysomnography state that Petitioner was in bed for 428 minutes but slept 115 minutes, achieving a sleep efficiency of 26%. *Id.* Petitioner underwent another polysomnography on January 23, 2014. *Id.* at 6. The results of the January 23, 2014 polysomnography show that Petitioner was in bed for 463 minutes and asleep for 182[4] minutes, achieving a sleep efficiency of 39%. *Id.* Petitioner returned on February 3, 2014 for another comprehensive polysomnography, with a CPAP. *Id.* at 9. Petitioner was in bed for 382 minutes, slept for 243 minutes and had a sleep efficiency of 67%. *Id.*

On May 1, 2014, Petitioner visited PA Amanda Renninger (under the supervision of Dr. Stephen Ross, a neurologist) at the Penn State Hershey Medical Center. Ex. 7 at 1. The notes from this visit summarize Petitioner's clinical course after the flu shot: "He progressively got better over a year, did not reach 100%, was able to function. Approximately 6-8 months ago, he began to get progressively worse in his symptoms both mentally and physically. He suffers from chronic fatigue and pain." *Id.* The record notes that "[i]t is also possible that he may have had some

[4] Exhibit 17 was scanned poorly and at times is illegible. The numbers of 463 and 182 are not clear.

neurologic episode from the flu shot…" *Id.* at 3.

On July 30, 2014, Petitioner began seeing Regina Smith, D.O. Ex. 17 at 20. In a letter dated August 6, 2014, Dr. Smith wrote that she performed a physical exam and reviewed Petitioner's extensive medical records; she stated that it was her opinion Petitioner's "medical and cognitive issues are a direct result of the flu vaccination that he received on 10/11/2011." Ex. 11.

On September 8, 2014, Dr. Smith saw Petitioner again and noted fatigue or malaise, as the primary concern, but also muscle weakness, constipation, insomnia, memory loss, abnormality of gait, depressive disorder, tremor, joint pain, and low testosterone. Ex. 14 at 2. Dr. Smith sent a referral to Dr. Jon Vickery to analyze Mr. Bryan's fatigue, muscle weakness, memory loss, abnormality of gait, and tremors. *Id.* at 2-3.

On September 9, 2014, Petitioner saw Dr. Christopher Royer, Psy.D., for a neuropsychological evaluation. Ex. 15 at 1. Dr. Royer's impression was that Petitioner's symptoms were indicative of a mixed neurocognitive profile. *Id.* at 6. Dr. Royer summarized Petitioner's past diagnostic history as "serum sickness, sleep disorder, and depressive disorder," and further noted that "these problems are likely sufficient to account for the cognitive difficulties seen here." *Id.*

On January 9, 2015, Mr. Bryan saw Dr. Jon Vickery at Vickery Neurodiagnostics Group, Ltd. Ex. 17 at 1. The medical records from this visit state:

> 46 year old male presents with c/o memory loss fatigue & cognitive troubles "started 3 years ago after getting a flu shot." Developed pain in R knee. In bed for a week… with pain more or less everywhere. "Couldn't move". Then got better & got back to work in his field of HVAC in ~ 2 weeks. Then, symptom constellation gradually got worse again, states that in 2013 things went downhill with pain all over.

Id. Dr. Vickery assessed Petitioner with cognitive deficits along with chronic fatigue syndrome, REM sleep behavior disorder, and depressive disorder. *Id.* at 2. Dr. Vickery informed Petitioner and his wife that he found no evidence of a neurological disease. *Id.* at 3.

Dr. Smith saw Petitioner again on June 15, 2015. Ex. 27 at 1. Dr. Smith noted chronic fatigue syndrome along with anxiety, low back pain, myalgia and myositis, jaw pain, other cerebellar ataxia, and motion sickness. *Id.* at 2.

III. Affidavits/Statements and Fact Testimony

A. Affidavits/Statements

1. Self-Written Statement of Theodore Bryan

Petitioner filed a self-written statement on November 11, 2014. Ex. 8. Petitioner provided a personal history of his health, his relationship with his wife, and his hobbies prior to the allegedly

causal vaccination. *Id.* at 1. Following the vaccination, "Within a week [Petitioner]… was basically paralyzed in bed for 4 days." *Id.* at 2. He received a steroid prescription which enabled him to walk, but he still experienced pain. *Id.* He required assistance performing everyday tasks such as tying his shoes and getting dress for "approximately 16 weeks." *Id.* Petitioner stated, "things seemed to be a little better for about one year". *Id.* After that, Petitioner's symptoms grew worse and included pain and a strange sensation in his feet and lower legs, weak legs, blurred vision, feeling like he was going in slow motion, experiencing excessive fatigue after doing normal activities, a tremor while doing simple but intricate tasks he could previously do, red/green/brown color blindness, irritability, short temperedness, and anger. *Id.* Petitioner's boss noticed some of these symptoms. *Id.* at 3. Petitioner began using a CPAP machine which reduced his movement during sleep but did not help his sleep quality or reduce his fatigue upon waking. *Id.*

2. Affidavit of Jackie Bryan

Jackie Bryan, Petitioner's wife, signed her affidavit on April 16, 2015. Ex. 20. Ms. Bryan stated her husband was an active person prior to the October 2011 vaccination and that he was an avid hunter, fisherman, outdoorsman, and golfer. *Id.* at 1. Ms. Bryan also stated that Petitioner loved his job as a plumber and HVAC technician and was in the process of remodeling their home after work as well. *Id.* at 1-2.

After the vaccination, Ms. Bryan stated her husband developed excessive fatigue and sometimes slept for 36 hours straight and as a result began to miss work because of the extreme fatigue and pain. Ex. 20 at 2. Ms. Bryan noticed that Petitioner's symptoms included body pain, joint pain, weak legs, memory loss, blurry vision, migraine headaches, dizziness, loss of balance, numbness/clumsiness in both hands and feet, abnormal gait, agitation, irritation, anxiety, and lack of sexual interest and romance. *Id.* at 3.

Ms. Bryan added Petitioner's quality of life was greatly diminished. Ex. 20 at 4. Petitioner has gained weight, cannot lift objects over 20-25 pounds, and cannot drive long distances. *Id.*

3. Affidavit of Doug Vaughan

Doug Vaughan, Petitioner's co-worker, signed his affidavit on April 20, 2015. Ex. 21. Mr. Vaughan worked with Petitioner for several years. *Id.* at 1. Both Mr. Vaughan and Petitioner were responsible for a 15-story office business and a separate 12-story garage, where Petitioner performed plumbing, electrical, and general building maintenance work. *Id.* Mr. Vaughan stated, "Ted got sick at some point. He was unable to do a fraction of the things he did before and his rate of decline was pretty fast." *Id.* Mr. Vaughan also indicated that Petitioner's decline was noticed by building tenants. *Id.* By the end of his work tenure, Mr. Vaughan stated that "Ted could not do much at all." *Id.*

4. Affidavit of Bruce Kageorge

Bruce Kageorge, Petitioner's employer, signed his affidavit on April 16, 2015. Ex. 22. Mr. Kageorge has known Petitioner since June 2008 and found Petitioner to be a dependable and dedicated employee. *Id.* at 1. Petitioner received positive performance reviews and interacted

well with co-workers, contractors, and tenants. *Id.* Mr. Kageorge and Petitioner were partners in a weekly golf league and became good friends. *Id.*

After the October 2011 vaccination, Mr. Kageorge stated that Petitioner "was out for over a week immediately following the vaccine due to the paralyzing effect it had on him." Ex. 22 at 2. According to Mr. Kageorge, when Mr. Bryan returned to work, he had many issues doing anything physical, including walking, standing, or kneeling. *Id.* In 2013, Mr. Kageorge noticed that Mr. Bryan's pain and discomfort was "getting worse on a more regular basis along with very noticeable neurological difficulties like trouble remembering things, stressing out and getting very emotional over the smallest of things." *Id.* Petitioner had tremors that made him unable to handle a drill and balance issues that made him unable to safely climb a ladder. *Id.* Petitioner also suffered from muscle weakness and cramps that hindered his ability to do his job. *Id.* Because of the physical nature of his job, Petitioner would need additional sleep to recover and would miss at least two days of work a week. *Id.*

5. Affidavit of Dennis Corbett

Dennis Corbett, a friend of Petitioner, signed his affidavit on April 17, 2015. Ex. 23. Mr. Corbett has known Petitioner since May 2012 through social activities and regular golf outings. *Id.* at 1. Mr. Corbett noticed shaking in Petitioner's leg while he was sitting for breakfast and/or lunch. *Id.* Mr. Corbett stated that eventually, Petitioner's leg tremors would shake the table they shared for meals. *Id.* According to Mr. Corbett, Petitioner stopped golfing because he could not handle the physicality. *Id.* Mr. Corbett noticed that Petitioner's speech was slower and that he would depend on Ms. Bryan to "fill in some of his thoughts." *Id.* Mr. Corbett stated that Petitioner's personality and mood would fluctuate based on how he was doing physically. *Id.*

6. Affidavit of Cortney Hartnett

Cortney Hartnett, Petitioner's neighbor, signed her affidavit on April 20, 2015. Ex. 24. Ms. Hartnett has known Petitioner since 2008. *Id.* at 1. Ms. Hartnett noticed that Petitioner "has been struck down by severe illness over the last two years… and his health has declined significantly." *Id.* Ms. Harnett stated Petitioner "was a thriving, busy, hardworking, golfing, fishing kind of a man" when she first met him but is now unproductive, homebound, and in pain. *Id.* Ms. Hartnett has observed a drastic physical change in Petitioner and stated that his illness has taken a heavy toll on him and his family. *Id.*

B. Fact Testimony

Petitioner Theodore Bryan, Mr. Dennis Corbett, Mr. Bruce Kageorge, Ms. Jackie Bryan, and Mr. David Timme testified as fact witnesses at the January 9 and 10, 2019 entitlement hearing.

1. Petitioner Theodore Bryan

Petitioner provided a history of his work prior to the 2011 vaccination. Tr. at 6-14. Petitioner also stated he led a very active lifestyle, participating in competitive bass fishing, golf, volleyball, and roller hockey. He testified that he also was an active runner until 2000. *Id.* at 14.

Petitioner addressed his history of depression. *Id.* at 16-17. He stated that he had received the diagnosis when he was around 22 or 23 and started taking Prozac but stopped treatment when he began feeling better. *Id.* at 17.

Prior to the October 2011 vaccination, Petitioner suffered from fatigue due to the physical nature of his work but "never missed working because of it" and certainly "didn't miss [any of his] hobbies because of it." Tr. at 18. In comparison to his current symptoms, Petitioner stated, "it seems almost laughable that I called that fatigue." *Id.* Prior to 2011, Petitioner stated that his fatigue would be cured when he had a good night sleep or slept in. *Id.*

Regarding the October 2011 vaccination, Petitioner testified that he experienced knee pain two days after vaccination, along with swollen and stiff knees three days after vaccination. Tr. at 24. He described that "[o]n the fourth day I couldn't move. I couldn't get out of bed. And all my -- I was like a board. My joints -- my hands were double the size, my legs were double the size. All my joints were just kind of like locked in place." *Id.* Petitioner said his doctor gave him Medrol, a steroid, to treat his symptoms. *Id.* at 24-25. Petitioner also remembered that Dr. Albright said it "was most likely something called serum sickness." *Id.* at 25. During this time, Petitioner needed help going to the bathroom and tying his shoelaces and was still experiencing pain. *Id.* at 26. Petitioner took time off work; when he returned, he performed light duties, which included paperwork and phones calls. *Id.* at 28, 31.

Two months post-vaccination, Petitioner's swelling had largely dissipated but he still experienced pain from the hips down and numbness in his feet, particularly his left foot. Tr. at 30. Petitioner testified that he sometimes experienced pain that felt like sharp jabs along with cramping. *Id.* at 31.

Four months post-vaccination, Petitioner testified that he saw Dr. Qazizadeh, a neurologist. Tr. at 34. It was then that Petitioner's vitamin D deficiency was discovered and thought to have been the cause of his fatigue. *Id.* at 33. Petitioner began seeing Dr. Smith because he believed Dr. Albright was unable to answer questions that were not specific to the appointment purpose. *Id.* at 82.

2. Dennis Corbett

Mr. Corbett met Petitioner through Mr. Corbett's brother in 2012. Tr. at 144. Mr. Corbett and Petitioner played golf almost weekly. *Id*. at 144, 146-47. Mr. Corbett also shared meals with Petitioner and Ms. Bryan on a near weekly basis in 2012. *Id.* at 148. Mr. Corbett testified that he began noticing Petitioner's leg shaking in early 2013 during meals. The leg shaking increased to the point that silverware would rattle on the table. *Id.* at 149. Mr. Corbett testified that he does not remember Petitioner golfing with him after July 2013 because Petitioner did not have the energy to complete a hole. *Id.* at 152. In the years since he stopped golfing, Mr. Corbett noticed that Petitioner started to walk slower, he had much less energy, he needed assistance walking up and down stairs, he had issues speaking, and he had lost a noticeable amount of weight. *Id.* at 154-55.

3. Bruce Kageorge

Mr. Kageorge hired Petitioner in 2008 for Penn National Insurance. Tr. at 161-62. Petitioner was a licensed plumber with a certification for HVAC. *Id.* at 162. Mr. Kageorge testified that Petitioner was well-liked by the building's customers and did his job well. *Id.* at 165. Petitioner was very dependable and would sometimes travel with Mr. Kageorge to other sites managed by Penn National to assist him. *Id.* at 163. Mr. Kageorge stated that their occupation was extremely physical and involved different types of work, not just plumbing. *Id.* at 166-67. Mr. Kageorge also formed a friendship with Petitioner outside of work that included playing golf together. *Id.* at 168. Mr. Kageorge testified that Petitioner had no issues with playing 36 holes of golf on their golf trips prior to the vaccination. *Id.*

Mr. Kageoge testified that he received a call from Petitioner or Ms. Bryan in October 2011 saying Petitioner had "blown up" and he could not bend his arms and legs and was experiencing pain. Tr. at 169. Petitioner returned to work performing light duties and eventually resumed his full duties, however, not at full speed. *Id.* at 170. Mr. Kageorge stated it was noticeable that Petitioner did not have the same stamina as prior to the vaccination because he would be exhausted at the end of the day. *Id.* at 170, 172. Eventually, Petitioner's tremors became progressively worse and he also experienced memory issues. *Id.* at 170. Mr. Kageorge made accommodations for Petitioner; for example, he allowed Petitioner to take naps and gave him lighter duties, but these accommodations did not solve the underlying problem. *Id.* at 173. Mr. Kageorge testified that Petitioner finally left his position in 2014 because he would often have to miss three to four days of work a week. *Id.* at 171-72.

4. Jackie Bryan

Ms. Bryan has been married to Petitioner for 24 years. Tr. at 182. Ms. Bryan testified that Petitioner received his plumbing license through a union apprenticeship program and had worked as a plumber for multiple years prior to his position with Penn National. *Id.* at 183-84. He enjoyed his work immensely. *Id.* at 184. Ms. Bryan also testified that before the vaccination, Petitioner began renovation projects in their home and would work on them on the weekdays after dinner. *Id.* at 185.

Ms. Bryan testified that Petitioner had swelling for over two weeks after the October 2011 vaccination. Tr. at 189. Petitioner would need her assistance getting dressed because he was unable to move. *Id.* Petitioner was also unable to work eight to ten hours days at Penn National and could not work on the renovation projects in their home, as he did prior to vaccination. *Id.* at 190. Ms. Bryan observed that when Petitioner spoke, he would often pause and lose his train of thought. *Id.*

Ms. Bryan testified that Petitioner was a competitive fisher and golfer prior to the October 2011 vaccination. Tr. at 186, 192. Petitioner was unable to compete or participate in his hobbies post-vaccination. *Id.* at 192. Petitioner now naps every day and can still sleep for 36 hours straight. *Id.* at 195. He is unable to see his children and grandchildren due to his inability to drive long distances. He does not have the same quality of life that he once did. *Id.*

5. David Timme

Mr. Timme has worked as a physician assistant for over 25 years. Tr. at 320. Petitioner began seeing Mr. Timme in 1993 for depression. *Id.* at 322. He treated Petitioner for a number of years, stopped for a few years, and then resumed seeing Petitioner again in 2012. *Id.* at 322-23. The practice where Mr. Timme originally saw Petitioner in 1993 has since closed and no medical records of Mr. Timme's treatment of Petitioner prior to 2012 exist. *Id.* at 321, 324. Mr. Timme testified that he saw Petitioner for depression and provided him with medication to treat the depression. *Id.* at 324-25. When Mr. Timme saw Petitioner again in 2012, he noticed a very different man than the person he had come to know. He described the difficulty Petitioner experienced just trying to get out of his car to come into the office. Petitioner needed help from Ms. Bryan, and then used a walker to enter the building. *Id.* at 326-27. This was markedly different from the man he knew previously, who was an avid golfer and fisherman. *Id.* at 325.

IV. Expert Opinions

A. Dr. Charles Lapp

Petitioner filed one expert report from Dr. Charles Lapp. *See* Expert Report, filed as Ex. 52 (hereinafter "Lapp Rep."). Dr. Lapp also testified at hearing.

1. Qualifications

Dr. Lapp received his medical degree from Albany Medical College in 1974. Ex. 53 at 1 (hereinafter "Lapp Brief Resumé"); Ex. 54 at 1 (hereinafter "Lapp CV"). Dr. Lapp completed two residencies in internal medicine and pediatrics at the North Carolina Memorial Hospital and began his practice in internal medicine and pediatrics in 1978. Lapp Brief Resumé at 1; Lapp CV at 1. Dr. Lapp is board certified in internal medicine, pediatrics, and independent medical examination. Lapp CV at 1. Dr. Lapp has also conducted clinical research for companies including (but not limited to) Pfizer, Eli Lilly, Cephalon, and Hemispherx Biopharma. *Id.* at 2.

Dr. Lapp began his work in CFS in 1983 when there was what he described as "an epidemic of chronic fatigue syndrome" in Raleigh, North Carolina, where he started his medical practice. Tr. at 220-21. He contacted the CDC around 1985 to report the epidemic. *Id.* at 222. After this initial work, Dr. Lapp continued his involvement with CFS, as a consultant/medical advisor for CFIDS (Chronic Fatigue Immune Dysfunction Syndrome) Association from 1992-2013, which published what is known as the CDC criteria or the International Case Definition Criteria for chronic fatigue syndrome. *Id.* at 224, 235. From 2003-2007, Dr. Lapp developed a training program to teach other medical professionals about the diagnosis and medical treatment of CFS patients. *Id.* at 235-36. That transitioned to webinars in 2008. *Id.* at 236.

Dr. Lapp also worked and performed research for a pharmaceutical company, Hemispheryx Biopharma, from 1988, which identified Ampligen as an effective treatment of CFS. Tr. at 237. He is one of two medical providers allowed to administer the drug in the United States. *Id.* at 237-38. Over the years, Dr. Lapp has published approximately 35 papers about CFS. *Id.* at 238; *see also* Lapp CV at 3-5. Dr. Lapp was also involved with the more recently developed IOM criteria. Tr. at 226.

Dr. Lapp treats CFS patients from all 50 states and 20 foreign countries. Tr. at 242. He has treated approximately 28,000 CFS patients during the course of his career. *Id.* at 447. Dr. Lapp has spoken in foreign countries about CFS and was contracted by the Norwegian government to help set up a treatment clinic in Oslo when a burst water line caused a Giardia outbreak, which in turn led to over 300 people developing CFS. *Id.* at 242-43. Dr. Lapp is currently the Director of the Hunter-Hopkins Center, which specializes in treatment of CFS, FM, and other related disorders. Lapp CV at 1. I recognized Dr. Lapp as a medical expert with special expertise in CFS. Tr. at 238.

2. Dr. Lapp's Opinion

In Dr. Lapp's report, he summarized Petitioner's symptoms and opined that Petitioner met the 1994 CDC Case Definition of CFS. Lapp Rep. at 2. Regarding causation, Dr. Lapp stated that the physiologic cause of CFS has never been determined but the disorder "is frequently triggered by infections and various adverse reactions, including vaccinations." *Id.*

3. Dr. Lapp's Expert Testimony

a. *History and Development of CFS Diagnostic Criteria*

Dr. Lapp testified regarding his involvement with the Fukuda paper and the IOM criteria. Tr. at 222-32. With respect to the differences between the Fukuda and IOM criteria, Dr. Lapp testified that the Fukuda paper was targeted for broad additional research on CFS thus "[w]e wanted to find the patients that were most alike … for the purposes of research." *Id.* at 239. Regarding the IOM criteria, Dr. Lapp opined it was "developed more for the clinician, the provider, and they were not for research purposes. They were made to be simple to follow." *Id.* at 240.

Dr. Lapp used the Fukuda criteria in analyzing Petitioner's symptoms because they were the only criteria available when Petitioner fell ill and Medicare uses it to assess Social Security determinations. Dr. Lapp testified that he believes Petitioner satisfies the IOM criteria as well. Tr. at 241-42.

Dr. Lapp testified that there is not one well-defined cause of CFS and there are many proposed theories of pathophysiology. Tr. at 244. Dr. Lapp testified that 85% of CFS cases have sudden onset and within those cases, 75% are attributed to bacterial or viral infections. *Id.* Remaining triggers include trauma in childbirth, allergic reaction, stress, and immunizations. *Id.* at 244-45.

Dr. Lapp testified about the Kerr paper and that it demonstrates that patients with CFS have a Th2 profile. Tr. at 245. The Th2 profile involves the increased secretion of interleukin-6 ("IL-6") and interleukin-4 ("IL-4") by T lymphocytes. *Id.* at 245-46. The Th2 profile also involves elevated interferon-gamma, decreased IgG and TGF-beta. *Id.* at 246.

Dr. Lapp discussed how CFS is diagnosed. Tr. at 249. He stated that CFS cannot be diagnosed through a single blood test, urine test, or x-ray but is diagnosed through symptomology.

See id. at 249-50. However, certain tests can be used to eliminate other possible diseases and help confirm CFS.

In discussing how the flu vaccine can cause CFS, Dr. Lapp testified about a paper from Dr. Brenu at Griffith University (filed as Ex. 59) which involved a small sample size of CFS patients who received the flu vaccine. *Id.* at 253. Based on the observed cytokine response discussed in the paper, Dr. Lapp testified that the CFS patients had a proclivity toward Th2 immunity after they received the flu vaccine. *Id.* at 253-54.

b. *General Observations regarding Patients with CFS*

Dr. Lapp testified that he has seen many patients with CFS who present after the flu as well as two or three cases where the flu vaccine was the trigger. Tr. at 256-57. According to Dr. Lapp, the Hepatitis B vaccine is a more common trigger. *Id.* at 257. Dr. Lapp also opined that CFS presents abruptly, "like a flu-like illness or a mono-like illness or some sort of an illness and then the symptoms develop over time." *Id.* at 280. CFS symptoms can "change from hour to hour, day to day, week to week, and month to month," and it was Dr. Lapp's personal opinion that symptoms come in cycles and a relapse or flare is when all of the symptoms occur at the same time. *Id.* at 281.

Dr. Lapp testified that Petitioner's sleeping issues prior to vaccination were later diagnosed as obstructive sleep apnea, for which he was given a CPAP machine. Tr. at 258. Petitioner's non-restorative sleep issues were not cured by the CPAP machine, which is further evidence that his prior sleep issues were not related to CFS. *Id.* at 258-59. Furthermore, Petitioner's pre-vaccination medical records identify that his sleeping issues include "trouble falling asleep and staying asleep," which is not the unrefreshing sleep that is seen in CFS patients. *Id.* at 260. Dr. Lapp defined the fatigue seen in CFS patients as "exertional intolerance with post exertional malaise." *Id.* at 261. Dr. Lapp then opined that Petitioner's long-lasting depression could not have caused his CFS because "the only depression that could plausibly explain symptoms severe enough would be a psychotic depression, that is out of touch with reality." *Id.* at 265-66. Petitioner never showed signs of this. *Id.* at 266.

c. *Symptomology and Progression of CFS*

Dr. Lapp testified that the joint pain Petitioner experienced two days after vaccination was a result of an immune reaction to the influenza vaccine. *See* Tr. at 268-69. According to Dr. Lapp, Dr. Dubchek noted that Petitioner had "early onset fatigue" at the same time he was experiencing joint pain. *Id.* at 272. Based on those medical records, Dr. Lapp testified the flu vaccination was the triggering event for Petitioner's CFS, and that onset took place two days later. *Id.* Dr. Lapp stated that Dr. Albright's observations of muscle weakness in December 2011 were also consistent with the progression of CFS. *Id.* at 278. Dr. Lapp testified that Dr. Albright's notes of difficulty focusing, inability to multitask, vision blurriness, joint pain, stiffness, and vertigo four months post-vaccination, is also consistent with CFS. *Id.* at 289.

According to Dr. Lapp, Petitioner's improvement from 2012-2013 is also consistent with CFS. Tr. at 292-93. With regards to CFS progression, Dr. Lapp testified it is typical for there to

be good periods and bad periods and there is no way to predict when they will occur. *Id.* at 293. However, Dr. Lapp added, "The only thing you can say about the bad periods is that they can be brought on by exertion, by stress, by illness. Those are probably the major things that can bring on a bad period, and those can be very prolonged as a matter of fact." *Id.* at 294. Dr. Lapp testified that about 40 percent of CFS patients report modest improvement over time and fewer than 5% recover. *Id.* at 295.

Treatment for CFS involves treating the symptoms and more importantly, learning to pace oneself and set limits. *Id.* at 296. Regarding Petitioner's case specifically, Dr. Lapp observed ,

> I think what I saw in Ted yesterday was typical of the patients that we see and that is they go through a chaotic period for the first couple of years where they push very hard. They go to multiple doctors trying to find a solution to this problem… they've learned from the past that if they push, things are going to get better; if they try harder things are going to try to get better and unfortunately, it works adversely.

Id. at 296-97.

In 2014, Petitioner's symptoms began worsening again. Dr. Lapp opined that Dr. Albright's notes of "arthralgia, back pain, difficulty concentrating, fatigue, headache, muscle weakness, somnolence, and weight loss" are consistent with CFS. Tr. at 308-09. Petitioner's neuropsychological evaluation by Dr. Royer was also consistent with CFS. *Id.* at 310. More specifically, Dr. Royer's notes of impairments in motor speed and coordination, cognitive flexibility (the ability to multitask), and processing speed are symptoms of CFS. *Id.* at 311.

d. *Serum Sickness*

Dr. Lapp also addressed the multiple references to serum sickness in Petitioner's medical records. Dr. Lapp defined serum sickness as,

> basically an allergic reaction to an injection…. It's an IgE reaction that will last as long… as the offending agent is in the body, and the body attempts to clear that reaction, and the reaction will cause the kind of symptoms that we have seen here. In the case of an injection like this, it's usually characterized by swelling, a reaction that goes to the joints. So you get joint swelling and pain and overall edema, which is fluid building up in the body, can cause feverishness and a number of different systemic symptoms that … usually last days to a couple weeks.

Tr. at 288-89. Regarding the possibility that serum sickness could last multiple months, Dr. Lapp testified, "It's not likely. Not from what I've seen in my personal experience…. It seems the body should have cleared it by then." *Id.* at 289-90.

e. *Sleep Studies*

Dr. Lapp opined that Petitioner's first sleep study was likely the result of the "first night effect," where the new bed, environment, and discomfort from the attached wiring probably caused

Petitioner's lack of sleep. Tr. at 301. In Dr. Lapp's opinion, the second and third sleep studies were a better reflection of Petitioner's sleep issues. *Id.* Dr. Lapp pointed out that in the second and third sleep studies Petitioner had difficulty reaching REM sleep and had a low sleep efficiency. These features are consistent with patients suffering from CFS. *Id.* at 302-03.

f. *Lyme Disease*

Dr. Lapp testified that Petitioner did not have Lyme disease. *See* Tr. at 314. Petitioner tested negative numerous times for Lyme disease and had no history of a tick bite or rash. *Id.* at 314-15. Furthermore, Dr. Smith attempted to treat Petitioner for Lyme disease to no avail. *Id.* at 317-18.

g. *Dr. Lapp's Causation Theory*

Dr. Lapp's theory of causation is summarized as follows: "[Petitioner] had an allergic reaction to [the] vaccine and that allergic reaction stirred up the immune system, which in this particular case, because he's susceptible, has turned his immune system toward a Th2 immune response, which is typical of chronic fatigue syndrome." Tr. at 434. Dr. Lapp elaborated stating,

> when a foreign substance gets into the body, it stimulates macrophages and it stimulates the immune system and sets off alarms which are – they're cytokines, the alarms that get set off. And that stimulates lymphocytes to – it stimulates the lymphocytes to generate more cytokines and that drives the immune system in to a Th2 type pattern. . . . And it's totally conceivable that something like that happened in this case and drove Ted's body toward a Th2 response, which is typical of chronic fatigue syndrome. And in chronic fatigue syndrome what happens in susceptible individuals is that that response is not shut off. NK cells, which are supposed to shut off part of the reaction, don't work properly and suppressor cells, which are supposed to shut off the reaction, don't work properly. And so you get a perpetual, abnormal, activated immune system.

Id. at 435-36.

Dr. Lapp testified that a 48-hour onset was an appropriate window of time for the onset of symptoms after flu vaccine. Tr. at 440.

B. Dr. Susan Levine

Petitioner filed one expert report from Dr. Levine. *See* Expert Report, filed as Ex. 36 (hereinafter "Levine Rep."). Dr. Levine did not testify at the entitlement hearing.

1. Qualifications

Dr. Levine received her medical degree from Albert Einstein College of Medicine in 1981. Ex. 37 at 1 (hereinafter "Levine CV"). Dr. Levine is board certified in internal medicine and infectious diseases. *Id.* Dr. Levine serves as the Chairman of the U.S. Chronic Fatigue Syndrome

Advisory Committee, Principal Investigator at the Chronic Fatigue Initiative, Co-Medical Director of the New Jersey Chronic Fatigue Syndrome Association, Inc., and was a former member of the Name Change Working Group of the U.S. Chronic Fatigue Syndrome Coordinating Committee. *Id.* at 1-2. Dr. Levine has published over 40 articles regarding CFS. *See id.* at 2-7.

2. Expert Opinion

Dr. Levine noted that the following symptoms reported by Petitioner are consistent with CFS: knee, wrist and back pain; thigh spasms and stiffness; severe fatigue; weight loss of nine pounds; ringing in his ears; irregular heart beat; getting up at night to pass urine; headaches; dizziness; night sweats; anxiety; depression and difficulty falling asleep. Levine Rep. at 2.

As a proposed mechanism for how Petitioner developed CFS from the flu vaccine, Dr. Levine stated it has been established that vaccines have led to the development of Gulf War Syndrome, another fatiguing illness, "and likely reflects a shift in the immune response towards a TH2 profile." Levine Rep. at 2. In patients who meet the clinical criteria for CFS, levels of cytokine activity are linked to the severity of CFS and "[s]hifts in cytokine levels lead to alterations in the cardiovascular and cognitive systems. *Id.* at 2-3. Dr. Levine stated:

> the onset of [Petitioner's] arthralgias two days following receipt of influenza vaccine, is one consequence of the overproduction of pro-inflammatory cytokines in response to a foreign antigen. The persistence over time (over a three year period following the administration of the influenza vaccine) of this patient's arthralgias, sleep disturbances, cognitive issues and dizziness reflects a permanent shift in the immune milieu...

Id. at 3.

Dr. Levine further posited that the pathogenesis of CFS could be a result of the "kindling theory," which is the theory that "repeated exposure to an initially sub-threshold stimulus can eventually exceed threshold limits, resulting in persistent hypersensitivity to the stimulus and ultimately, full blown illness." Levine Rep. at 2. Dr. Levine stated that Petitioner suffered from psoriasis, an autoimmune disorder, and following vaccination, a release of IL-1 beta occurred "which led to an alteration in the electrical activity of his brain, resulting in permanent cognitive dysfunction." *Id.*

Live viruses, such as the Epstein Barr virus and herpesviruses, contain genomic sequences that can influence the secretion of adenocorticotrophic hormone ("ACTH") in the brain. Levine Rep. at 2. This immune response interacts with the hypothalamic pituitary axis ("HPA"), which results in lower cortisol levels, which is observed in patients with profound fatigue, insomnia, adverse responses to stress and sensitivity to noise and light in CFS patients. *Id.*

Dr. Levine additionally stated that Petitioner's symptoms of blurred vision and irregular heartbeat are consistent with autonomic dysfunction. Levine Rep. at 3. To explain these symptoms, Dr. Levine noted that 71 patients who were administered a routine flu vaccine displayed a reduction in heart rate variability, and CFS patients with disrupted sleep have also been

shown to have reduced heart rate variability. *Id.* Alternatively, Petitioner's autonomic dysfunction symptoms of palpitations and dizziness might be related to pain or analgesia. *Id.* at 3. Dr. Levine concluded that because Petitioner suffered symptoms of arthralgia two days after his October 10, 2011 vaccination and suffered numerous symptoms consistent with CFS, it is her opinion "to a reasonable degree of medical certainly [sic] that the flu vaccine was the cause of Mr. Bryan's subsequent Chronic Fatigue Syndrome." *Id.*

C. Dr. Marcel Kinsbourne

Petitioner filed one expert report from Dr. Kinsbourne. *See* Expert Report, filed as Ex. 34,[5] (hereinafter "Kinsbourne Rep."). Dr. Kinsbourne did not testify at the entitlement hearing.

1. Qualifications

Dr. Kinsbourne received his medical degree from Oxford University in 1955. Ex. 32 at 1 (hereinafter "Kinsbourne CV"). Dr. Kinsbourne did post-doctoral training in neurology and pediatrics and is Board Certified in Pediatrics. Kinsbourne CV at 1. Dr. Kinsbourne has had a number of hospital and academic appointments but has been a research professor at the Center for Cognitive Studies at Tufts University since 1992 and a Professor of Psychology at New School University since 1995. *Id.* at 2. Dr. Kinsbourne serves on numerous editorial boards, including Brain Research, Cognitive Neuropsychiatry, Journal of Psycholinguistic Research, and many others. *Id.* at 3. Dr. Kinsbourne has published over 400 articles regarding pediatrics and psychology. *See id.* at 5-32.

2. Expert Opinion

After review of Petitioner's medical records, Dr. Kinsbourne states that although Petitioner was never diagnosed with chronic fatigue syndrome, he fits the diagnostic criteria provided by the CDC. Kinsbourne Rep. at 3. The CDC criteria includes:

> Clinically evaluated, unexplained, persistent or relapsing chronic fatigue that is * of new or definite onset (has not been lifelong), * is not the result of ongoing exertion * is not substantially alleviated by rest and * results in substantial reduction in previous levels of occupational, educational, social or personal activities.

Id. The CDC also requires four or more of the following symptoms to have persisted or recurred for six or more months and predated the fatigue:

> 1. Self-reported impairment in short-term memory or concentration severe enough to cause substantial reduction in previous levels of occupational, education, social or personal activities
>
> 2. Sore throat

[5] This expert report was originally filed as Ex. 31 however, Petitioner discovered a typographical error and moved to strike the report (ECF No. 68). Special Master Hastings denied the motion and instructed Petitioner to re-file the report with a new exhibit number (ECF No. 69).

3. Tender cervical or axillary lymph nodes

4. Muscle pain

5. Multi-joint pain without joint swelling or redness

6. Headaches of a new type, pattern or severity

7. Unrefreshing sleep

8. Post-exertional malaise lasting more than 24 hours

Id. Dr. Kinsbourne cited medical records in which he identified what he believed were manifestations of the above-mentioned symptoms. *See id.* at 3-4. Dr. Kinsbourne stated that despite Petitioner's attempts to find a diagnosis for his condition, "no one else has diagnosed him with CFS,[6] or any other underlying systemic illness. Nor have providers accepted that his fatigue is an adverse effect of the influenza vaccination."[7] *Id.* at 4. Dr. Kinsbourne further indicated that he cannot propose a "brain-based mechanism of injury." *Id.* at 5.

D. Dr. Regina Smith

Regina Smith, D.O., provided testimony regarding Petitioner's medical treatment since 2014. Tr. at 44. Dr. Smith received a degree in osteopathic medicine (D.O.) from Ohio University, College of Osteopathic Medicine. *Id.* at 40. She completed a residency in internal medicine at St. Joseph's Hospital and is board certified in internal medicine. *Id.* I recognized Dr. Smith as an expert in internal medicine. *See id.* at 43-44.

Dr. Smith began treating Petitioner in July 2014; her treatment continued as of the day of trial. Tr. at 45, 47. It was her medical opinion that Petitioner suffers from CFS. *Id.* Petitioner presented to Dr. Smith in July 2014 with fatigue, sleep disorder, cognitive trouble, and pain. *Id.* at 47. Dr. Smith opined that Petitioner met the Institute of Medicine's diagnostic criteria for CFS. *Id.* at 48. Based on his history of symptoms and how they progressed, Dr. Smith testified the flu vaccine was the triggering event "because prior to the flu shot he was not having difficulties with any of these symptoms on a severity level that he has after the flu shot." *Id.* at 67. Regarding how the flu vaccine could cause CFS, Dr. Smith stated, "The influenza vaccine can definitely trigger the immune system which can, in a predisposed individual, can lead to this condition." *Id.* at 68. Dr. Smith added,

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[6] This is incorrect. On January 5, 2012, Dr. Albright assessed Petitioner with chronic fatigue syndrome. *See* Ex. 2 at 22. Dr. Vickery also assessed him with chronic fatigue syndrome on January 9, 2015. *See* Ex. 17 at 2.

[7] This is also incorrect. In a letter dated August 6, 2014, Dr. Smith wrote that it was her opinion Petitioner's "medical and cognitive issues are a direct result of the flu vaccination that he received on 10/11/2011." Ex. 11.

> when someone has an immune activation of some sort from a flu shot or an infection, it can trigger an underlying condition or trigger a new syndrome which can cause chronic fatigue syndrome. So with the timing of the event and the severity of Ted's symptoms after the flu shot, it would appear that that was when his chronic fatigue symptoms really began. So by looking at that as the time when things went downhill, the most likely etiology was the flu vaccination.

Id. at 69-70.

Dr. Smith testified that she did treat Petitioner for Lyme disease with several weeks of Doxycycline but the drug did not resolve any of his symptoms. Tr. at 72-73. Dr. Smith testified that there is an overlap of symptoms between Lyme disease and CFS, however she is more confident in the diagnosis of CFS because of Petitioner's fatigue and cognitive issues. *Id.* at 64, 75-77.

E. Dr. Kenneth Fife

Respondent filed two expert reports from Kenneth Fife, M.D., Ph.D. *See* Expert Reports, filed as Ex. A (hereinafter "First Fife Rep.") and Ex. C (hereinafter "Second Fife Rep."). Dr. Fife also testified at the entitlement hearing.

1. Qualifications

Dr. Fife received his medical degree from Johns Hopkins University. Ex. B at 1 (hereinafter "Fife CV"). Dr. Fife also received a Ph.D. in microbiology from Johns Hopkins University. *Id.* He completed a fellowship at the University of Washington Division of Infectious Diseases. *Id.* Dr. Fife is currently a professor of microbiology and pathology at the Indiana University School of Medicine and has been since 1995. *Id.* at 2. Dr. Fife has written over 140 articles and is board certified in internal medicine. First Fife Rep. at 1; Fife CV at 4, 8-22. I recognized Dr. Fife as an expert in the field of infectious disease. Tr. at 383.

2. Expert Opinion in Expert Reports

Dr. Fife noted that Petitioner had complained of fatigue to a "sufficient severity that his primary care provider (Dr. Albright) listed it as one of his diagnoses and included it as an active problem" on the day Petitioner received his allegedly causal vaccination. First Fife Rep. at 2. Dr. Fife acknowledged Dr. Levine as a CFS expert but points out that Dr. Levine postulated that changes in cytokines are "associated with CFS and states that such changes occurred in [Petitioner's] case." *Id.* However, Dr. Fife opined that there is no record of any cytokine level measurement in Petitioner's medical record and "Dr. Levine can only speculate about cytokine levels because there are no objective measurements of any cytokines to support her theory." *Id.* Dr. Fife also noted that Dr. Levine identifies Petitioner's palpitations as a sign of autonomic instability, a feature of CFS, however indicates that Petitioner was evaluated on June 30, 2013 for palpitations, which is prior to the allegedly causal vaccination. *Id.* Dr. Fife stated that "Dr. Levine's conclusion of a causal relationship between [Petitioner's] diagnosis of CFS and the

influenza vaccine is completely without objection support". He further stated that none of the references cited by Dr. Levine provide any support for her hypothesis. *Id.* at 2-3.

Dr. Fife concluded that Petitioner's arthralgias following vaccination may have been related to the vaccine but were improved with treatment. First Fife Rep. at 3. But more importantly, Petitioner's underlying symptoms of idiopathic chronic fatigue were present prior to the receipt of the vaccine and waxed and waned in the subsequent years. *Id.*

Dr. Fife's second report was written after reviewing additional medical records and Dr. Lapp's expert report. *See* Second Fife Rep. at 1. Dr. Fife disagreed with Dr. Lapp's analysis of Petitioner's health prior to the October 2011 vaccination, and again identified fatigue as one of Petitioner's symptoms prior to vaccination. *Id.* Dr. Fife additionally questioned Dr. Lapp's use of the 1994 diagnostic criteria for CFS when the Institute of Medicine published revised criteria in 2015. *Id.* Applying the 2015 IOM criteria, Dr. Fife indicated that Petitioner does not meet the diagnostic criteria because he has experienced prolonged episodes of normal activity, and further, his fatigue symptoms were not new and could have been a result of Petitioner's depression. *Id.*

Dr. Fife additionally stated that Dr. Lapp had not provided medical literature to support a theory of causation as to how the influenza vaccine can cause CFS. Second Fife Rep. at 2. Dr. Fife reiterated his medical opinion that Petitioner's fatigue "antedated the receipt of the vaccine" and has waxed and waned in the subsequent years. *Id.*

3. Testimony

During the entitlement hearing, Dr. Fife testified that upon hearing the testimony of Petitioner and other fact witnesses, "it's pretty clear that prior to [the October 2011 vaccination] [Petitioner] did not meet the criteria for chronic fatigue syndrome." Tr. at 385-86. Thus, Petitioner's fatigue prior to October 2011 "probably should not disqualify the current diagnosis of chronic fatigue syndrome." *Id.* at 386. Dr. Fife testified that he believes that Petitioner now meets the IOM diagnostic criteria for CFS and the CDC criteria from the Fukuda article. *Id.* Dr. Fife testified that Petitioner had not identified a plausible mechanism of causation by which the influenza vaccine could cause CFS. *Id.* at 386, 394.

Additionally, Dr. Fife stated an onset date was unclear and difficult to determine because of Petitioner's period of improvement after his initial reaction to the vaccine. *Id.* at 388. Petitioner's symptom of joint pain post-vaccination improved after treatment and serum sickness is "a well-described complication of [the] influenza vaccination." *Id.* at 388-89, 391. Dr. Fife stated that Petitioner's visits with Dr. Qazizadeh showed that Petitioner had no identifiable neurological problem post-vaccination. *Id.* at 392. Furthermore, Petitioner reported to Dr. Qazizadeh that he was feeling better after a few months. *Id.* Dr. Fife did admit that serum sickness lasting five or six months would not be typical. *Id.* at 423.

Despite Dr. Lapp's testimony, Dr. Fife stated that the causal mechanism for CFS remains unknown. Tr. at 394. In her expert report, Dr. Levine proffered a theory that an increase in cytokines from the influenza vaccination could have caused Petitioner to develop CFS. Dr. Fife

concurred with Dr. Lapp that cytokine assays are not readily available to most practitioners. He testified:

> the other problem with all of the cytokine theories is that it continues to be an evolving field…. It becomes very difficult to attribute things to these cytokines because, again, new cytokines continue to be identified. And it may be that they haven't found the right one or it may be the cytokines aren't involved at all. It's difficult to tell but, again, we have no evidence in this case of any cytokine disturbances because they were never tested and cannot really be tested easily.

Id. at 395. Regarding Dr. Levine's kindling theory, Dr. Fife stated that it is merely a theory and there is no evidence to support the theory. *Id.* at 396. Dr. Fife testified that to his knowledge, no subsequent studies have taken place regarding either of Dr. Levine's theories. *Id.*

V. Applicable Law

A. Petitioner's Overall Burden in Vaccine Program Cases

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.,* 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination he received caused his 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." *Id.* at 1278.

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that a vaccine likely caused an injury or that the proffered medical theory is reasonable, plausible, or possible does not satisfy a petitioner's burden. *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs*., 121 Fed. Cl. 230, 245 (2015).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing … that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs*., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians'

conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs*., No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs*., 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd, Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr.

Apr. 10, 2013), *mot. for review den'd* (Fed. Cl. Feb. 11, 2019), *appeal docketed*, No. 19-1753 (Fed. Cir. 2019); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is

usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human*

Servs., 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VI. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, Petitioner's claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that he suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

A. CFS Generally

CFS is a disease of unknown etiology that involves "profound dysregulation of the central nervous system and immune system…" Carruthers et al., *Myalgic encephalomyelitis: International Consensus Criteria*, 270 JOURNAL OF INTERNAL MEDICINE at 328 (2011) (filed at Ex. 39) (hereinafter "Carruthers"). It is characterized by "profound fatigue, cognitive dysfunction, sleep abnormalities, autonomic manifestations, pain, and other symptoms that are made worse by exertion of any sort." Institute of Medicine of the National Academies, *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness*, NAT'L ACAD. PRESS, p. 9 (2015) (filed as Ex. 40) (hereinafter "IOM Rep."). CFS is thought to have a prevalence of .4-1% worldwide. Devanur & Kerr, *Chronic fatigue syndrome*, JOURNAL OF CLINICAL VIROLOGY, p. 2 (2006) (filed as Ex. 41) (hereinafter "Devanur & Kerr").

As its name suggests, fatigue is the disease's central symptom. While in other conditions, fatigue is generally proportional to an individual's level or duration of effort, "[t]he pathological low threshold of fatiguability of [CFS] … often occurs with minimal physical or mental exertion and with reduced ability to undertake the same activity within the same or several days." Carruthers at 328. "Another distinguishing feature of the illness, in comparison with other 'fatigue states', is its prolonged relapsing and remitting course over months or years." *See* Ex. C1 at 46; A REPORT OF THE CFS/ME WORKING GROUP, 1-82, January 2002 (filed as Ex. C1) (hereinafter "Working Group Rep.").

While the cause of CFS is unknown, Carruthers states that "[m]ost patients have an acute infectious onset with flu-like and/or respiratory symptoms." Carruthers at 332. This is consistent with Dr. Lapp's testimony at hearing where he indicated that 75% of CFS cases are attributable to viral or bacterial infection. Tr. at 244. Researchers believe that the immune system plays a key role in the pathogenesis of CFS. Devanur & Kerr at 2.

B. Petitioner has Demonstrated that CFS is his Correct Diagnosis

Dr. Smith diagnosed Petitioner with CFS and Dr. Lapp confirmed this diagnosis during his testimony. *See* Tr. at 241-42. Although Respondent contested Petitioner's CFS diagnosis during the initial portion of the entitlement hearing, it is no longer in dispute. Dr. Fife testified at hearing that after listening to Petitioner's testimony, he was convinced Petitioner was correctly diagnosed with CFS. Tr. at 386-87. Respondent has conceded the issue in his post-hearing brief: "there

remains no dispute between the parties that petitioner's appropriate diagnosis is CFS." Resp't's Post-Hr'g Br. at 7, ECF No. 127. Accordingly, I find there is preponderant evidence to support the preliminary point that CFS is Petitioner's correct diagnosis.

C. Petitioner has Carried his Burden of Proof

1. *Althen* Prong 1

a. *General Evidence that Vaccination Can Cause CFS*

Petitioner has filed medical literature which articulates a link between vaccination generally, and CFS. I would categorize this literature as providing general support for Petitioner's theory, although these articles do not articulate a causal mechanism. For instance, Devanur & Kerr write that "immunisation with various vaccines have [sic] been reported to trigger CFS. These vaccines include MMR, pneumovax, influenza, hepatitis B, tetanus, typhoid and poliovirus." Devanur & Kerr at 7. Additionally, the Working Group Report, a report prepared to advise the U.K.'s National Health Service, states as follows:

> A few case reports have suggested that CFS/ME has occurred after immunisations, though intercurrent events, including infection, might have played a part in the disease process. It is biologically plausible that some processes seen after infections could also occur after immunisations, but this has yet to be confirmed by a good quality cohort study in the case of CFS/ME. Current advice to avoid immunisations during infections is designed to avoid such triggering.

Working Group Rep. at 32. Of course, Petitioners are not required to produce "good quality cohort studies" in order to prevail in the Vaccine Program. Later in their report, the Working Group further notes that "other factors have been associated with onset of CFS/ME in individual cases, including some immunisations…" *Id.* at 48.

Dr. Lapp also testified about his extensive work in treating CFS patients. Dr. Lapp has dedicated the majority of his career to working in the field of CFS, and in so doing has treated approximately 28,000 patients with CFS. *See* Tr. at 447. In his experience, Dr. Lapp described personally treating two or three patients who developed CFS after flu vaccine. *Id.* at 257.

While these above-mentioned references and Dr. Lapp's treatment experience do not articulate a specific theory as to how vaccination can cause CFS, they do provide some support for Petitioner's theory that vaccinations *can cause* CFS.

b. *Petitioner's Theory*

At the entitlement hearing, Dr. Lapp proffered a theory of causation by which CFS can develop following vaccination. Dr. Lapp posited that Petitioner's flu vaccination caused immune dysregulation and this dysregulation resulted in CFS. Dr. Lapp testified:

What we're saying is that in his case, he had an allergic reaction to that vaccine and

> that allergic reaction stirred up the immune system, which in this particular case, because he's susceptible, has turned his immune system toward a Th2 immune response, which is typical of chronic fatigue syndrome. And I think that that perhaps has just perpetuated. It's continued.

Tr. at 434.

> Dr. Fife testified at hearing about the difference between Th1 and Th2 immunity.
>
> [T]hey're two responses to an immunologic challenge and typically Th1 response triggers B-cell activation, which is B-cells producing antibodies. And Th2 responses trigger other T-cells which triggers a cellular immune response.
>
> Both are normal responses and where problems arise is when one becomes more dominant than it should be. There's a lot of back and forth regulation within the immune system to try to balance those responses.
>
> And, again, a theory of autoimmune disease and a number of other conditions is that in some cases that balance gets off and one reaction gets -- becomes more responsive than it should be and causes harm.

Tr. at 404-05.

Dr. Lapp's theory that there is a shift in CFS patients from a Th1 to a Th2 immune response generally finds support in the medical literature. *See* Hardcastle et al., *Serum Immune Proteins in Moderate and Severe Chronic Fatigue Syndrome*, 12 INT J MED SCI., p. 4 (2015) (filed as Ex. 42) (hereinafter "Hardcastle"). The Hardcastle article states that "CFS/ME patients have shown evidence of a bias towards a Th2 immune response as IFN-γ and IL-4 were increased in CFS/ME patients compared with healthy controls." Hardcastle at 4. The Carruthers article also describes "a shift towards a Th2 profile." Carruthers at 6. The Devanur & Kerr article notes that "[v]arious studies suggest that CFS exhibits a Th2 profile of CD4 helper T lymphocyte responsiveness." Devanur & Kerr at 3.

Dr. Levine's expert report also provides support for this theory. Dr. Levine stated, "The development of a fatiguing illness following inoculation with vaccines of many types has best been established in the case of Gulf War Syndrome (GWS) and likely reflects a shift in the immune response towards a TH2 profile." Levine Rep. at 2.

According to Dr. Lapp, CFS is characterized by a shift to a Th2 dominant immune response. This response is never turned off, and results in chronic immune activation. Dr. Lapp's theory that CFS can occur following flu vaccination has three main steps. First, the flu vaccination causes an inflammatory response. Second, this inflammatory response causes immune dysregulation in susceptible individuals. Third, immune dysregulation leads to CFS.

c. *Step 1: Flu Vaccination Can Cause an Inflammatory Reaction*

It is well accepted that flu vaccination causes a mild inflammatory response. *See* Perring & Jones, *Assessment of changes in cardiac autonomic tone resulting from inflammatory response to the influenza vaccination*, 32 CLIN. PHYSIOL FUNCT IMAGING, 437-44 (2012) (filed as Ex. 46) (hereinafter "Perring") ("Our findings indicate that influenza vaccination … can be used as a model to study the response of mild stimulation of the inflammatory system."). Vaccination triggers activation of the innate immune system, as this is necessary for the vaccinee to develop a robust immune response.

An example of an inflammatory response that can occur after vaccination is serum sickness. The IOM has defined serum sickness as "[a]n immune complex disease appearing some days (usually 1-2 weeks) after injection of a foreign serum or serum protein, with local and systemic reactions such as urticaria, fever, general lymphadenopathy, edema, arthritis, and occasionally albuminuria or severe nephritis." Institute of Medicine, 2012, *Adverse Effects of Vaccines: Evidence and Causality*, THE NATIONAL ACADEMIES PRESS, at 644. Dr. Lapp also discussed serum sickness and defined it as,

> "an allergic reaction to an injection…. It's an IgE reaction that will last as long… as the offending agent is in the body, and the body attempts to clear that reaction, and the reaction will cause the kind of symptoms that we have seen here. In the case of an injection like this, it's usually characterized by swelling, a reaction that goes to the joints. So you get joint swelling and pain and overall edema, which is fluid building up in the body, can cause feverishness and a number of different systemic symptoms that … usually last days to a couple weeks."

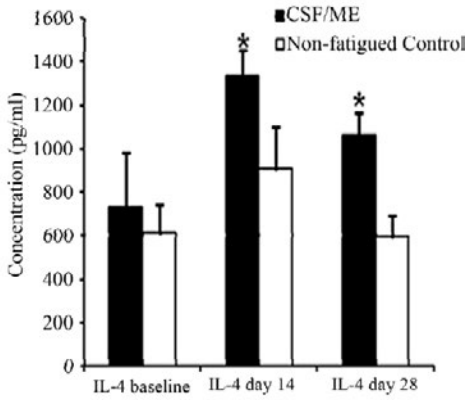
Tr. at 288-89. Dr. Fife testified that serum sickness is "a well-described complication of [the] influenza vaccination." Tr. at 391.

Petitioner has demonstrated that the flu vaccine generally causes a mild inflammatory response and can also cause a more robust response (as is the case when a vaccinee develops serum sickness).

d. *Step 2: The Inflammatory Reaction from Flu Vaccination Can Lead to Immune Dysregulation*

The second step in Petitioner's theory is that flu vaccination can cause immune dysregulation. Specifically, Dr. Lapp testified that vaccination can cause a shift toward a Th2 immune response. Dr. Lapp cited one primary medical article in support of this proposition. *See* Brenu et al., *The Effects of Influenza Vaccination on Immune Function in Patients with Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis*, 3 INTERNATIONAL JOURNAL OF CLINICAL MEDICINE 2012, pp. 554-51 (filed as Ex. 59) (hereinafter "Brenu"). The Brenu article studied seven patients meeting the CDC criteria for CFS as well as eight healthy controls. Bloodwork from each participant was collected before receipt of the flu vaccine, and at both 14 and 28 days after vaccination. The study described a number of findings with respect to different levels of cytokines pre and post vaccination. The study found that "NK activity was significantly decreased

at baseline and at 28 days, while at 14 days it significantly increased in the CFS/ME patients compared to the healthy controls." Brenu at 544. The authors also observed that IL-4 (a Th2 cytokine) was increased in the CFS patients when compared to controls. *Id.* at 548. The following graph depicts a statistically significant increase in IL-4 at 14 and 28 days post vaccination:



Id. at 547.

Additionally, although there were no statistically significant differences in general wellbeing between the CFS patients and the healthy controls at baseline, "at day 14 and particularly day 28 post vaccination, the CFS/ME patients recorded a significantly lower general wellbeing compared to the controls." Brenu at 547. Ultimately, the study concluded that "immunization with influenza vaccine is accompanied by a degree of immune dysregulation[8] in CFS/ME patients compared with controls, and further, the study "suggests that vaccination with seasonal influenza vaccine, Influvac may affect cellular immune function in CFS/ME patients…" *Id.*

Dr. Lapp testified about the significance of Brenu at the entitlement hearing. He stated: "At 28 days, the proinflammatory cytokines were increased and natural killer cell was decreased in the patients. So clearly patients that have a proclivity toward this Th2 activity, Th2 immunity, have a change when they're exposed to the vaccine." Tr. at 253-54.

In analyzing the Brenu article, it is important to note that the study did not address individuals who developed CFS after receiving the flu vaccine, but instead studied patients who were already diagnosed with CFS and how they responded to vaccination.[9] Still, this study did demonstrate that vaccination can trigger immune dysfunction in some susceptible individuals. Further, the study demonstrates that in susceptible individuals, the cytokine response generated by

[8] The study did find several Th1 cytokines were also increased post vaccination.

[9] I will note that the Federal Circuit in *W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1361 (Fed. Cir. 2013) affirmed the special master's decision, finding that his reliance on a series of studies which showed that MS patients did not experience disease flares after flu vaccination was not arbitrary and capricious. The same reasoning employed by the special master in W.C. -- that studies involving how individuals who already have a disease respond to vaccination are relevant to the Petitioner's prong one theory -- is applicable in this case as well.

the flu vaccine appears to go beyond the short-lived cytokine up-regulation that is known to occur after vaccination.

Although Petitioner's evidence in support of this component of his theory is not robust, I find that it is sufficient to preponderantly establish that the inflammatory reaction from the flu vaccination can lead to immune dysregulation in a small percentage of susceptible individuals.

e. *Step 3: Immune Dysregulation is Linked to CFS*

There is evidence in the medical literature that immune dysregulation is a feature of CFS. Petitioner submitted the 2015 Institute of Medicine (IOM) report on CFS, *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness*, Nat'l Acad. Press (2015) (filed as Ex. 40) (hereinafter "IOM Rep."). In its report, the IOM found that there is sufficient evidence to support the finding of immune dysfunction in CFS. IOM Rep. at 17. The IOM further concluded that there is data demonstrating "poor NK cell cytotoxicity (NK cell function, not number) that correlates with illness severity in ME/CFS patients and could serve as a biomarker for the severity of the disease…." *Id.*

Several other articles filed by Petitioner also make this point. For example, the Hardcastle article states "immunological dysregulation consistently occurs in the illness." Hardcastle at 1. The Carruthers article describes CFS as "a complex disease involving profound dysregulation of the central nervous system and immune system." Carruthers at 1.

Dr. Lapp testified at hearing about this third step in his theory, that a shift in the immune system towards Th2 immunity can cause CFS.

> NK cells, which are supposed to shut off part of the reaction, don't work properly and suppressor cells, which are supposed to shut off the reaction, don't work properly. And so you get a perpetual, abnormal, activated immune system.

Tr. at 435-36.

I also note that Special Master Moran has conducted a reasoned analysis of this precise issue. While not binding on me[10], he concluded that although it is not *medically accepted* that immune dysregulation can cause CFS, it is a viable and reputable theory under *Althen* prong one. *See McCabe v. Sec'y of Health & Human Servs*., 2018 WL 3029175, at *47-48 (Fed. Cl. Spec. Mstr. May 17, 2018). I agree with his analysis with respect to this issue and arrive at the same conclusion in the present case.[11]

[10] *See Boatmon*, 941 F.3d at 1358-59 (finding that "special masters are not required to distinguish non-binding decisions of other special masters" in part because each case has a different evidentiary record).

[11] The decision in *McCabe* ultimately concluded that Petitioner did not establish the first *Althen* prong because she did not present evidence that the inflammatory reaction from the flu vaccination can lead to immune dysregulation. I will note that this case is distinguishable from *McCabe* in several respects. Unlike the case at bar, Petitioner in *McCabe* did not file any medical literature in support of the proposition that an inflammatory reaction to the flu vaccine can lead to immune dysregulation. Additionally, Respondent's

I find that Petitioner has presented preponderant evidence that the flu vaccine can cause CFS in a small percentage of susceptible individuals.

2. *Althen* Prong 2

Under the second *Althen* prong, Petitioner must demonstrate by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Capizzano*, 440 F.3d at 1324 (quoting *Althen*, 418 F.3d at 1278).

a. *Petitioner's Treating Physicians*

In weighing evidence, special masters are expected to consider the views of treating doctors. *Cappizano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec'y of Health & Human Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015).

Petitioner's treating physician, Dr. Smith, has opined that Petitioner's flu vaccination caused him to develop CFS. In medical records from June 4, 2015 Dr. Smith stated, "[b]ased on these symptoms, he fits the CDC criteria for chronic fatigue syndrome, and his symptoms definitely were triggered by the flu shot he had in 2011." Ex. 27 at 2. She further discussed her opinion during the entitlement hearing. Dr. Smith testified that "[t]he influenza vaccine can definitely trigger the immune system which can, in a predisposed individual, can lead to this condition." *Id.* at 68. Dr. Smith added,

> when someone has an immune activation of some sort from a flu shot or an infection, it can trigger an underlying condition or trigger a new syndrome which can cause chronic fatigue syndrome. So with the timing of the event and the severity of Ted's symptoms after the flu shot, it would appear that that was when his chronic fatigue symptoms really began. So by looking at that as the time when things went downhill, the most likely etiology was the flu vaccination.

Id. at 69-70.

Dr. Smith's opinion is persuasive in this case, as she has been Petitioner's treating physician since 2014 and had direct interaction with him for four-and-one-half years, as of the date she testified at the January 9-10, 2019 hearing. *Id.* at 45. I have given her opinion substantial weight.

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expert in this case only relied upon two pieces of medical literature (A Report of the CFS/ME Working Group (Ex. C1), and the IOM Article, *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome Redefining an Illness* (Ex. A1)) and did not discuss the epidemiological study related to flu vaccine and CFS that was filed in *McCabe*. Further, Petitioner's expert, Dr. Lapp is a CFS expert, whereas one of the experts in *McCabe* (Dr. Mikovits) is not and has been repeatedly discredited in the Vaccine Program.

b. *Petitioner Experienced an Abnormal Response to the Flu Vaccine*

In order to establish a logical sequence of cause and effect between the vaccination and the illness, Petitioner should present evidence which suggests that the vaccinee responded to the vaccine in a manner which is consistent with the causal theory. In this case, Petitioner experienced an abnormal response to the flu vaccine that began two days after vaccination. This response is well-documented in Petitioner's medical records and is consistent with his *Althen* prong one theory.

The first medical visit post-vaccination took place on October 20, 2011, ten days after Petitioner received his flu shot. Petitioner visited Dr. Albright and complained of joint pain. Ex. 2 at 5. Dr. Albright noted that Petitioner was most likely experiencing a reaction to the flu vaccine. He had previously prescribed Medrol (a steroid) and noted in the records, "getting better, medrol is helping." *Id.* The records do not contain any information about the circumstances that led Petitioner to receive a Medrol prescription. Petitioner's testimony at hearing helps fill in the gaps. When asked to describe his symptoms after vaccination, Petitioner testified as follows:

> The first effect -- the first effect was the, was knee pain, just on one knee and that was on the second day. On the third day both knees were swelled and very, very stiff. On the fourth day I couldn't move. I couldn't get out of bed. And all my -- I was like a board. My joints -- my hands were double the size, my legs were double the size. All my joints were just kind of like locked in place. And called -- my wife called the doctor and told him that, you know, I was not being able to move. And he said -- he called in a steroid.

Tr. at 23-24.

On November 14, 2011, Petitioner saw Dr. Natalie Dubchek (a rheumatologist). Ex. 3 at 1. Dr. Dubchek noted that Petitioner "was in a good general state of health until October 12th of this year when he developed diffuse arthralgias and joint swelling two days after he received his flu shot…. **Also he noticed early onset fatigue**." *Id.* (emphasis added).

Petitioner returned to Dr. Dubchek on November 29, 2011. Ex. 3 at 3. The doctor noted that "[h]e continues to experience the same symptoms of generalized fatigue, generalized pain, now mostly localized to the lower legs, knees, and calves." *Id.*

Petitioner visited Dr. Albright twice in December 2011 and once in January 2012. He presented with difficulty concentrating, fatigue and muscle weakness. Ex. 2 at 14, 18, 21. Dr. Albright again questioned whether these symptoms were in connection with Petitioner's flu vaccine. *Id.* at 18. On January 5, 2012, Dr. Albright assessed Petitioner with chronic fatigue syndrome.[12] *Id.* at 22.

[12] 780.71 is the diagnostic code for chronic fatigue syndrome. *See* Centers for Disease Control and Prevention, International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) (2011), https://www.cdc.gov/nchs/icd/icd9cm.htm (last accessed Sept. 18, 2020).

Assessment/ Plan
Fatigue, chronic (780.71)
main complaint is lower ext weakness..
Comments: will refer to neuro

On February 6, 2012, Petitioner saw Dr. Salim Qazizadeh (a neurologist). Ex. 4 at 13-17. During this visit, Dr. Qazizadeh noted that since his flu shot, Petitioner had experienced "difficulty focusing, [an inability] to multitask, blurriness of vision, extreme fatigue, muscle weakness, tremor, numbness, tingling, cramps in the legs, joint pain, interrupted sleep, memory problems, low back pain, stiffness, and vertigo." *Id.* at 13.

On March 8, 2012, Petitioner returned to Dr. Qazizadeh for follow-up regarding memory loss. Ex. 4 at 18. During this visit, Petitioner described his symptoms as fatigue, tiredness, and joint pain. *Id.* at 20. The summary for the visit noted that "[t]he possibility of serum sickness is being entertained." *Id.* Dr. Qazizadeh described him as "slightly better, but … not back to baseline." *Id.* at 18.

In examining the medical records and in evaluating Petitioner's testimony, it appears that Petitioner experienced improvement in his symptoms starting in mid-2012 and continuing through part of 2013. While the worst of these symptoms subsided sometime in 2012, Petitioner did not return to baseline. Establishing when and the extent to which Petitioner's health improved is somewhat challenging. Petitioner was unwell in March of 2012, but when he returned to Dr. Qazizadeh for follow-up on May 8, 2012, the records indicate that Petitioner was having serum sickness since the flu vaccine, but also indicate that he was improving. Ex. 4 at 23. Petitioner's medical records and testimony when taken together, paint the picture of someone trying to hold on to a sense of normalcy in terms of work, hobbies, and other activities while still experiencing some symptomology. Petitioner discussed this during the hearing.

> **Q.** But generally speaking, what do you remember about your abilities in 2012?
>
> **A.** They were diminished but not, not to the -- I don't know what percentage point -- I was -- I knew something was wrong, yet I didn't want to admit it and I wanted to just be myself. I wanted to be normal, go to work, not be tired and come home and be able to work on my house and not have to sleep all weekend to recover.

Tr. at 84.

During the hearing, Petitioner discussed the fact that he had to give up his hobbies due to his health limitations. He stopped playing volleyball in 2011. Tr. at 87. He quit competitive fishing in 2012 because standing on the boat for hours at a time would result in him being in bed and feeling sick for the next two days. *Id.* at 86. With respect to golf, Petitioner testified that he "struggled" through 2012.

> At that point I could physically play. Now, I'm not -- my flexibility wasn't there so I wasn't as good as I once was, but it would just cause me to sleep the next day. So

> I could physically play and still have fun; just not as good as I once was, which is fine by me; it was just being out there.
>
> But then I would end up the next day or the day after it sleeping for over 20 to 24 hours just to recover from that. That's driving in a cart and not trying to walk.

Id. at 85. Petitioner had to give up the sport entirely in 2013. *Id.*

Petitioner testified about his work performance during the 2013 timeframe.

> **Q.** So we're in 2013 now. How was your work performance at that time?
>
> **A.** Going downhill. Tasks were taken away from me due to safety precautions for myself and anybody around me. Ladder work was taken away. Unfortunately, a lot of my job was standing on top of a ladder and it was -- I was still working on the water heater project and it was to the -- it was getting to where I could only cut maybe three or four pieces of pipe and my arms would cramp so bad that I had to stop for the day and I'd go down to my desk to talk to my boss and tell him, You know, I don't know what's going on. Something is just not -- I said, you can look at my arms; they're cramped up and shaking. And he said, Well, what did you do? I said, I cut three pieces of pipe.

Tr. at 87-88.

Petitioner did have a reduced number of medical visits related to fatigue in 2013. This absence of records suggests that he was feeling better. However, Petitioner's medical records do indicate that he experienced some symptoms in 2013. On July 15, 2013, Petitioner visited Dr. Albright to review recent lab work and to discuss his hyperlipidemia. During this visit, Petitioner indicated that he was experiencing fatigue. Ex. 2 at 42.

Further, on May 1, 2014, Petitioner visited the neurology clinic at Penn State Hershey Medical Center. The notes from this visit summarize Petitioner's clinical course after the flu shot: "He progressively got better over a year, did not reach 100%, was able to function. Approximately 6-8 months ago, he began to get progressively worse in his symptoms both mentally and physically. He suffers from chronic fatigue and pain." Ex. 7 at 1. Six to eight months before this May 1 appointment places the worsening of Petitioner's condition during the September 1-November 1, 2013 timeframe.

In all, the medical records and testimony taken together make it clear that Petitioner experienced a severe reaction to the flu vaccine for at least five months. Petitioner's symptoms included joint pain, swelling, fatigue, muscle weakness, memory and cognitive issues. Although Petitioner's severe symptoms dissipated sometime in the April/May 2012 timeframe, he still continued to experience symptoms of fatigue that did not exist pre-vaccination. These reduced symptoms occurred from April/May 2012 through September/November 2013. After that time, Petitioner's symptoms worsened again.

c. *The Onset of Petitioner's CFS*

Petitioner's theory is that his well-documented severe response to the flu vaccine was not serum sickness, but instead constituted the beginning of his CFS. In refuting the theory that Petitioner's adverse reaction to his vaccination was due to serum sickness, Dr. Lapp explained that serum sickness will generally resolve when the body has a chance to clear the foreign antigen. Tr. at 289. He further testified that serum sickness typically lasts for days to a couple of weeks. *Id.* Regarding the possibility that serum sickness could last multiple months, Dr. Lapp stated, "It's not likely. Not from what I've seen in my personal experience…. It seems the body should have cleared it by then. I think something else is going on there. I think the immune reaction and – my personal opinion is that the immune reaction has been triggered here and is continuing on, is what's happening." *Id.* at 289-90.

Dr. Fife also acknowledged that Petitioner's response to the flu vaccine exceeded the time he would expect for serum sickness to continue after vaccination. Dr Fife testified as follows:

> **Q.** So you would expect, at least in most cases, serum sickness would last a matter of weeks, maybe a month, something like that? It would be unusual for it to last four months or five months or six months, something like that, wouldn't it?
>
> **A.** That would not be typical, correct.

Tr. at 423.

Respondent's position is that Petitioner's improvement during the 2012-2013 timeframe is inconsistent with CFS which began two days after vaccination. In their post-hearing brief, Respondent stated,

> [P]etitioner's fatigue symptoms waxed and waned in intensity the year following his vaccination, which is inconsistent with the Institute of Medicine's ("IOM") diagnostic criteria for CFS[13], and ceased completely for nine months following an adjustment made to petitioner's depression medications. This brings into question when the onset of petitioner's CFS occurred.

Resp't's Post-Hr'g Br. at 3.

[13] The IOM's diagnostic criteria for CFS indicate that "Frequency and severity of symptoms should be assessed. The diagnosis of ME/CFS (SEID) should be questioned if patients do not have these symptoms at least half of the time with moderate, substantial, or severe intensity." IOM Rep. at 11. I do not find Petitioner's symptoms, documented in his medical records and discussed in his testimony at hearing make his CFS diagnosis inconsistent with this statement from the IOM. Petitioner consistently testified that he had reduced capacity during the 2012-2013 timeframe, and that although he was improved from his severe post-vaccine reaction, he never returned to baseline. Further, the IOM indicates the diagnosis should be "questioned if patients do not have these symptoms", not that the diagnosis is ruled out. Ultimately, I credit Petitioner's treating physician, Dr. Smith as well as Dr. Lapp on this issue.

It is clear that a unique feature of CFS is the waxing and waning course of the disease. The Working Group Report addressed this very issue. They stated that "[a]nother distinguishing feature of the illness, in comparison with other 'fatigue states', is its prolonged relapsing and remitting course over months or years." Working Group Rep. at 48. This report (filed by Respondent) specifically states that CFS can wax and/or wane over the course of *years*. Dr. Lapp also testified about the waxing and waning of CFS symptoms and how this is characteristic of the disease.

> **SPECIAL MASTER:** Could you explain generally, not in relation to this case, but generally how chronic fatigue syndrome, is it sort of something that is a steady state or do patients change over time, get better, get worse?
>
> **…**
>
> **THE WITNESS:** That's typical of chronic fatigue syndrome, is good periods and bad periods and there's no way to predict them unfortunately. The only thing you can say about the bad periods is that they can be brought on by exertion, by stress, by illness. Those are probably the major things that can bring on a bad period, and those can be very prolonged as a matter of fact.

Id. at 293-94.

The medical record evidence and the expert testimony establish that Petitioner experienced a severe reaction to the flu vaccine. This severe reaction lasted for at least five months, which is not consistent with a serum sickness. I find, in accordance with the testimony of Petitioner's treating physician, Dr. Smith, and with the expert opinions of Dr. Lapp and Dr. Levine, that Petitioner's severe reaction to the flu vaccine constituted the beginning of his CFS. Petitioner has presented preponderant evidence in support of *Althen* prong 2.

3. *Althen* Prong 3

The timing prong contains two parts. First, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, he must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Human Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds,* 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

a. *Petitioner Developed CFS Two Days after Vaccination*

Dr. Lapp testified at hearing that Petitioner's CFS began two days after his flu vaccine. *See* Tr. at. 252. Dr. Smith also testified at the entitlement hearing that the onset of Petitioner's CFS was two days after his vaccination. *See id.* at 69-70.

Dr. Fife testified that the onset of Petitioner's CFS is unclear.

> Well, that's why I said I think the timing of the chronic fatigue syndrome, when that actually happens, is a little unclear, at least in my mind, because of the period -- a long period of time when there did not appear to be that level of symptoms. As I said, I believe he meets the criteria now, but I think because of the long period where there weren't those symptoms present, that's why I have trouble timing it specifically associated with the vaccine.

Id. at 407. As discussed earlier in this ruling, I am convinced by preponderant evidence, based on the testimony of Petitioner, Dr. Lapp, and Dr. Smith, that Petitioner developed CFS two days after his flu vaccine.

b. *Two Days Is a Temporally-Appropriate Onset Interval*

Dr. Lapp testified at hearing that Petitioner's severe reaction to the flu vaccine constituted the beginning of his CFS, and that onset 48 hours after vaccination is an appropriate temporal interval. *See* Tr. at 434-40. He stated that "85% of cases of [CFS] are acute in origin…." *Id.* at 253. Dr. Lapp further opined that the "abrupt onset is usually like a flu-like illness or a mono-like illness or some sort of an illness and then the symptoms develop over time." Tr. at 280. Lapp's opinion that the onset of Petitioner's CFS is medically appropriate is rooted in substantial experience treating patients with CFS.

Dr. Lapp's testimony on this point is supported by several of the medical articles filed in this case. For example, Devanur & Kerr state: "When a cohort of patients suffering from acute infection with a particular infectious agent are followed in time, a subset of these have been shown to develop CFS with an onset contemporaneous with the onset of the particular microbial infection." Devanur & Kerr at 5. This reference suggests that an infection can trigger CFS, and that onset of CFS occurs at the same time as the trigger. Although Petitioner did not suffer from an infection, he did experience a documented reaction to his flu vaccination which included the contemporaneous onset of fatigue.

The Working Group also discussed onset of CFS, indicating that it can be "sudden". Working Group Rep. at 48. The Working Group further stated that "[a]n insidious and gradually progressive course is uncommon." *Id.*

For the reasons discussed above, I find that Petitioner developed CFS two days after his flu vaccination, and that this period of time constitutes a medically appropriate onset interval. Petitioner has presented preponderant evidence in support of the third *Althen* prong.

VII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, testimonies, as well as the experts' opinions and medical literature, I conclude that Petitioner has met his burden of proof under *Althen*. Petitioner is entitled to compensation. An order regarding damages will issue shortly.

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master