In the United States Court of Federal Claims

No. 12-742V

(Filed: December 1, 2016 | Reissued for Publication: December 16, 2016)*

SYDNEY RICH,	)	
Petitioner,	)	Keywords: Vaccine Act; Contemporaneous Medical Records; Althen Test; Arbitrary and Capricious.
v.	)	
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

Andrew D. Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for Petitioner.

Sarah C. Duncan, Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, with whom were *Gabrielle M. Fielding*, Assistant Director, *Catharine E. Reeves*, Acting Deputy Director, *C. Salvatore D'Alessio*, Acting Director, and *Benjamin C. Mizer*, Principal Deputy Assistant Attorney General, for Respondent.

OPINION AND ORDER

KAPLAN, Judge.

This case is before the Court on Petitioner Sydney Rich's motion to review the special master's decision denying compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (Vaccine Act). Ms. Rich alleged that an influenza vaccination caused her to develop acute disseminated encephalomyopathy (ADEM).[1] On June 30, 2016, a

* Pursuant to Vaccine Rule 18(b), this opinion was initially filed on December 1, 2016, and the parties were afforded 14 days to propose redactions. The parties did not propose any redactions. Accordingly, this opinion is reissued in its original form for publication, with the exception of one minor change in the caption for section VI.B. The original caption read "Liability Determination." The revised caption reads "Entitlement Determination."

[1] Also known as acute disseminated encephalomyelitis, this is an inflammation of both the brain and spinal cord characterized by, among other things, the destruction, removal, or loss of the myelin sheath of nerves. See Dorland's Illustrated Medical Dictionary (Dorland's) 486, 613 (32d ed. 2012). It manifests in neurologic deficits. J. Nicholas Brenton, MD et al., Acute

special master denied compensation, concluding that Ms. Rich failed to demonstrate that the vaccination caused her injury. Ms. Rich then moved for review in this Court on July 29, 2016.

For the reasons set forth below, the special master's decision is supported by the evidence in the record and is not arbitrary, capricious, an abuse of discretion, or contrary to law. The Court, therefore, **SUSTAINS** the decision.

BACKGROUND

The facts relevant to Ms. Rich's motion for review are set forth in detail in the special master's Finding of Fact, issued September 16, 2015, and in her decision on the merits, issued June 30, 2016. The Court has reviewed the special master's Finding of Fact in detail and concludes that it accurately reflects the testimony of the witnesses and the documentary evidence in the record. What follows is a summary of that testimony and documentary evidence.

I. Testimony of Ms. Rich and Her Witnesses Regarding the Decline in Her Health Following Her Vaccination

Ms. Rich was born on May 13, 1992. Pet.'s Ex. 1 ¶ 1, ECF No. 5-1. In the fall of 2010, she was a freshman at the University of Oklahoma and was living on campus in a dormitory. Id. ¶ 2. Ms. Rich had previously been diagnosed with asthma but was otherwise healthy. Id. ¶ 3.

On September 26, 2010, Ms. Rich received an influenza vaccination at Memorial Christian Church in Oklahoma City. Order & Ruling on Facts at 10, ECF No. 35.[2] According to the testimony of Ms. Rich and her witnesses, summarized below, her health took a turn for the worse in the months following her vaccination.

A. Ms. Rich's Testimony

Ms. Rich submitted a declaration and also testified at the onset hearing held in the case. She stated that "a few weeks after" she received the vaccination, "in mid-October," she began to notice that she was becoming fatigued "easily." Pet.'s Ex. 1 ¶ 6; Tr. of Hr'g (Tr.) 137–38, October 30, 2014, ECF No. 66. In addition, she was sleeping in "later and later," was taking afternoon naps, and "just never seemed to have any energy." Pet.'s Ex. 1 ¶¶ 6–7; Tr. 137–38. Ms. Rich stated that her condition continued to worsen through October, and that, beginning in early to mid-November, she started to wake up every day with a headache. Tr. 139. She also started to experience dizziness. Id. By the beginning of December, according to Ms. Rich, she was constantly exhausted, having trouble breathing, suffering from headaches and dizziness, experiencing difficulty focusing, and her eyes had become sensitive to light. Id. at 157–58. She

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Disseminated Encephalomyelitis, Medscape (Dec. 30, 2015), http://emedicine.medscape.com/article/1147044-overview.

[2] Ms. Rich had also received influenza vaccinations on an annual basis the preceding five years, beginning in 2009. Finding of Fact at 4, ECF No. 80.

also suffered from a sensation of heaviness in her legs and was having difficulty walking. See id. at 155, 162–63.

In her declaration, Ms. Rich states that on the morning of December 27, 2010, while at home on winter break, she woke up early feeling unwell and called in sick to her employer. Pet.'s Ex. 1 ¶ 13. According to Ms. Rich, she was "dizzy, had a throbbing headache, couldn't breathe, and felt nauseous." Id. She called her mother, who was at work, and she took Ms. Rich to the emergency room at the Integris Baptist Medical Center. Id. As described in greater detail below, Ms. Rich was admitted to the hospital where her condition worsened and where, on January 7, 2011, she was diagnosed with ADEM.

B. Testimony of Caramia Enrich

Ms. Rich's roommate at the time, Caramia Enrich,[3] also submitted a declaration and testified at the onset hearing. She stated that a few weeks after Ms. Rich received the flu shot, she began to display signs of fatigue and to report that she was experiencing headaches and feeling sick. Pet.'s Ex. 3 ¶ 6, ECF No. 5-3. Ms. Enrich testified that Ms. Rich "started complaining a lot about . . . being very tired from the walk" across campus and that "she'd talk about how her legs would feel heavy." Tr. 100. Ms. Enrich recalled that on Halloween, Ms. Rich had struggled to hand out candy to children who were trick-or-treating in the dormitory. Tr. 100–01. Sometime after Halloween, she observed that Ms. Rich's symptoms were getting worse, and included complaints of pain and weakness in her legs. See Pet.'s Ex. 3 ¶¶ 6–7; see also Tr. 102–03. Ms. Enrich testified that by the end of the fall semester, Ms. Rich was complaining that light bothered her eyes and that she was "very fatigued all the time." Tr. 105. She observed that "as soon as she would come in, she would just go to bed," and that "it was really, really affecting her every day." Id.

C. Testimony of Aurora Tapia

Aurora Tapia,[4] Ms. Rich's friend and co-worker at Panera Bread, also stated that Ms. Rich began to complain of headaches, dizziness, and fatigue in October and November 2010. Pet.'s Ex. 24 ¶¶ 2–3, ECF No. 60-1; see also Tr. 77. During this time period, she observed Ms. Rich's performance at work begin to suffer; according to Ms. Tapia, Ms. Rich was becoming slower and was incorrectly performing tasks that she had previously mastered. Pet.'s Ex. 24 ¶ 4; see also Tr. 79. She characterized Ms. Rich as suffering from a "brain fog" beginning in October 2010. Pet.'s Ex. 24 ¶ 7. In other words, Ms. Tapia stated, Ms. Rich had an "inability to mentally process what [she was] doing." Tr. 82. Ms. Tapia testified that from October to December of 2010, Ms. Rich's condition progressively worsened and that she "was not her normal self." Tr. 81.

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[3] Ms. Rich's roommate married between the time she submitted her statement and when she testified at the onset hearing; her maiden name, as seen on that statement, was Testa. See Tr. 94–95.

[4] Ms. Tapia testified under the name of Aurora Tapia-Contreras at the onset hearing. Tr. 73.

D. Heather Rich's Testimony

Ms. Rich's mother, Heather Rich, testified that she spoke to her daughter almost every day during the fall of 2010. See Tr. 12–13, 17. She recalled that a few weeks after her daughter received the flu shot, she began to complain of headaches, weakness, and a lack of energy. Pet.'s Ex. 16 ¶¶ 5–10, ECF No. 23-1. She testified that Ms. Rich was reporting headaches "all the time" and that she told her mother that "she was tired a lot." Tr. 18. Ms. Rich also testified that near the time of her daughter's November 10th visit to the college infirmary (described below), her daughter told her that she had been "unable to go to class . . . [and unable to] walk across the campus." Tr. 24. Ms. Rich's mother also recalled that at this time, her daughter was "slurring her words a little bit . . . [and] having trouble a little bit with getting her sentences out." Tr. 25.

II. Medical Care Sought During Fall 2010

During the fall of 2010, Ms. Rich sought medical care on three occasions. First, on October 8, 2010, approximately two weeks after she received her vaccination, Ms. Rich attended an appointment with her pediatrician, Dr. Colleen Dooley. Pet.'s Ex. 4 at 8, ECF No. 5-4. Ms. Rich reported to Dr. Dooley that she was having trouble breathing at night, that she had been using her inhaler "a lot," and that she had been unable to obtain Advair, one of the medications she had been prescribed for her asthma. Id. Although she was experiencing heaviness in her legs by October 8, Ms. Rich testified, she did not report it to Dr. Dooley because she "didn't think it was a big deal," she "related it back to [her] asthma," and she just thought she was "tired." Tr. 143.

Dr. Dooley's impression based on her examination of Ms. Rich was that she was experiencing an exacerbation of her asthma. Pet.'s Ex. 4 at 8. She gave Ms. Rich a new prescription for Advair, a prescription for Singulair, samples of both medications, and a sample of what appears from Dr. Dooley's handwritten notes to be "ProAir." Id. Dr. Dooley instructed Ms. Rich to return to the clinic if she did not improve. Id.

On October 23, 2010, Ms. Rich again visited Dr. Dooley. Id. at 7. She testified that she did so at the insistence of her mother, to whom she had been complaining of fatigue and difficulty breathing. Tr. 141. Her mother accompanied Ms. Rich to the appointment and, according to Ms. Rich, provided "most of the history about what was wrong with [her] and why [she was] there." Id. Specifically, Ms. Rich testified, her mother told the doctor that "she [Heather Rich] thought it was my asthma." Tr. 141–42.

Ms. Rich did not tell Dr. Dooley during this appointment that her legs were feeling heavy or that she was having difficulty walking across campus. Tr. 142. The chief complaint recorded in the medical records for the October 23 appointment was "Asthma – worse when comes home." Pet.'s Ex. 4 at 7. The doctor's notes indicate that Ms. Rich was continuing to use her inhaler "a lot" and had increased symptoms of asthma over the previous two weeks. Id. Dr. Dooley continued to prescribe medications for asthma, including Prednisone, Singulair, and Albuterol. See id.

On November 10, 2010, Ms. Rich again sought medical care, this time at her college's medical center. Pet.'s Ex. 15, ECF No. 20-1. According to Ms. Rich, she visited the infirmary at

her mother's urging. Tr. 147; see also Pet.'s Ex. 1 ¶ 10. She testified that between her October 23 visit with Dr. Dooley, and her visit to the infirmary, she "was getting to the point where it was so hard to function, and [she] didn't want to tell anyone about it because [she] didn't want them to worry." Tr. 146. She stated "it was really bad" and that she "was so tired, and [her] body felt so heavy . . . like [she] was going to pass out every time [she] would go to class." Id. Ms. Rich testified that she was "so scared" but that she "just kept thinking [she] was going to get better." Tr. 146–47. In her declaration, Ms. Rich similarly explained that "one day as I was walking back to my dorm after class I got dizzy and, for the first time in my life, I felt like I was going to pass out." Pet.'s Ex. 1 ¶ 10. She stated that she was "light headed and extremely weak" and "felt nauseous." Id. Ms. Rich noted that "I was able to make it back to my dorm, but I was scared." Id. Therefore, she called her mother, who wanted her to come home. Id. But Ms. Rich "didn't think [she] could drive that far, so [she] made an appointment at the on-campus medical clinic." Id.

At that visit to the clinic on November 10, 2010, Ms. Rich listed her worst symptom as "Coughing & trouble breathing" on the intake form she filled out upon arriving. Pet.'s Ex. 15 at 2. The intake form also presented a list of symptoms and Ms. Rich was asked to check all that applied to her condition. Id. She checked fever, night sweats, sore throat, headache, ear ache/pain, cough, wheezing, and muscle aches. Id. She wrote that her symptoms had started five days previously and characterized them as "improving somewhat" since then. Id.

As noted, in her statement Ms. Rich said that she was feeling dizzy, light-headed, weak, and nauseous prior to making the November 10, 2010 appointment and that she had almost passed out while walking back to her dorm after class. Pet.'s Ex. 1 ¶ 10. She did not, however, report these symptoms or this incident to the medical personnel at the infirmary. See Pet.'s Ex. 15; see also Tr. 147–48. Nor did she report the chronic fatigue, heaviness in her legs, slurred speech, or mental processing difficulties which she, her roommate, her co-worker, and/or her mother testified she had been experiencing during the mid-October to early November time period. See Pet.'s Ex. 15; see also Tr. 147–48.

Ms. Rich testified that she did not see a doctor at the college infirmary and only saw a physician's assistant. Tr. 147. However, the medical record documenting the visit is signed and stamped by Dr. Stephanie Parker. Pet.'s Ex. 15 at 2. Dr. Parker recorded that Ms. Rich had "[n]o N/V/D or any other c/o" other than what was checked on the intake form.[5] See id. Ms. Rich was

[5] N/V/D stands for nausea-vomiting-diarrhea. N/v/d, Dictionary.com, http://www.dictionary.com/browse/n-v-d (last visited Nov. 29, 2016). C/O stands for "complains of." Medical Definition of C/O, Merriam-Webster, http://www.merriam-webster.com/medical/c/o (last visited Nov. 29, 2016). Further down the note, in the physical examination section, Dr. Parker also wrote "+PND," which stands for paroxysmal nocturnal dyspnea, shortness of breath that wakes a patient during the night. See Vaskar Mukerji, Dyspnea, Orthopnea, and Paroxysmal Nocturnal Dyspnea, National Center for Biotechnology Information (1990), https://www.ncbi.nlm.nih.gov/books/NBK213/.

diagnosed with bronchitis and asthma, was provided a nebulizer treatment at the clinic, was prescribed home medications, and was instructed that she should follow-up as needed.[6] Id.

III. December Hospitalization and ADEM Diagnosis

Ms. Rich ultimately completed the semester and returned home for winter break. Pet.'s Ex. 1 ¶ 12. On the afternoon of December 27, 2010, however, she went to the emergency room, reporting wheezing, dyspnea, shortness of breath, and chest tightness, starting the previous day. Pet.'s Ex. 5 Part 1 at 9, ECF No. 6-1. No musculoskeletal or neurologic symptoms were recorded at that time. See id. The physical examination revealed that Ms. Rich was "[a]lert and oriented to person, place, time, and situation," and "[n]o focal neurological deficit [was] observed." Id. at 10. In the emergency room, the medical personnel concluded that she was experiencing status asthmaticus and hypoxemia.[7] She was admitted to the intensive care unit (ICU), provided medications and breathing treatment, and scheduled for diagnostic tests. Id. at 10–11.

Dr. John Edward Huff evaluated Petitioner in the ICU. Id. at 46. Ms. Rich reported to Dr. Huff that she had experienced sudden and increasing shortness of breath with wheezing beginning the prior evening. Id. He noted that Ms. Rich had been diagnosed with bronchitis three weeks previously, but that she reported having recovered from it. Id. Dr. Huff also noted that CT scans performed in the emergency room revealed pneumonia and a pneumothorax.[8] Id. at 46–47. According to Dr. Huff's report, Ms. Rich reported fever, chills, shortness of breath, dyspnea, cough with sputum production, wheezing, asthma, and pleuritic chest pain. Id. at 48. She denied weakness, fatigue, and night sweats. Id. Dr. Huff diagnosed community-acquired pneumonia in the right upper lobe, right small pneumothorax, asthma exacerbation, left lower lobe pulmonary nodule, allergic rhinitis, and hypoxemia. Id. at 49–50.

Ms. Rich's respiratory status continued to decline and she was ultimately intubated. Id. at 41. Over the next few days, she also became less responsive. Id. On January 6, 2011, Ms. Rich underwent a brain MRI. Pet.'s Ex. 5 Part 8 at 48–49, ECF No. 6-8. It revealed, inter alia, an acute infarction of the splenium of the corpus callosum[9] with areas of diffusion restriction, T2

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[6] Dr. Parker used the abbreviation "prn," which comes from the Latin pro re nata and stands for "as needed." PRN, Merriam-Webster, http://www.merriam-webster.com/dictionary/prn (last visited Nov. 29, 2016).

[7] Status asthmaticus is a particularly severe episode of asthma that does not respond adequately to ordinary therapeutic measures. Dorland's 1767. Hypoxemia is an oxygen deficiency in the blood. Id. at 908.

[8] A pneumothorax is an accumulation of air or gas in the pleural space of the lungs. Dorland's 1476.

[9] The corpus callosum is an arched mass of white matter in the brain. Dorland's 417. The splenium is its posterior subsection. Id. An infarction is the formation of an area of cell death due to blood deficiency. See id. at 934, 961, 1235. Acute means having a short and relatively severe course. Id. at 24.

alteration, and abnormal contrast enhancement within the pons, inferior right cerebellar hemisphere, medulla, and cervical spine, which possibly related to hypoxic injury. Id. at 50. Based on these results, she was started on prophylactic seizure medication. Pet.'s Ex. 5 Part 1 at 41.

On January 7, 2011, doctors added a diagnosis of "suspect[ed] ADEM" and began a course of Solumedrol. Pet.'s Ex. 5 Part 4 at 20, ECF No. 6-4. Dr. Aline Brown noted that it "appears most likely [Petitioner] has ADEM which is usually post infectious." Id. at 21. As a result, she ordered a "sputum DTX" test. Id. Also on January 7, 2011, Ms. Rich underwent a cervical spine MRI. Pet.'s Ex. 5 Part 8 at 50. This test revealed, inter alia, a "probable evolving early subacute ischemic infarct of the upper cervical cord with restricted diffusion and minimal enhancement," mild expansion of the upper cervical cord due to edema, and evolving small subacute infarcts in the posterior fossa. Id. Her cervical condition was later described as a "progression of cervical spine ischemic injury" with a "high spinal cord injury." Pet.'s Ex. 5 Part 1 at 52. The findings were considered "consistent with acute disseminated encephalomyopathy." Id. at 41.

Ms. Rich's "sputum DTX" test came back positive for H1N1,[10] and she was put on Tamiflu. Id. at 41–42. On January 13, 2011, she also began an IVIG[11] treatment for ADEM, and doctors noticed slight improvement. Id. at 42, 53. However on January 17, 2011, Ms. Rich underwent a tracheostomy because she was unable to wean from the ventilator. Id. at 42. Petitioner then began to develop myopathy.[12] Id. Dr. Travis Kanaly diagnosed critical illness myopathy and prescribed gabapentin. Id.

By February 17, 2011, Ms. Rich's condition had begun to stabilize and she was discharged to an inpatient rehabilitation facility. Id.; see also id. at 53. At that time, her diagnoses were 1) acute demyelinating encephalomalacia with paralysis and quadriparesis[13]; 2) respiratory failure with community-acquired pneumonia, treated, and a long history of asthma, now with a tracheostomy; 3) critical care myopathy; 4) neuropathic pain on gabapentin; 5) seizure disorder on Keppra; 6) obesity; 7) atrophic dermatitis; 8) lazy eye; 9) anemia; and 10) anxiety and depression. Id. at 55.

Ms. Rich was discharged home from the rehabilitation facility on March 25, 2011. Id. at 28. Doctors noted that she was dependent on others for movement, feeding, and self-care, and

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[10] H1N1 is a human seasonal flu virus which also circulates in pigs and was originally referred to as the "swine flu." H1N1 – Swine Flu, Flu.Gov, http://www.flu.gov/about_the_flu/h1n1/index.html (last visited Nov. 29, 2016).

[11] IVIG stands for intravenous immunoglobulin, a treatment for autoimmune conditions. Noah S. Scheinfeld et al., Intravenous Immunoglobulin, Medscape (Feb. 3, 2016), http://emedicine.medscape.com/article/210367-overview.

[12] Myopathy is a disease of the muscle. Dorland's 1224.

[13] Quadriparesis is a weakness in all four limbs. See Dorland's 1565, 1906.

would require home health care, physical and occupational therapy, and a wheelchair. See id. at 29–30.

IV. Subsequent Medical Care

Ms. Rich received home health care and therapy after she was discharged from the hospital. See generally Pet.'s Ex. 6, ECF No. 7-1. In February 2012, she began care with Dr. Jenny Le at the University of Oklahoma's internal medicine clinic. Id. at 26. In describing Ms. Rich's medical history, Dr. Le stated that she "had an asthma exacerbation in 2010 that turned into bronchitis and then pneumonia," and that, "[d]uring her recovery, she contracted the 'swine flu' (Jan 2011) which turned into encephalitis." Id. at 27. On April 4, 2012, Ms. Rich was seen by Dr. William Schueler, a physician at the University of Oklahoma's Department of Neurosurgery. Id. at 22. Dr. Schueler described Ms. Rich's present illness as "swine flu back in January 2011" which left her "paralyzed from the neck down." Id. He reiterated that connection in his assessment and plan, stating that Petitioner "unfortunately got paralysis secondary to swine flu." Id. at 23.

Currently, Ms. Rich continues to use a wheelchair and suffers from ongoing paralysis. Pet.'s Ex. 1 ¶¶ 29, 31.

V. Expert Opinions

Early on in the proceedings, and prior to the onset hearing, Ms. Rich submitted a report from Dr. David J. Siegler, dated December 8, 2013. Pet.'s Ex. 18, ECF No. 39-1. Dr. Siegler is board-certified in neurology. See Pet.'s Ex. 19 at 2, ECF No. 39-2. He was asked to provide an opinion as to whether the flu vaccine Ms. Rich received on September 26, 2010 was "causally-related to her subsequent development of diagnosed Acute Disseminated Encephalomyelitis 3 months post-vaccine." Pet.'s Ex. 18 at 1.

Dr. Siegler reviewed Ms. Rich's medical records, the sworn statements of Ms. Rich, her mother, and her roommate, and the relevant medical literature. Id. He stated that it was challenging to establish a cause and effect relationship between the vaccine and the ADEM that Ms. Rich developed because of 1) "the long latency" between her September 2010 vaccination and December 2010 diagnosis; 2) the "paucity of medical records during the interval"; 3) "the present day lack of available diagnostic tests to confirm vaccines as causative in vaccine adverse events"; and 4) "the extremely rare occurrences of vaccine-induced demyelinating disorders." Id.

Nonetheless, Dr. Siegler identified several factors that might support a diagnosis of "influenza vaccine-induced ADEM." Id. These included, in particular, "the timing of onset of neurologic symptoms shortly following receipt of the vaccine (as reported in compelling statements by [Ms. Rich], her roommate, Caramia, and [Ms. Rich's] mom and established in court documents[])." Id. Dr. Siegler believed that these statements were "compelling in description of signs and symptoms (fatigue, weakness, leg pain, dizziness and headaches) and

which the court notes as having started a few weeks after [having] been injected with the influenza vaccination." Id. at 2.[14] "If we accept the validity of [the statements]," he observed:

> [T]hen we have a pattern of CNS symptom development "a few weeks" after the vaccine including: Sydney's report of "fatigue, excessive sleepiness, weakness and dizziness." Caramia's report of "something being wrong" including getting "fatigued easily" and having "trouble making it up the stairs" with "headaches and complaining that she felt sick." She reported that Sydney "progressively got worse" including "her backpack felt very heavy, she complained of pain and weakness in her legs and her limbs felt []heavy.[] She seldom left the room. She stayed in bed and watched TV." Ms. Rich['s mother] reported Sydney developed fatigue, headaches and trouble sleeping a few weeks following the vaccine. If these statements are accepted as valid observations, then the statements indicate that several weeks following her influenza vaccine, Sydney developed constitutional symptoms (fatigue, insomnia), CNS symptoms (headaches, dizziness) and PNS symptoms (leg weakness and leg pain).

Id.

The government submitted a report prepared by Dr. Michael H. Kohrman, dated September 2, 2014. Resp't's Ex. A, ECF No. 55-1. Dr. Kohrman is board-certified in neurology with a subspecialty of clinical neurophysiology. Resp't's Ex. B at 2, ECF No. 55-2. He highlighted the "normal neurological examination" that was conducted when Ms. Rich was admitted to the hospital on December 27, 2010, as well as the lack of documented neurologic problems in medical records dated October 8, October 25, and November 10, 2010. Resp't's Ex. A at 8.[15] He identified the first neurologic problem as having occurred January 4, 2011, when the hospital documented Petitioner as "lethargic." Id. Dr. Kohrman also noted that when admitted, Ms. Rich tested negative for acute H1N1 infection, but then tested positive on January 7, 2011. Id. He concluded that the "H1N1 infection, bronchitis or pneumonia infections are likely, to a reasonable degree o[f] medical certainty, the cause of [Ms. Rich's] ADEM." Id. at 9. Because Ms. Rich received the flu vaccine in September, but there were no documented neurological

[14] At the time Dr. Siegler wrote this letter, the special master had not yet issued any findings with respect to symptoms or onset. See Finding of Fact. Further, as discussed below, the special master did not conclude that such symptoms were present in the weeks after the vaccination. See id. Thus when Dr. Siegler stated "which the court notes," he could only have been referring to a passing reference in the special master's Order and Ruling on Facts Pertaining to Petitioner's Receipt of a Covered Vaccination, ECF No. 35, at page ten, in which the special master appears to simply restate Ms. Rich's contention that she "began to suffer fatigue, weakness, dizziness, and headaches only a few weeks" after receiving the vaccination.

[15] Dr. Kohrman refers to the second visit to Dr. Dooley in October 2010 as having taken place October 25, 2010, rather than October 23, 2010. See Resp't's Ex. A at 3, 8.

problems until her hospitalization, and because there was a "lack of a close temporal relationship between Sydney's illness and vaccination," Dr. Kohrman concluded the flu vaccine was "very unlikely" to be the cause of Ms. Rich's ADEM. Id.

VI. The Special Master's Decision

A. Onset Finding

The parties requested an onset hearing to determine when Ms. Rich's ADEM symptoms began. See Orders, ECF Nos. 56, 58; see also ECF Nos. 72–73. That hearing was held on October 30, 2014, in Oklahoma City. Order, ECF No. 62.

On September 16, 2015, the special master issued a Finding of Fact. ECF No. 80. In that decision, the special master rejected Ms. Rich's assertion that "shortly after having received the influenza vaccine on September 26, 2010, she began to experience the onset of neurological symptomology that was subsequently diagnosed as ADEM," specifically "extreme fatigue, headaches, lack of concentration, dizziness, and feeling nauseous." Finding of Fact at 12 (quoting Pet.'s Pre-Hr'g Submission at 1–2, ECF No. 61). The special master relied upon "the contemporaneous medical records throughout the fall of 2010," which she noted reflected symptoms "related to [Petitioner's] asthma and [] developing bronchitis/pneumonia, and not to ADEM." Id. at 13. She discredited the testimony of Ms. Rich and her witnesses because she found it implausible that, if Ms. Rich were suffering the severe fatigue, weakness, leg heaviness, chronic headaches, and dizziness about which they testified, she would not have reported those symptoms during the three medical consultations she sought during that time. See id. at 14.

For example, the special master explained, although Ms. Rich testified that "she was confused, dizzy, having trouble walking coupled with heavy legs, and had blurry vision prior to her November 10 appointment" at the college infirmary, "[t]he records from the health center reflect none of those concerns." Id. at 13. She noted that Ms. Rich "had three separate opportunities to tell someone at the clinic about these symptoms: when she filled out the intake sheet, when she spoke with the doctor, and when she spoke with the nurse after the first nebulizer treatment, but she did not avail herself of those opportunities." Id. "The focus of that visit," the special master observed, "as had been the focus of her earlier medical visits, was exclusively her difficulty breathing and related issues." Id.

Further, the special master noted, when Ms. Rich reported to the emergency room on December 27, 2010, she "presented . . . with shortness of breath, chest tightness, wheezing, and dyspnea which started one day prior" and affirmatively denied weakness, fatigue, nausea, and muscle pain or weakness. Id. at 14 (citing Pet.'s Ex. 5 at 9, 48–49). "[H]er responsiveness did not begin to decline," the special master observed, "until several days after her admission for pneumonia, pneumothorax, and hypoxemia." Id. at 14.

The special master found that in light of her history of asthma, "Petitioner was familiar with doctors," as well as "with the practice of visiting a physician and reporting symptoms, particularly when prompted." Id. "She continued this practice when she went to college: she went to the doctor three times that first semester, and she reported the symptoms from which she was suffering so that they could be treated." Id. The special master, accordingly, was "not

persuaded that Petitioner would not be forthcoming with her doctors, particularly if the symptoms were as unprecedented, persistent and severe as has been described." Id.

Based on the foregoing, the special master concluded that while Ms. Rich's "medical records clearly document her worsening condition throughout the fall of 2010," "the worsening condition that they document is pulmonary." Id. She found that Ms. Rich failed to "put forward evidence sufficient to refute the contemporaneous medical records, which firmly support the onset of the symptoms of ADEM concurrently with or shortly after Petitioner's hospitalization for pneumonia, pneumothorax and hypoxemia, on or after December 27, 2010." Id.

B. Entitlement Determination

After the special master issued her onset finding, the parties moved for judgment on the administrative record. ECF Nos. 88, 90. At the special master's invitation, Ms. Rich submitted a November 30, 2015 letter written by Dr. Siegler to supplement his conclusions in light of the special master's onset finding. See Pet.'s Ex. 28, ECF No. 85-1. Dr. Siegler reiterated his belief that flu vaccine-induced ADEM is "medically plausible" and that the witness statements supported the development of neurological symptoms in the weeks after the vaccination. Id. at 1. However, he concluded that based upon the special master's decision discrediting the testimony of Ms. Rich and her witnesses regarding the "multiple neurologic symptoms" which developed a few weeks after she received the vaccine, he could not offer an opinion on causation in Ms. Rich's case. See id.

The special master issued her decision on June 30, 2016. See Rich v. Sec'y of HHS, No. 12-742V, 2016 WL 3996334 (Fed. Cl. Office of the Special Masters June 30, 2016). Relying upon the earlier fact-finding, the special master concluded that Ms. Rich failed to present a prima facie case and was not entitled to compensation. Id. at *8.

Specifically, the special master concluded that Ms. Rich failed to make the necessary showings under prongs two and three of the inquiry set forth in Althen v. Secretary of Health and Human Services, 418 F.3d 1274 (Fed. Cir. 2005), that there was: 1) "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" and 2) "a proximate temporal relationship between vaccine and injury." 2016 WL 3996334, at *7–*8. She observed that Ms. Rich's expert, Dr. Siegler, "affirmed that he knew of no credible medical evidence to suggest that a three-month latency period between a vaccination and the onset of ADEM is consistent with causation," and that the government's expert, Dr. Kohrman, "concurred." Id. at *8. Additionally, the special master noted that "at least two of Petitioner's treating physicians ascribed her ADEM to her H1N1, not the vaccination." Id. In short, the special master concluded that Ms. Rich did not "demonstrate[], by a preponderance of the evidence, that the vaccination caused her injury." Id.

VII. This Action

On July 29, 2016, Ms. Rich moved for review in this Court. Pet.'s Mot. for Review (Pet.'s Mot.), ECF No. 93. Oral argument was held on November 16, 2016. See Order, ECF No. 98.

DISCUSSION

I. Jurisdiction and Standard of Review

Congress established the National Vaccine Injury Compensation Program in 1986 to provide a no-fault compensation system for vaccine-related injuries and deaths. Figueroa v. Sec'y of HHS, 715 F.3d 1314, 1316–17 (Fed. Cir. 2013). The Vaccine Act is remedial legislation that should be construed in a manner effectuating its underlying spirit and purpose. Id.

A petition seeking compensation under the Vaccine Act is filed in the Court of Federal Claims, after which the Clerk of Court forwards it to the chief special master for assignment to a special master. 42 U.S.C. § 300aa-11(a)(1). The special master to whom the petition is assigned "issue[s] a decision on such petition with respect to whether compensation is to be provided under the [Vaccine Act] Program and the amount of such compensation." Id. § 300aa-12(d)(3)(A).

The Vaccine Act grants the Court of Federal Claims jurisdiction to review the record of the proceedings before a special master, and authority, upon such review, to:

1) Uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision;
2) Set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law; or
3) Remand the petition to the special master for further action in accordance with the Court's direction.

42 U.S.C. § 300aa-12(e); see also Vaccine Rule 27.

On review of the special master's decision, the court applies the arbitrary and capricious standard to factual findings and the "not in accordance with law" standard to legal rulings. Moberly ex rel. Moberly v. Sec'y of HHS, 592 F.3d 1315, 1321 (Fed. Cir. 2010). The court's scope of review is a narrow one. The court "do[es] not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses," because those "are all matters within the purview of the fact finder." Porter v. Sec'y of HHS, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing Broekelschen v. Sec'y of HHS, 618 F.3d 1339, 1345 (Fed. Cir. 2010)). As long as a special master's finding is based on evidence in the record that is "not wholly implausible," the Court must uphold it. Id. at 1249 (quoting Cedillo v. Sec'y of HHS, 617 F.3d 1328, 1338 (Fed. Cir. 2010)). "[T]he standard of review is uniquely deferential" to special masters' decisions; if a special master has considered the relevant evidence of record, drawn plausible inferences, and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate. Milik v. Sec'y of HHS, 822 F.3d 1367, 1376 (Fed. Cir. 2016) (quoting Hodges v. Sec'y of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993) (internal citations omitted)).

II. Merits

To secure compensation under the Vaccine Act, a petitioner must prove by a preponderance of the evidence that the injury at issue was caused by a vaccine. See 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1). Where a petitioner sustains an injury in association with a vaccine listed in the Vaccine Injury Table, causation is presumed. Broekelschen, 618 F.3d at 1341–42 (citing 42 U.S.C. § 300aa-11(c)(1)(C)(i) and Andreu v. Sec'y of HHS, 569 F.3d 1367, 1374 (Fed. Cir. 2009)). Where, as in this case, the injury is not listed in the Table, "the petitioner may seek compensation by proving causation in fact." Id. (citing Moberly, 592 F.3d at 1321). "Once the petitioner has demonstrated causation, she is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine." Id. (citing Doe v. Sec'y of HHS, 601 F.3d 1349, 1351 (Fed. Cir. 2010) and 42 U.S.C. § 300aa-13(a)(1)(B)).

The Federal Circuit has established a three-pronged test for proving causation in non-Table injury cases. Althen, 418 F.3d at 1278. Under that test, to demonstrate that a vaccination caused the petitioner's injury, he or she must provide: "(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.

In this case, the special master found that the onset date for Ms. Rich's ADEM was on or after December 27, 2010. Finding of Fact at 15. In other words, the special master concluded that there was a delay of at least three months between Ms. Rich's receipt of the influenza vaccination and the injury about which she complains (ADEM). As the special master noted, both of the medical experts in the case agreed that they "knew of no credible medical evidence to suggest that a three-month latency period between a vaccination and the onset of ADEM is consistent with causation." See Rich, 2016 WL 3996334, at *8. Therefore, the special master concluded that Ms. Rich failed to meet both Althen's second prong, requiring a showing that the vaccine caused the alleged injury, and Althen's third prong, requiring that there be an appropriate temporal relationship between vaccine and injury to support the petitioner's theory of causation. Id.

In her motion for review, Ms. Rich does not dispute that—if the special master's onset determination is correct—the evidence does not support a finding that her ADEM was caused by the vaccination. See Pet.'s Mot. at 2–3. Her challenge is focused therefore on whether that determination was arbitrary and capricious and/or based on a misapplication of relevant legal standards. See id. She contends that the special master "disregarded all of the factual testimony presented by multiple witnesses as to [the] date of onset of [her] neurological symptoms." Pet.'s Mem. of Objs. (Pet.'s Mem.) at 4, ECF No. 94. Ms. Rich further argues that "to prove that a disorder first appeared within a particular time period, the petitioner does not have to prove that a symptom or manifestation was observed by a physician and contemporaneously recorded within that time period—which is what [the special master] is requiring." Id. at 5 (emphasis in original). In short, Ms. Rich contends, the special master "set[] forth a rule that places too much importance on contemporaneous medical records and not enough deference to witness testimony." Id. at 17.

Ms. Rich's arguments lack merit. First, as the Federal Circuit has recognized, "[m]edical records, in general, warrant consideration as trustworthy evidence" because "[t]he records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." Cucuras v. Sec'y of HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993); see also Canuto v. Sec'y of HHS, No. 2016-2096, 2016 WL 5746370, at *3 (Fed. Cir. Oct. 4, 2016) (per curiam) (concluding special master correctly attributed more weight to medical records than later-filed affidavits because medical records are impartial and trustworthy). Indeed, "[w]ith proper treatment hanging in the balance, accuracy has an extra premium" in the preparation of medical records. Cucuras, 993 F.2d at 1528. Further, medical records are considered reliable because they are "generally contemporaneous to the medical events." Id. Thus, it was entirely appropriate for the special master to rely upon the absence of neurological symptoms in the medical records compiled during the fall of 2010 as a basis for determining when those symptoms first occurred.

Further, the special master did not discredit Ms. Rich's testimony or that of her witnesses solely because neurological symptoms were not noted or observed or recorded by her treating physicians in her medical records. See Pet.'s Mem. at 17 (arguing that "[t]he absence of a reference to specific symptoms in a medical record does not conclusively establish the absence of symptoms during that time frame" (citing Murphy v. Sec'y of HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir. 1992))). She discredited Ms. Rich's testimony and that of her witnesses because—as Ms. Rich acknowledges and the medical records confirm—during the fall of 2010, Ms. Rich never reported or complained about neurological symptoms to any of the medical professionals with whom she sought treatment. The special master concluded that it was Ms. Rich's failure to report these symptoms—not merely the fact that they were not observed or noted by medical personnel—which undermined her contention that she was experiencing such symptoms in the months following her receipt of the influenza vaccination.

As the special master found, between the time of vaccination on September 26, 2010, and the time of Ms. Rich's hospitalization on December 27, 2010, Ms. Rich sought medical care on at least three separate occasions: twice in October 2010 and once in November 2010. Pet.'s Exs. 4, 15. With respect to the November 2010 visit to the college infirmary, Ms. Rich had alleged that prior to making the appointment, she was feeling dizzy, light-headed, weak, and nauseous. Pet.'s Ex. 1 ¶ 10. She further stated that in the time period before she sought care at the infirmary, her symptoms had gotten "to the point where it was hard to function, as she felt so tired and her body felt so heavy, that she felt like she would pass out every time she went to class." Pet.'s Mem. at 10. Indeed, as described above, Ms. Rich testified that the reason she went to the college infirmary was because she had almost passed out as she walked across campus, an incident which she stated caused her to become "so scared." See Tr. 146–47; see also Pet.'s Ex. 1 ¶ 10.

But when Ms. Rich went to the infirmary, where she was diagnosed with bronchitis, she did not report this allegedly frightening incident or the chronic weakness, fatigue, nausea, dizziness and headaches she was allegedly experiencing and had been experiencing since at least mid-October. Pet.'s Ex. 15 at 2; see also Tr. 147–48. Rather, she reported fever, night sweats, sore throat, headache, ear ache/pain, cough, wheezing, muscle aches, and difficulty breathing, and she denied any other symptoms, including nausea. See Pet.'s Ex. 15 at 2. In addition, she

indicated that these symptoms were acute in nature, reporting that they had started in the previous five days and that they were improving "somewhat." Id.

Similarly, Ms. Rich did not report any weakness, nausea, headache, fatigue or other neurological symptoms to her pediatrician during the two visits she paid to her in October. Pet.'s Ex. 4 at 7–8. Ms. Rich's only complaints during those visits related to her asthma and difficulty breathing. Id.

Finally, Ms. Rich did not report neurological symptoms when she presented to the emergency room on December 27, 2010. Pet.'s Ex. 5 Part 1 at 9–11. The records from the emergency room reflect only the breathing difficulties noted above. See id. In addition, the physical examination conducted by the emergency room physicians appears to refute the notion that she was neurologically impaired at the time of her admission: the record of that examination states that Ms. Rich was "[a]lert and oriented to person, place, time, and situation," and that "[n]o focal neurological deficit [was] observed." Id. at 10. In addition, she denied suffering from weakness or fatigue when admitted. Id. at 48. And, Ms. Rich was not diagnosed with ADEM by a medical professional until January 7, 2011, eleven days after she entered the hospital. Pet.'s Ex. 5 Part 4 at 20. Further, several doctors attributed her ADEM to H1N1. Pet.'s Ex. 6 at 22–23, 27.

It was the special master's view that if the neurological symptoms about which Ms. Rich and her witnesses testified were present to such a severe and persistent degree during the months of October, November, and into December, then Ms. Rich would have reported those symptoms to medical professionals during at least one of the four times she sought their assistance. As the special master observed:

> Petitioner was familiar with doctors, as she had had asthma, a chronic illness, since childhood and would go to the doctor occasionally for a flare-up of asthma or to refill an asthma related medication prescription. Tr. at 126–27. Therefore, she was familiar with the practice of visiting a physician and reporting symptoms, particularly when prompted. She continued this practice when she went to college: she went to the doctor three times that first semester, and she reported the symptoms from which she was suffering so that they could be treated. The undersigned is not persuaded that Petitioner would not be forthcoming with her doctors, particularly if the symptoms were as unprecedented, persistent and severe as has been described. The undersigned finds that Petitioner reported the symptoms she was experiencing, related to the severe pulmonary illness for which she was eventually hospitalized.

Finding of Fact at 14.

In light of these considerations, the special master rejected Ms. Rich's various explanations for her failure to disclose her neurological symptoms. These included, but were not limited to, the following: 1) that "she (mistakenly) related [all of her symptoms] back to her asthma"; 2) that she "just thought she was going to get better and did not feel it was important"; 3) that "she was never asked about the problem with her legs or dizziness"; 4) that she "felt that

if she got [her breathing problems] addressed and it was treated, and her asthma got better, then the rest of the symptoms would go away as well"; 5) that she was afraid that if she told the doctors her symptoms, she would be prescribed medication that would make her gain weight; and 6) that she did not communicate the symptoms during her October 23 visit with Dr. Dooley because her mother spoke for her when she accompanied her to the doctor's office and she related all of her daughter's symptoms to her asthma. Pet.'s Mem. at 9, 11–12, 15, 18–19.

The special master's rejection of these explanations as unpersuasive and her decision not to credit the testimony of Ms. Rich's witnesses were not arbitrary or capricious. The inference she drew from Ms. Rich's failure to report any of her neurological symptoms to medical personnel—that she was not experiencing them at the time she sought medical treatment—was not an unreasonable, much less a "wholly implausible" one.

This Court is mindful of the Federal Circuit's instruction in Porter that it is outside the authority of the reviewing court to "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses" for "these are all matters within the purview of the fact finder." 663 F.3d at 1249. Therefore, and for the reasons set forth above, the Court must reject as unavailing Ms. Rich's arguments that the special master failed to give sufficient weight to the testimony of Ms. Rich and her witnesses when she determined that the symptoms of ADEM did not begin until shortly after Ms. Rich was hospitalized on December 27, 2010.

Ms. Rich's final argument is based on the statement in the special master's decision that "Petitioner's medical records clearly document her worsening condition throughout the fall of 2010 but the worsening condition that they document is pulmonary." Finding of Fact at 14. Seizing upon this observation, Ms. Rich argues that the special master erred by offering her opinion about whether Ms. Rich's symptoms were pulmonary or neurological. Pet.'s Mem. at 20–22. According to Ms. Rich, in determining the onset date of Ms. Rich's ADEM, the special master should have simply specified the dates on which Ms. Rich developed particular symptoms and then allowed the medical experts to determine whether those symptoms were neurological or pulmonary. See id.

This final argument is unpersuasive. The special master's statement that Ms. Rich's worsening condition was "pulmonary" not neurological was not a medical diagnosis; it was a short-hand way of restating her conclusion that Ms. Rich did not experience the neurological symptoms about which she testified but which were not reflected in her medical records. These included fatigue, lethargy, chronic headaches, dizziness, leg pain, weakness and other symptoms that she and her expert Dr. Siegler had already identified as "neurological" symptoms of ADEM. The special master characterized the decline in Ms. Rich's health as due to respiratory (or "pulmonary") causes because the symptoms reflected in her records consisted of difficulty breathing, wheezing, and the like. In other words, the special master found that the symptoms that were reflected in Ms. Rich's medical records were the only ones that she was experiencing during the relevant period. And, as Dr. Siegler himself acknowledged, once Ms. Rich's testimony and that of her witnesses was discredited by the special master, the non-neurological symptoms reflected in the medical records could not support a finding of causation.

In short, the special master's onset determination in this case was not arbitrary or capricious or contrary to law. Therefore, her conclusion that Ms. Rich failed to demonstrate a causal relationship between her vaccination and the ADEM she developed must be sustained.

CONCLUSION

The special master's decision of June 30, 2016, finding no liability, is **SUSTAINED.**

IT IS SO ORDERED.

s/ Elaine D. Kaplan
ELAINE D. KAPLAN
Judge