In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-724V
April 27, 2015
To be Published

IDA MOSLEY,	*	
	*	
Petitioner,	*	
	*	
v.	*	Remand Decision; tetanus toxoid (Td) vaccine; transverse myelitis; one-day onset
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Diana Stadelnikas Sedar, Sarasota, FL, for petitioner.
Lisa A. Watts, Washington, DC, for respondent.

MILLMAN, Special Master

REMAND DECISION[1]

On October 14, 2008, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10–34 (2006), alleging that a tetanus toxoid ("Td") vaccination on September 6, 2007, caused her to suffer from Guillain-Barré syndrome ("GBS").[2] On June 23, 2014, the undersigned issued a decision denying petitioner compensation, holding that she failed to establish that the vaccine caused her injuries. On January 28, 2014, the Honorable

[1] Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

[2] Petitioner filed an expert report on June 6, 2011, from Dr. William Triggs, a neurologist, in which he opined that Td vaccine caused petitioner's transverse myelitis ("TM"). The undersigned interpreted this as petitioner's amended petition that Td vaccine caused her TM.

Elaine D. Kaplan vacated that decision and remanded to the undersigned for further consideration. Judge Kaplan held that the undersigned committed legal error when she failed to consider and explain the impact of petitioner's treating physicians' opinions. In this remand decision, after consideration of the treating physicians' opinions, the undersigned again concludes that petitioner has failed to prove that the vaccine caused her injuries.

PROCEDURAL HISTORY

Petitioner filed her petition on October 14, 2008. Former Chief Special Master Gary Golkiewicz assigned the case to himself. From February 2, 2009 to November 30, 2010, the parties attempted to reach a litigative risk settlement, but failed to agree.

On June 23, 2011, the case was transferred to former Special Master Daria J. Zane. On July 11 and 20, 2012, former Special Master Zane held a hearing in this case. Dr. William Triggs, a neurologist, testified for petitioner. Dr. Thomas P. Leist, a neurologist, testified for respondent.

On August 31, 2013, former Special Master Zane retired. On September 23, 2013, Chief Special Master Denise K. Vowell assigned the case to herself to explore the possibility of settlement. Settlement was not availing. On November 6, 2013, this case was transferred to the undersigned.

On June 23, 2014, the undersigned issued a published decision denying compensation to petitioner on the ground that petitioner's TM occurred one day after her Td vaccination, an onset interval too brief to permit a finding of causation. Mosley v. Sec'y of HHS, 2014 WL 3503389 (Fed. Cl. Spec. Mstr. June 23, 2014). Consequently, since the onset was too short for a finding of causation, petitioner failed to show that Td vaccine caused in fact her TM. Id.

On July 23, 2014, petitioner filed a motion for review, arguing that the undersigned committed error by failing to consider or to discuss the opinions of petitioner's treating physicians, who found that Td vaccine caused her neurological disorder.

On January 28, 2015, Judge Kaplan issued a decision vacating and remanding the undersigned's decision, holding that the undersigned erred when she failed to discuss the opinions of petitioner's four treating physicians as recorded in the medical records. Slip op. at 8. Judge Kaplan referenced petitioner's argument that the treating doctors' conclusions imply "that a one-day interval for the onset of symptoms was a medically appropriate time period within which to infer causation." Slip op. at 11.

The undersigned held a status conference on February 4, 2015, in which the parties stated they wished to file briefs to be considered for the remand decision.

Petitioner filed a memorandum regarding the treating physicians' opinions on March 11, 2015. Petitioner discusses records from infectious disease specialist Dr. Duharte, internal medicine physician Dr. Beltre, petitioner's treating neurologist Dr. Ramkissoon, and petitioner's treating physician Dr. Nelson, all of whom state petitioner likely developed GBS as a result of her tetanus vaccination. Pet'r's Mem. at 2–3, Mar. 11, 2015, ECF No. 129 (citing Med. recs. Ex. 5, at 127; Ex. 19, at 197; Ex. 3, at 5–7, 11, 13, 17; Ex. 8, at 5–6; Ex. 65; Ex. 1, at 10, 14, 17, 26; Ex. 9, at 4, 8, 12, 16, 20; Ex. 39, at 23–24, 26, 29–30, 34, 206, 209, 212, 221; Ex. 40, at 16).

Petitioner discusses that a special master is required to "consider the *entire record* and *the course of the injury, disability, illness or condition*" when determining whether to award compensation. Pet'r's Mem. at 4 (citing 42 U.S.C. §§ 300aa-13(b)(1)(B) (emphasis added)). She cites the Federal Circuit's statement that Congress envisioned "close calls regarding causation would be resolved in favor of injured claimants." Id. at 5 (quoting Althen, 418 F.3d 1274, 1280 (Fed. Cir. 2005)). She also states a petitioner "need not necessarily supply evidence from medical literature" to support his or her causation theory, "so long as the petitioner supplies the medical opinion of a qualified expert." Id. Petitioner argues that the treating physicians' opinions should be given significant weight, discussing Capizzano v. Sec'y of HHS, 440 F.3d 1317 (Fed. Cir. 2006), Andreu v. Sec'y of HHS, 569 F.3d 1367 (Fed. Cir. 2009), and Zatuchni v. Sec'y of HHS, 69 Fed. Cl. 612, 624 (Fed. Cl. 2006), aff'd, 516 F.3d 1312 (Fed. Cir. 2008).

Petitioner argues that the treating doctors' opinions in favor of vaccine causation "necessarily include[] the temporal association," since "[o]ne can not [sic] conclude a causative event within the context of a medical diagnosis without determining that the timing was medically appropriate." Pet'r's Mem. at 8, 10 (citing Capizzano, 440 F.3d at 1326, and Dobrydnev v. Sec'y of HHS, 566 Fed. Appx. 976 (Fed. Cir. 014)).

Petitioner asserts that the onset of her TM was 54 hours after the shot, not 24 hours after the shot. Pet'r's Mem. at 11. She distinguishes between her urinary frequency on the evening of September 8, 2007, which she states is due to her diagnosed urinary tract infection ("UTI"), and her inability to urinate/neurogenic bladder during the afternoon of September 9, 2007, which she states was the onset of her neurological illness. Id. at 11–13.

Petitioner also argues that the testimony of respondent's expert, Dr. Leist, that petitioner suffered from viral meningoradiculitis is not supported by her UTI diagnosis, the treating doctors' opinions, the standard of care followed during her hospitalization, or her residual disability. Id. at 13–14. She further argues against respondent's theory by asserting that no reliable evidence was presented to support Dr. Leist's identification of five days as a medically acceptable onset. Id. at 14.

Respondent filed a responsive memorandum on April 8, 2015. Respondent argues that none of the treating physicians in this case "actually considered, reflected upon, commented, or opined that the onset of petitioner's claimed injury occurred within a 'medically appropriate' timeframe to ascribe causation to the Td vaccine." Resp't's Post-Remand Submission 3, Apr. 8,

2015, ECF No. 130. She addresses each of the treating physicians' opinions that petitioner argues the undersigned failed to consider (Dr. Duharte's, Dr. Beltre's, Dr. Ramkissoon's, and Dr. Nelson's) in turn.

In conformance with Judge Kaplan's direction, the undersigned has evaluated the opinion of each treating doctor who offered a statement about causation including, particularly, petitioner's treating neurologist, Dr. Ramkissoon. The undersigned finds these statements deficient because the doctors either do not specify an onset interval, specify the onset interval as more than one day (Dr. Ramkissoon), or state the onset interval was one day but give no basis for their opinion. This topic is discussed more fully later in this opinion.

FACTS

The Parties' Factual Stipulations

On February 3, 2012, the parties stipulated to the following facts. Petitioner received Td vaccine at about 11:10 p.m. on Thursday, September 6, 2007. Med. recs. Ex. 5, at 11–12; Ex. 19, at 903. Petitioner visited the Emergency Room ("ER") on September 8, 2007, complaining of joint aches, generalized weakness, frequent urination, and the onset of fever on Thursday, September 6, 2007. Med. recs. Ex. 5, at 141, 149–51. Because urinalysis revealed bacteria in petitioner's urine, the ER doctor diagnosed her with a urinary tract infection ("UTI") and prescribed Bactrim. Id. at 142, 145.

On September 9, 2007, petitioner returned to the ER, complaining of increased leg weakness, pain radiating into her legs, and difficulty voiding. Med. recs. Ex. 5, at 20; Ex. 28, at 2. In the ER, petitioner had preserved deep tendon reflexes ("DTRs") and no sensory loss. Med. recs. Ex. 5, at 76. Petitioner's white blood cell ("WBC") count was elevated at 11,100 with increased neutrophils, and her erythrocyte sedimentation rate was elevated at 41. Med. recs. Ex. 19, at 210, 494, 495.

Petitioner was admitted to Florida Heartland Hospital where Dr. Ramkissoon, a neurologist, evaluated her on September 11, 2007. Med. recs. Ex. 5, at 116. He found normal DTRs and slightly reduced strength. Id. at 121; Ex. 19, at 186. A lumbar puncture revealed elevated protein (at 87) in petitioner's cerebrospinal fluid ("CSF"), with a WBC of 60, and 100% lymphocytes (pleocytosis). Med. recs. Ex. 5, at 23, 113. Possible diagnoses at that time included viral meningitis, spinal cord lesion, and GBS. Med. recs. Ex. 5, at 23; Ex. 28, at 2. MRIs of petitioner's brain and spinal cord at that time revealed no lesions. Med. recs. Ex. 5, at 51–53; Ex. 19, at 992–93, 997; Ex. 39, at 189–90.

Dr. Ramkissoon examined petitioner on September 14, 2007, and found she had loss of DTRs in her knees and ankles, down-going toes, and normal reflexes in her upper extremities. Med. recs. Ex. 5, at 77–79. A repeat lumbar puncture showed normal protein in her CSF, a WBC of 33, and continued pleocytosis. Id. at 49, 52, 77–79, 81; Ex. 28, at 3. Dr. Ramkissoon

noted absent F waves on petitioner's nerve conduction studies. Med. recs. at Ex. 5, at 45. Differential diagnoses included viral meningitis and GBS. Id.

Petitioner was transferred to the ICU, where she was treated for GBS with a five-day course of intravenous immunoglobulin ("IVIG"). Id. at 77–79; Ex. 28, at 3. Petitioner's symptoms stopped progressing, and her reflexes, sensory changes, and strength showed some improvement. Med. recs. Ex. 4, at 21. On September 20, 2007, petitioner was transferred to in-patient rehabilitation at Winter Haven Hospital. Med. recs. Ex. 4, at 12–22. The doctor performing petitioner's admission examination noted that she had developed malaise, polyarthralgia, polymyalgias, weakness, and fevers one day after receiving a tetanus shot. Id. at 12. The doctor diagnosed petitioner with "acute inflammatory demyelinating polyneuropathy with onset dating back to September 7, 2007." Id. at 13.

Facts from the Medical Records

Petitioner was born on February 18, 1962.

On Thursday, September 6, 2007, at 10:20 p.m., petitioner went to Florida Hospital, Heartland Division, Sebring, ER. Med. recs. Ex. 5, at 3. She had punctured her right thumb on a piece of metal. Id. at 12. Petitioner received Td vaccine at 11:10 p.m. Id. at 8.

On Saturday, September 8, 2007, at 6:17 p.m., petitioner returned to Florida Hospital ER in a wheelchair, complaining of body aches, joint aches, and fever, which started on Thursday, September 6, 2007. Id. at 149. She had generalized weakness and frequent urination. Id. at 141. Her temperature was 99.4 degrees. Id. at 149. Dr. Pigman's clinical impression was petitioner had a urinary tract infection. Id. at 142. Petitioner gave a history that she was at Florida Hospital on Thursday night for a tetanus injection, and she started to feel unwell on Friday, September 7, 2007. Id. at 149. She was given antibiotics and a prescription for an antibiotic. Id. at 143.

On Sunday, September 9, 2007, at 3:31 p.m., petitioner returned to Florida Hospital ER, complaining of aching all over with weak legs for three days. Id. at 15, 13. She was unable to urinate. Id. at 15. She complained of suprapubic pain radiating down both legs. Id. at 20. She complained of dull pain and pressure in her abdomen whose onset was gradual over four days. Id. She was catheterized at 4:20 p.m. Id. Her initial urinary output was 1,000 mL. Id. She was admitted to the hospital. Id. at 14. A progress note of September 10, 2007, states petitioner received Td vaccine and, 24 hours later, had general malaise, weakness, tremor, and fever. Id. at 127. A progress note of September 11, 2007, states petitioner received tetanus toxoid on September 6, 2007, after suffering an injury. Id. at 68. She developed progressive lower extremity weakness the next day. Id. She had a temperature of 102.1 degrees on September 10, 2007. Id. On September 14, 2007, petitioner had a lumbar puncture performed. Id. at 23. Dr. Bridglal Ramkissoon interpreted the results as suggestive of viral meningitis. Id. The initial

spinal tap performed on September 11, 2007, showed elevated protein of 87. Id. It also showed 61 white blood cells with 100 percent lymphocytes, which was not consistent with GBS. Id.

On September 17, 2007, Dr. Luis A. Duharte wrote that he had examined petitioner and reviewed her chart. Id. at 129. She had remained afebrile for two days and said she felt a little bit stronger. Id. Dr. Duharte suspected petitioner had a viral infection, probably enterovirus 71 because of her symptoms. Id.

From September 20 to October 3, 2007, petitioner was at Winter Haven Hospital. Med. recs. Ex. 4, at 15. On September 21, 2007, Dr. Alain Delgado did a neurological consultation at Winter Haven Hospital. Id. Petitioner gave Dr. Delgado the history that she cut her finger, went to the ER, had a tetanus shot and, the next day, developed malaise, polyarthralgia, polymyalgia, weakness, and fevers. Id. at 12. Dr. Delgado's impression was that petitioner had acute inflammatory demyelinating polyneuropathy whose onset was September 7, 2007. Id. at 13. Dr. Delgado noted that petitioner's case was atypical because she had elevated white blood cells at 60, which appeared to be 100 percent lymphocytic, suggesting some kind of viral etiology. Id.

Also on September 21, 2007, petitioner saw Pablo H. Norona for a psychological screening report. Id. at 23. She stated that she punctured her finger, went to the ER for a tetanus toxoid shot, and, following the shot, began experiencing weakness, stiffness, and inability to walk, followed by two falls at home. Id. She returned to the ER. Id.

Dr. William L. Earp, writing the discharge summary for Winter Haven Hospital on October 3, 2007, noted petitioner's history of transferring from Florida Hospital at Sebring, with complaints of weakness, some sensory changes, and decreasing endurance. Id. at 15. Petitioner described her current problems as possibly beginning with a cut on her finger. Id. She went to the ER and received a tetanus shot. Id. The next day after her tetanus shot, she started developing malaise, polymyalgia, polyarthralgia, weakness, and fever. Id. The doctor diagnosed her with a urinary tract infection and treated her with an antibiotic. Id.

On October 9, 2007, petitioner saw Dr. Audwin B. Nelson, an internist, and gave him the history that on September 6, 2007, she cut the first digit on her right hand at work, went to the ER later that day, and received a tetanus booster. Med. recs. Ex. 1, at 8, 10. She developed weakness in her legs the next day and was eventually hospitalized on September 9, 2007, after the weakness and numbness of her legs worsened. Id.

On October 30, 2007, petitioner began physical therapy. Med. recs. Ex. 6, at 38. Physical therapist Evelyn Ongsiako evaluated petitioner, noting that petitioner reported her current condition started on September 7, 2007, after she received a tetanus shot. Id. Petitioner stated that on that day, she started having difficulty moving around. Id. She then went to the ER, which sent her home. Id. The following day, September 8, 2007, she continued to have difficulty ambulating and went back to the hospital. Id. She was not admitted to the hospital until September 9, 2007. Id. Two to three weeks after her hospital admission, the doctors finally

diagnosed her with GBS. Id. A week later, she was transferred to a rehabilitation facility in Winter Haven, where she continued strengthening. Id. She was discharged home and was much improved. Id. Upon a recent visit with her primary care physician, she was referred for outpatient physical therapy for further evaluation and treatment. Id. Her medical history is significant for dizziness. Id.

In March 2008, petitioner qualified for Social Security Disability Income ("SSDI") benefits. Med. recs. Ex. 23, at 1.

On September 9, 2008, petitioner saw Dr. James McCluskey for an independent medical examination.[3] Med. recs. Ex. 19, at 910–24. Dr. McCluskey wrote a detailed history based on his conversation with petitioner. On Thursday, September 6, 2007, petitioner nicked her right thumb on an exposed screw head while exiting a stairwell at work around 6:45 p.m. Id. at 911. She went home, but at around 10:00 p.m., she went to Florida Hospital Heartland ER to get a tetanus shot. Id. She felt fine the rest of the evening until her husband, who works the midnight shift, prepared to leave for work. Id. At that time, she had a headache and took Excedrin. Id. She also called the hospital, told the nurse she was having a headache, and asked if there were a relationship between the tetanus shot and the headache. Id. At 4:00 a.m., September 7, 2007, petitioner woke at her normal time and reported that her toes/feet were tingling, but she did not have a headache. Id. She went to work at around 8:00 or 8:30 a.m. Id. Between 10:30 and 11:00 a.m. on September 7, 2007, petitioner noted tingling in her fingers but no pain in her arms or legs. Id. She told her co-worker she did not feel well and asked to leave in the mid-afternoon. Id. After leaving work, she stopped at a convenience store to buy a soda and went home. Id. She lay down and woke several hours later feeling weak, particularly in her legs. Id. When she walked into her kitchen, she suddenly felt heat, numbness, and tingling in her arms and legs. Id. She also had a headache. Id. Later in the evening of Friday, September 7, 2007, she was scheduled to work at her part-time job with South Florida Community College from 10:00 p.m. to 2:00 a.m. Id. Shortly after 6:00 p.m. on September 8, 2007, petitioner went back to the Florida Hospital Heartland ER, where they diagnosed her with a urinary tract infection, gave her an antibiotic, and prescribed an antibiotic. Id. She did not fill the prescription. Id. Petitioner went to work but left after about an hour because she did not feel well. Id. She had a strong urge to urinate. Id. On the way home, petitioner bought gas, which she pumped into her car, and went to bed when she arrived home. Id. At about 2:30 a.m. on September 9, 2007, petitioner got up to use the toilet and her legs felt weak. Id. She sat on the bathroom floor until 5:00 a.m. when her sons helped her back to bed. Id. She remained in bed until 7:30 or 8:00 a.m. Id. At that time, she walked into her kitchen to get some champagne grapes for a snack and slid onto the floor because her legs gave out. Id. Petitioner's family took her to Florida Hospital ER midday, where she was informed she had a UTI-URI. Id. She went home to bed. Id. Sometime

[3] On February 8, 2012, petitioner moved to exclude the expert report of Dr. McCluskey, which was written for petitioner's disability claim against her employer. On February 21, 2012, respondent filed her response opposing the motion. Former Special Master Zane heard argument on petitioner's motion on February 24, 2012, and denied the motion on March 3, 2012.

between 7:00 p.m. and 8:30 p.m., she called South Florida Community College and told them she could not come to work because she felt unwell. Id. She returned to the ER that night, and they admitted her to the hospital. Id. Subsequently, she was diagnosed with GBS. Id.

Dr. McCluskey, in his September 9, 2008 examination, noted that petitioner was receiving Social Security disability payments. Med. recs. Ex. 19, at 913. She never returned to work after her September 2007 hospitalization. Id. During his physical examination of petitioner, Dr. McClusky noted petitioner was alert and oriented to person, place, and time, and that she answered all questions without difficulty. Id. at 914. Petitioner had difficulty with movement. Id. She walked with assistance and required help to get on the exam table. Id. She responded appropriately to questioning, and her short-term memory appeared intact. Id. Her DTRs were 2/4 at the knee and biceps tendon bilaterally. Id. Sensation appeared intact throughout. Id. Dr. McCluskey reviewed petitioner's vaccination history and stated in his report that the Td vaccination of September 6, 2007 was at least the fourth vaccine containing tetanus toxoid that she has received. Id. at 921.

On December 19, 2008, petitioner entered into a worker's compensation settlement with her employer's carrier. Med. recs. Ex. 20, at 11. Winter Haven Hospital agreed that petitioner punctured her right thumb while in its employ. Id. at 2. The lump sum settlement included $5,000.00 for the cost of petitioner's future medical care and treatment, and $10,000.00 in full satisfaction of the obligation to pay. Id. at 3.

INITIAL EXPERTS' REPORTS

Petitioner filed the expert opinion of Dr. Triggs as Exhibit 28. Dr. Triggs states that, although doctors diagnosed petitioner with GBS, her medical records and clinical presentation point to an "immune-mediated demyelinating disorder more consistent with a central nervous system process and the diagnosis of transverse myelitis." Ex. 28, at 5. Dr. Triggs lists the basis for his reasoning. First, petitioner's CSF showed a level of pleocytosis that excludes the diagnosis of an inflammatory demyelinating neuropathy such as GBS or chronic inflammatory demyelinating polyneuropathy, but is consistent with transverse myelitis ("TM"). Id. Secondly, petitioner retained her deep tendon reflexes, which is contrary to a diagnosis of GBS but is consistent with TM. Id. Thirdly, petitioner's neurologic disorder included "urinary bladder dysfunction that was both an early clinical manifestation of her illness and was relatively disproportional to her weakness." Id. Dr. Triggs states that TM results in neuronal injury and demyelination. Id. at 6.

Respondent filed the expert report of Dr. Leist as Exhibit B. Dr. Leist notes that the presence of urinary tract symptoms on September 8, 2007, suggested the presence of a neurologic process affecting her bladder control. Ex. B, at 7–8. Dr. Leist notes the time petitioner signed the informed consent for Td vaccine was 11:10 p.m. on September 6, 2007. Id. at 7. Dr. Leist opines that there was an onset interval of five hours between petitioner's Td vaccination and the onset of her neurologic disorder. Id. at 8. To reach this conclusion, Dr. Leist

relies on Dr. McCluskey's extensive interview and evaluation of petitioner on October 20, 2008, when petitioner told Dr. McCluskey that she became aware of tingling in her toes when she rose at 4:00 a.m. on September 7, 2007. Id. Dr. Leist writes that the time interval of five hours "between vaccination and onset of tingling in the toes is too short for induction or re-stimulation of a self-reactive immune process against the constituents of the Td vaccine," regardless of whether petitioner had GBS or TM. Id.

Dr. Leist states that when petitioner came to the ER on September 9, 2007, complaining of aching all over and leg weakness for three days, fever, chills, and difficulty voiding, the test results of her blood were consistent with an infection. Id. Her white blood cell count was elevated at 11,100 with increased neutrophils. Id. Her erythrocyte sedimentation rate was elevated at 41. Id. Dr. Leist states that bodily joint pain, fever, chills, increased white cell count with a left shift, and an elevated erythrocyte sedimentation rate are consistent with an infection. Id. at 8. Dr. Duharte, a treating doctor, noted on September 17, 2007, that petitioner still had a viral infection, probably enterovirus 71. Id. at 9 (citing Ex. 5, at 129).

Dr. Leist concludes that petitioner did not have GBS and that she could not have had a demyelinating process five hours after Td vaccination because the onset interval was too short. Id. at 10. Dr. Leist opines that an infection prior to petitioner's receipt of Td vaccine caused her flu-like symptoms, fever, and neurologic presentation, which began on September 7, 2007. Id.

MEDICAL LITERATURE

Filed together with Dr. Triggs' initial expert report are Exhibits 30 through 36, comprised of references Dr. Triggs made in his initial expert report.

Exhibit 30 is a case report entitled, "Acute transverse myelitis in a 7-month-old boy after diphtheria-tetanus-pertussis immunization." R.M.S. Riel-Romero, Acute transverse myelitis in a 7-month-old boy after diphtheria-tetanus-pertussis immunization, 44 Spinal Cord 688 (2006). (Petitioner also filed this case report as Exhibit 41.) A seven-month-old male was hospitalized with acute TM 17 days after he received DTaP vaccine. Ex. 30, at 1. He also had an upper respiratory infection two weeks prior to admission. Id. The author does not conclude that the vaccination caused the child's TM, as the child also had an upper respiratory infection within a similar time period (two weeks before hospitalization). Id. at 3. The author lists other case reports of vaccinees with TM post-vaccination: (1) a baby with TM 17 days after DPT vaccine; (2) a baby with paraplegia six days after DT and oral polio vaccines; (3) a toddler with acute TM 21 days after MMR vaccine; (4) a teenager with right-sided weakness and numbness one week after hepatitis B vaccine; (5) a four-year-old with acute TM 14 days after Japanese B encephalitis vaccine; (6) a nine-year-old with TM 16 days after measles and rubella vaccine; and (7) an adult who developed fatal inflammatory polyradiculopathy/myelopathy nine days after hepatitis B vaccine. Id.

Exhibit 31 is a case report in the form of a letter entitled, "Transverse myelitis after vaccination." G. Zanoni et al., Transverse myelitis after vaccination, 9 Eur. J. Neurology 696 (2002). (Petitioner also filed this case report as Exhibit 42.) A 15-month-old baby girl had acute TM 21 days after her first MMR and fourth DTaP vaccinations. Ex. 31, at 3. The authors note that an MRI failed to detect abnormalities or spinal cord swelling, but this is typical of 60 percent of myelitis cases. Id. The authors suggest further study to determine causality. Id. at 4.

Exhibit 32 is a case report entitled, "Transverse myelitis after measles and rubella vaccination." S. Lim et al., Transverse myelitis after measles and rubella vaccination, 40 J. Pediatric Child Health 583 (2004). (Petitioner also filed this case report as Exhibit 43.) A nine-year-old girl had urinary incontinence 16 days after receiving her first measles rubella vaccination. Ex. 32, at 2. Four days later, she developed low back pain and lower limb weakness and was hospitalized. Id. The authors recognize that TM is most frequently associated with an antecedent upper respiratory illness but may also follow other viruses. Id. at 3. They do not conclude the girl's TM was due to her vaccination, but they could not find another cause. Id.

Exhibit 33 is a case report entitled, "Acute Transverse Myelitis After Influenza Vaccination: Magnetic Resonance Imaging Findings." R. Bakshi et al., Acute Transverse Myelitis After Influenza Vaccination: Magnetic Resonance Imaging Findings, 6 J. Neuroimaging 248 (1996). (Petitioner also filed this case report as Exhibit 44.) A 36-year-old woman was hospitalized with a one-week history of progressive leg weakness, numbness below the chest, and urinary retention. Ex. 33, at 3. Her symptoms began four weeks after receiving influenza vaccine. Id. She had not had any antecedent illnesses. Id. She was diagnosed with post-vaccination syndrome by exclusion. Id. at 4.

Exhibit 34 is an article entitled, "Immunopathogenesis of acute transverse myelitis." D.A. Kerr et al., Immunopathogenesis of acute transverse myelitis, 15 Current Opinion Neurology 339 (2002). (Petitioner also filed this article as Exhibit 45.) The authors state that virtually all TM patients have some degree of bladder dysfunction. Ex. 34, at 2. For those with idiopathic TM, the time between onset of symptoms and nadir of symptomatology is four hours to 21 days. Id. The authors state that case reports must be viewed with caution, as two events occurring closely in time may be coincidental. Id. at 3. Possible biological causative mechanisms include molecular mimicry, superantigens, autoantibodies, or high levels of normal circulating antibodies. Id. at 4–5.

Exhibit 35 is a case report in the form of a letter entitled, "Acute transverse myelitis after tetanus toxoid vaccination." S.J. Read et al., Acute transverse myelitis after tetanus toxoid vaccination, 339 Lancet 1111 (1992). (Petitioner also filed this case report as Exhibit 57.) A 50-year-old man received tetanus toxoid vaccine. Ex. 35, at 3. Sixteen days later, he had generalized myalgia, lethargy, fatigue, and mild bi-frontal headache. Id. Twelve days after his initial presentation, he was admitted to the hospital with TM. Id.

Exhibit 36 is a case report entitled, "Transverse myelitis after diphtheria, tetanus, and polio immunization." E. Whittle et al., Transverse myelitis after diphtheria, tetanus, and polio immunization, 1 Brit. Med. J. 1450 (1977). (Petitioner also filed this case report as Exhibit 59.) A seven-month-old girl developed TM six to seven days after receiving her first diphtheria, tetanus toxoid, and polio vaccinations. Ex. 36, at 1. She also had a history of a slight cough and hoarse cry for four days. Id. The authors note that, although myelitis may have occurred by chance, the onset of the baby's symptoms occurred when reactions to vaccinations are most frequently found. Id.

Subsequently, petitioner filed other medical literature. Exhibit 46 is a case report entitled, "Acute Transverse Myelitis at the Conus Medullaris Level After Rabies Vaccination in a Patient with Behçet's Disease." L.S. Bir et al., Acute Transverse Myelitis at the Conus Medullaris Level After Rabies Vaccination in a Patient with Behçet's Disease, 30 J. Spinal Cord Med. 294 (2007). The onset interval of acute TM after rabies vaccination was two months. Ex. 46, at 1. The authors posit that the vaccine may have contributed to the acute TM. Id. at 3.

Exhibit 47 is a case report entitled, "Acute radiculomyelitis after antitetanus vaccination." F. Tezzon et al., Acute radiculomyelitis after antitetanus vaccination, 15 Italian J. Neurological Sci. 191 (1994). A 40-year-old woman had right lumbar sciatica three weeks after tetanus toxoid vaccination. Ex. 47, at 1. Her sciatica was soon followed by paresthesia and hypoesthesia of the lower limbs, and severe hyposthenia, making standing difficult. Id. The authors refer to a 1937 case report that was the first report of neurological complications after tetanus toxoid. Id. at 2. The case report referred to a case of fatal acute necrotic encephalomyelitis, whose onset was eight days after vaccination. Id. The authors describe another case report of a woman who, five days after antitetanus vaccine, had a serious neurologic illness that included both the central and peripheral nervous systems. Id. at 3. The authors refer to two 1992 case reports, the first reporting optic neuritis and acute myelitis three days after vaccination, and the second reporting severe acute encephalomyelitis ten days after antitetanus vaccine. Id. The authors state, "In the majority of the cases reported in the literature, the time interval between vaccination and the development of neurological complications varies between 10 and 20 days. In our case, the first signs of radiculomyelitis appeared 20 days after vaccination." Id. They conclude that the time interval between the vaccination and the neurological event suggests antibody movement or a cell-mediated mechanism. Id.

Exhibit 48 is a case report entitled, "Early-Onset Acute Transverse Myelitis Following Hepatitis B Vaccination and Respiratory Infection." L.F. Fonseca et al., Early-Onset Acute Transverse Myelitis Following Hepatitis B Vaccination and Respiratory Infection, 61 Arquivos Neuro-Psiquiatria 265 (2003). A three-year-old boy had acute TM ten days after receiving a hepatitis B vaccine while he had a mild upper airway respiratory illness manifested by rhinorrhea and cough. Ex. 48, at 2. The authors state the mean interval from infection to onset of neurological symptoms is reported as between nine days to three weeks. Id. at 3. The authors could not determine whether the viral respiratory infection or the hepatitis B vaccination caused the TM, but they posited it might be both antigens. Id. at 4.

Exhibit 49 is a case report entitled, "MR Imaging in a Case of Postvaccination Myelitis." L.M. Tartaglino et al., MR Imaging in a Case of Postvaccination Myelitis, 16 Am. J. Neuroradiology 581 (1995). A 40-year-old male had TM two weeks after receiving his first hepatitis B vaccination. Ex. 49, at 1. One month after he received his second vaccination, the sensory disturbance ascended. Id. The authors state, "[T]he striking temporal relationship between symptoms and the two doses of hepatitis B vaccine strongly suggests that the vaccine was the cause." Id.

Exhibit 50 is a case report entitled, "Acute myelitis following hepatitis B vaccination." F. Mahassin et al., Acute myelitis following hepatitis B vaccination, 22 La Presse Médicale 1997 (1993). The article is written in French with a one-paragraph abstract in English. The authors describe a 56-year-old man who had TM three weeks after receiving hepatitis B vaccine. Ex. 50, at 2.

Exhibit 51 is a case report entitled, "Acute Myelitis after Hepatitis B Vaccination." H-K Song et al., Acute Myelitis after Hepatitis B Vaccination, 12 J. Korean Med. Sci. 249 (1997). A 31-year-old man had acute TM two weeks after receiving his third dose of plasma-derived hepatitis B vaccine. Ex. 51, at 1. The authors surmise the temporal relationship between the symptoms and the vaccination "strongly suggests that the vaccine was the cause." Id. The authors write that a possible mechanism involves an autoimmune phenomenon associated with T-cell mediated immune reaction. Id.

Exhibit 52 is a case report in the form of a Letter to the Editor, translated from French, entitled, "Acute myelitis after hepatitis B immunization with a recombinant vaccine." A. Senejoux et al., Acute myelitis after hepatitis B immunization with a recombinant vaccine, 20 Gastroénterologie Clinique Biologique 401 (1996). A 65-year-old woman had acute TM six days after receiving her second dose of hepatitis B vaccine. Ex. 52, at 1.

Exhibit 53 is a case report entitled, "Acute transverse myelitis following typhoid vaccination." R.N. Das et al., Acute transverse myelitis following typhoid vaccination, 76 Ulster Med. J. 39 (2007). A 19-year-old man had acute TM five days after receiving typhoid vaccine. Ex. 53, at 1.

Exhibit 72 is a case report entitled, "Myelopathy following influenza vaccination in inflammatory CNS disorder treated with chronic immunosuppression." A.J. Larner et al., Myelopathy following influenza vaccination in inflammatory CNS disorder treated with chronic immunosuppression, 7 Eur. J. Neurology 731 (2000). A 42-year-old man with optic neuropathy developed TM a few days after influenza vaccination. Ex. 72, at 1.

Exhibit 73 is an article entitled, "Vaccine-induced Autoimmunity." A.D. Cohen et al., Vaccine-induced Autoimmunity, 9 J. Autoimmunity 699 (1996). The authors state that a number of autoimmune disorders have occurred two to four weeks after vaccination. Ex. 73, at 1.

Exhibit 74 is a case report in the form of a letter entitled, "Optic neuritis and myelitis after booster tetanus toxoid vaccination." H. Topaloglu et al., Optic neuritis and myelitis after booster tetanus toxoid vaccination, 339 Lancet 178 (1992). An 11-year-old girl had rapid onset of visual deterioration and weakness three days after tetanus toxoid vaccination. Ex. 74, at 1.

Although the undersigned has not described all the submissions of medical literature, the undersigned has reviewed them.

TESTIMONY

The first part of the hearing on July 11, 2012, began with Special Master Zane's summary of the issue in the case: whether or not petitioner had GBS or some other neurological disease caused by her Td vaccination of September 6, 2007. Tr. at 5. The second part of the hearing began on July 20, 2012. The transcript pagination is continuous from the first part through the second part of the hearing.

Petitioner testified first. Tr. at 7. On September 6, 2007, while exiting her place of employment, she pricked her finger on a screw, got a Band-Aid from a secretary, and went home. Id. at 10. Later that night, she went to the hospital and received a tetanus shot. Id. This was about 10:00 p.m., and it took about an hour to get home. Id. at 11. She woke up the next day, Friday, at around 4:30 a.m. to go to work and had a slight headache. Id. She did not feel well about mid-morning and left for home after lunch. Id. at 12. She went to her auditing job that night but stayed only about an hour or an hour and one-half. Id. On Saturday, she did not feel well, and her husband took her to the ER. Id. at 13. She felt fatigued and had a headache. Id. The ER physician diagnosed her with a urinary tract infection and gave her two prescriptions. Id. She went for an hour to her night job. Id. at 14. After she went to bed, she got up at 2:30 or 3:00 a.m. on Sunday to use the bathroom and then went to the kitchen to get some grapes, but she lost her balance and slid to the floor with the refrigerator door open. Id. at 15. She yelled for her husband and sons to help her, but they did not hear her. Id. Before 5:00 a.m., her daughter came downstairs to make a bottle for her baby girl and discovered her on the kitchen floor. Id. at 16. Petitioner could not get up, and her daughter got her brothers to help her. Id. She slept most of the day. Id. Her family took her back to the ER when her husband came home. Id.

On cross-examination, petitioner denied she had tingling, lower extremity weakness, body aches, or muscle aches during the first 24 hours after her Td vaccination. Id. at 30. When shown the ER records of September 8, 2007, in which she gave a history of aching all over, fever, and cough that started the day before (September 7, 2007), petitioner replied, "Well, it states here that that's what I said, but I don't remember." Id. at 32. When advised that the ER document had circles for "Review of Symptoms" indicating fever, chills, generalized weakness, problems urinating, and frequent urination, petitioner replied, "Like I said, I don't remember, but it's here on this paperwork, so evidently." Id. at 33. When shown under the category "Chief Complaint" at the ER on September 8, 2007, "Body aches and joint aches, fever. Started

Thursday. PT [patient] was here Thursday night for Td shot, and Friday she started not feeling good," petitioner replied, "That's what it says here. I don't remember, but that's what it says here." Id. at 35. Petitioner did not recall giving the ER staff all the information in their records, e.g., that her legs had been weak, and she had been aching for three days. Id. at 38.

On September 9, 2008, petitioner saw Dr. McCluskey, the worker's compensation doctor. Id. at 60. The report states the interview lasted from 10:00 a.m. to 12:50 p.m. or almost three hours. Id. Petitioner stated it was a lengthy visit, but she was not sure of the time. Id. She recalled talking with Dr. McCluskey for several hours. Id. at 61. She denied that she had tingling toes or fingers on Friday, September 7, 2007. Id. at 64. Her main complaint on Friday was headache. Id. She said that she did not report tingling until Sunday, September 10, 2007. Id. at 65.

Dr. William Triggs, a neurologist, testified for petitioner. Id. at 132. Demyelinating disorders are his subspecialty, and he is also an electromyographer. Id. at 134. He opined that petitioner received Td vaccine and, then, between 48 and 72 hours later, developed transverse myelitis. Id. at 180. To explain the basis for his opinion that Td vaccine caused petitioner's TM, Dr. Triggs stated it was an autoimmune event and that this was his "educated speculation." Id. He said autoimmunity is not well understood: "I mean, we don't know." Id. Dr. Triggs stated no one understands how or why the immune system goes awry. Id. at 181. He said there is still a lot that remains to be understood about it. Id. He did not think petitioner had an infectious etiology at the time, which would be an alternative cause, although if she had an infection, the cause could be both the infection and the vaccine. Id. at 183. He could not testify that molecular mimicry was definitely the mechanism here. Id. at 250. Molecular mimicry is a very popular theory for autoimmunity, but autoimmunity is probably much more complicated than that. Id. Molecular mimicry is an oversimplification for which we have some isolated examples in the field of immunology. Id. Other than petitioner having an immune response that targeted a part of her spinal cord, he could not be more specific. Id. at 260. Dr. Triggs would call it "just myelitis as opposed to transverse [myelitis]." Id. at 310. Technically, petitioner did not have transverse myelitis "because it didn't affect completely every neurological function at a level." Id. at 316. She had an inflammatory lesion of her spinal cord. Id. She had a mild or partial myelitis. Id. at 321. Giving "an educated speculation," Dr. Triggs said the way the immune system affects the cord produces a variable degree of swelling. Id. at 322. The immune system, not swelling, destroys tissue. Id.

Dr. Triggs thought petitioner's lesion was at the bottom part of the spinal cord in the conus medullaris. Id. at 330. The neural structures that control bladder function are in the conus medullaris, which is also the origin of nerve roots for the lower extremities. Id. Dr. Triggs said, "I'm hanging up on demyelination. I'm not convinced that the injury to her cord was necessarily demyelination. In fact, I think if it was demyelination, her outcome might have been better, and it's more likely an MRI would have been abnormal. So the immune system doesn't attack the cord necessarily by producing demyelination . . . although that's certainly one mechanism." Id. at 339. He opined that the vaccine caused an immune-mediated injury to petitioner's spinal cord.

Id. An onset of less than 24 hours would cause Dr. Triggs "to squirm a little . . . from [his] limited knowledge of immunology." Id. at 340. But as a clinician, he said he believes that if there is no other immune stimulation occurring in his patient and his patient gets myelitis, if the onset interval is 23 hours, he would not say it absolutely cannot be the vaccine. Id. He said he could not give a specific immunological mechanism because he is not an immunologist or a neuroimmunologist. Id. He said he thinks a two- or three-day onset is okay for causation. Id. at 341.

Dr. Triggs considered the onset of petitioner's neurological condition to be September 9, 2007. Id. at 210. He agreed that pain radiating in the legs and inability to void can be neurological signs. Id. at 211. Petitioner gave a history on September 9, 2007, that she had a several-day history of aching all over, and weak legs for three days, which is consistent with GBS or transverse myelitis. Id. at 213–14. Even if the onset of petitioner's neurologic problems occurred one day after her Td vaccination, Dr. Triggs said he would still opine that the vaccine was the cause. Id. at 243. He explained causation as autoimmune, but he could not tell if it involved molecular mimicry or some sort of super antigen phenomenon. Id. at 260. He said he could not cite specific evidence that this immune process could occur within less than 24 hours. Id. at 261. Dr. Triggs said that when petitioner went to the ER on September 8, 2007, her urinary tract infection was not the correct primary diagnosis. Id. at 297. She was having a reaction to the vaccine and was feeling muscle aches, joint aches, and low-grade fever. Id. He said he did not know if this was a neurological reaction. Id. at 298. He could not separate out the urinary tract infection from the vaccination as causal of petitioner's neurological condition. Id. at 300. Dr. Triggs said an onset on September 8 would not bother him, but an onset on September 7 would become a little more problematic based on his knowledge of animal immunology. Id. at 307. But if he had a patient asking about causation, and he had no other cause but the vaccine to consider, he would probably say that a vaccine caused a one-day reaction. Id. He said less than 24 hours becomes more problematic if you look at animal data and immunology. Id. at 307–08. Dr. Triggs would not attribute petitioner's leg weakness and urinary retention to something other than a neurological condition. Id. at 317.

Dr. Thomas P. Leist, a neurologist, testified for respondent. Id. at 350. When petitioner was in the ER on September 8, 2007, she had a normal white cell count. Id. at 362. On September 9, 2007, her white cell count had increased to 11,100, and she had an elevated erythrocyte sedimentation rate. Id. Her significantly elevated white cell count had lymphocytic predominance. Id. The elevated white cell count, lymphocytic predominance in the white cells, and elevated erythrocyte sedimentation rate are all congruent with a possible viral infection. Id. In transverse myelitis generally, the peripheral white cell count is not increased. Id. at 363.

Dr. Leist said he thinks petitioner had a viral meningoradiculitis. Id. at 369. Meningoradiculitis is a process between transverse myelitis and Guillain-Barré syndrome. Id. at 365–66. Meningoradiculitis principally involves the nerve roots and the spinal cord. Id. at 366. Dr. Leist said he does not believe tetanus vaccine could cause petitioner to develop a demyelinating or neurologic condition within one day. Id. at 377. It would take days for the

immune process to begin. Id. at 378. Dr. Leist thought the shortest time period for a cross-reactive immune response to manifest would be five days. Id. at 378. Petitioner's medical records show that her symptoms began on September 7, 2007. Id. She did not feel well, cut short her work hours, contacted her supervisor, and reported the next day, September 8, 2007, to the ER personnel that she had generalized malaise and urinary symptoms. Id. Dr. Leist said that the urinary symptoms were an indication that she had bladder dysfunction, not a urinary tract infection. Id. Dr. Leist disagreed with Dr. Triggs' interpretation that petitioner had a separate urinary tract infection with urinary retention following it. Id. at 378–79. Dr. Leist viewed the bladder presentation on September 7 as the same as the bladder presentation on September 8. Id. at 379. The process affecting the central or radicular nerve root was already established on September 8. Id. Therefore, petitioner's symptoms began on September 7, within the first 24 hours after petitioner's vaccination. Id. Petitioner's bladder symptoms on September 8 are congruent with urinary retention and can be viewed as a neurological symptom. Id. at 380. This is a single process, presenting to the ER on September 8 at about 6:00 p.m. and returning to the ER on September 9 at around 3:00 p.m. Id.

Dr. Leist said that an autoimmune process takes time. Id. at 502. A cross-reactive immune response needs to get into the central nervous system, where it encounters the cross-reactive antigen and is restimulated. Id. Dr. Leist said he did not think it was possible for such an onset after vaccination to occur within two days. Id. at 503. After the injection of the vaccine, T-cells respond to this antigen. Id. Then the response has to be transported into the central nervous system. Id. First, the cells go in, and then they need to attract additional lymphocytes in order to cause a local tissue injury, which also takes time. Id. at 503–04. It is highly unlikely to occur in two days. Id. at 504.

SUPPLEMENTAL EXPERT REPORT

On May 19, 2014, after the hearing, petitioner filed a supplemental expert report of Dr. Triggs in response to the undersigned's Order, as Exhibit 70. Dr. Triggs states that TM includes symptoms of bladder and bowel dysfunction. Ex. 70, at 1. He states that petitioner received tetanus vaccine at 10:52 p.m. on September 6, 2007. Id. at 2. He also states that petitioner went to the ER at 6:00 p.m. on September 8, 2007 with a urinary tract infection. Id. at 3. Dr. Triggs believes that the onset interval between petitioner's tetanus vaccination and her symptoms was "a little over 48 hours" because he puts onset at 5:00 a.m. on September 9, 2007. Id. He distinguishes between petitioner's urological complaints (which began within a day after her vaccination) and her neurological complaints. Id. at 4. Petitioner had bilateral lower extremity weakness with intermittent loss of reflexes and significant bladder dysfunction. Id. at 5. Dr. Triggs states he was reluctant at the hearing to commit to molecular mimicry as the mechanism causing petitioner's TM. Id. at 7. He states tetanus vaccine can stimulate a cross-reactivity of immune cells from the initial challenge and cause an inadvertent response within "self-cells." Id. Dr. Triggs states we do not have clear diagnostic evidence of demyelination in petitioner, but she had clinical signs of an inflammatory process. Id. at 8. He does not agree that five days (as Dr. Leist testified) is required in order to produce an inflammatory and/or autoimmune response, and

he cites case reports in the medical literature filed as Exhibits 41–60.[4] He refers to a TM Fact Sheet from NIH/NINDS, which notes that the onset of symptoms can occur from within hours to several days to the outer ranges of one to four weeks.[5] Id.

TREATING DOCTORS' OPINIONS

In accordance with Judge Kaplan's remand instructions, the undersigned now considers and discusses petitioner's treating doctors' opinions as expressed in the medical records and in Dr. Bridglal Ramkissoon's opinion letter dated January 31, 2012.

On September 9, 2007, petitioner went to the Emergency Department ("ED") of Winter Haven Hospital, where she saw Dr. Miguel Beltre, an internal medicine physician. Med. recs. Ex. 19, at 196. Petitioner told Dr. Beltre that she went to the ED four days earlier with a cut on her finger. Id. (Petitioner's history was incorrect. She went to the ED less than three days earlier on September 6, 2007.) She said she received a tetanus toxoid injection but returned to the ED, complaining of weakness and back pain. Id. Medical personnel prescribed Bactrim for infection. Id. She returned once more to the ED because of inability to void and inability to walk. Id. Petitioner appeared before Dr. Beltre with fever and chills, and he admitted her to the hospital with a working diagnosis of urinary tract infection. Id. Dr. Beltre's impression was that petitioner had acute febrile illness and "probably [sic] reaction to tetanus toxoid." Id. at 197. It

[4] The onset intervals for TM after vaccination in Exhibits 41–60 do not support Dr. Triggs' opinion that onset can happen two days after vaccination and be causal. All of the articles that address onset have onsets longer than two days. For example, Exhibit 41 has a 17-day onset. Exhibit 42 has a 21-day onset. Exhibit 43 has a 16-day onset. Exhibit 44 has a four-week onset. Exhibit 45 has numerous onsets (ranging from two to nine days), and the authors caution against assuming causation from coincidences. Exhibit 46 has a two-month onset. Exhibit 47 has a three-week onset. Exhibit 48 has a 10-day onset. Exhibit 49 has a two-week onset. Exhibit 50 has a three-week onset. Exhibit 51 has a two-week onset. Exhibit 52 has a six-day onset. Exhibit 53 has a five-day onset. Exhibit 57 has a 16-day onset. Exhibit 59 has a 6- to 7-day onset. The other articles do not address onset specifically. Exhibit 54 is a chapter on acute disseminated encephalomyelitis from a textbook on autoimmune neurological disease. Exhibit 55 is an article about neurological complications from swine flu vaccine. Exhibit 56 is an article about mono- and poly-neuritis (both peripheral neuropathies) after tetanus vaccination. Exhibit 58 is an article about the signs and symptoms of TM. Exhibit 60 is a chapter on acute disseminated encephalomyelitis from a textbook on clinical neuroimmunology. In sum, these exhibits do not support Dr. Triggs' statement that a brief (he would posit a little more than 48 hours) interval between tetanus vaccination and onset of TM is "well-established" in the case reports he cited in his initial expert report. Ex. 70, at 8.

[5] Dr. Triggs' description of the National Institute of Neurological Disorders and Stroke TM Fact Sheet (Ex. 75) misrepresents its contents. The TM Fact Sheet says that symptoms of TM can occur over several hours to several weeks. Ex. 75, at 1. It does not say that several hours to several weeks is the interval between a trigger, such as a vaccination, and the onset of the TM itself. The TM Fact Sheet does not discuss onset intervals after vaccination or a trigger at all. The description in the Fact Sheet of developing TM over hours to several days or from one to four weeks indicates solely the difference between acute TM and subacute TM; it does not refer to the interval between trigger and onset of TM. Id. at 2.

is difficult from these brief notes to determine when Dr. Beltre thought her reaction to Td vaccine began. While he knew petitioner had a Td vaccination, because of her inaccurate history, he thought it was four days earlier instead of less than three days earlier. The undersigned therefore cannot determine whether Dr. Beltre assumed petitioner had a one-, two-, three-, or four-day onset of a neurologic reaction to tetanus toxoid. Moreover, Dr. Beltre did not opine that petitioner had a demyelinating disease, and thus did not address whether a one-day onset was a medically appropriate timeframe for Td vaccine to cause a demyelinating disease, such as GBS or TM.

On September 10, 2007, petitioner saw an infectious disease specialist, Dr. Luis Duharte, and gave a history that she had general malaise, weakness, tremor, and fever 24 hours after receiving Td vaccine. Med. recs. Ex. 5, at 127. Dr. Duharte opined in his assessment: "Highly suspicious[6] of adverse rx [reaction] to tetanus toxoid." Id. Dr. Duharte, who is not a neurologist, does not give a reason for his suspicion. His plan was to have a neurologist evaluate petitioner. Id. If Dr. Duharte, an infectious disease specialist, believed that Td vaccine can cause an adverse reaction 24 hours later, he does not specify what that reaction was, or give the basis for his opinion.

On September 11, 2007, Dr. Audwin Nelson, petitioner's primary care physician, reviewed petitioner's chart and discussed her case with Dr. Ramkissoon. Med. recs. Ex. 5, at 68. Petitioner had a tetanus vaccination on September 6, 2007, after suffering an injury. Id. She developed progressive lower extremity weakness "the next day." Id. She was admitted to Winter Haven Hospital on September 9, 2007, after she was unable to walk. Id. She had some tightness in her abdomen but no shortness of breath. Id. She did not have an increase in weakness over the prior 24 hours. Id. She saw Dr. Ramkissoon and Dr. Wong as neurologic consultants for probable GBS. Id. Dr. Ramkissoon detected that petitioner had 2+ deep tendon reflexes bilaterally on neurologic examination. Id. Of note, petitioner had a temperature of 102.1 degrees on September 10, 2007. Id. Dr. Nelson's impressions included a "possible tetanus toxoid reaction." Id. It is hard to determine from Dr. Nelson's notes when he considered petitioner's neurologic reaction to have begun. If he did consider petitioner to have a possible Td reaction with a one-day onset, he does not give a reason for his opinion.

On September 11, 2007, Dr. Duharte, the infectious disease specialist, wrote a progress note, saying, "Guillain-barre [sic] syndrome has being [sic] described in patient after tetanus toxoid, neurology evaluation will be very helpfull [sic] to rule it out." Med. recs. Ex. 5, at 83. This note is difficult to parse, in that the undersigned cannot determine if Dr. Duharte is referring to other doctors describing petitioner as having GBS or medical literature generally describing patients having GBS after tetanus toxoid vaccination. Nor can the undersigned determine if Dr.

[6] Dr. Duharte's handwriting is very difficult to read. Petitioner asserts he noted "highly suggestive," Pet'r's Mem., ECF No. 119, at 2, while respondent asserts he noted "highly suspicious." Resp't's Mem., ECF No. 121, at 5. The undersigned concludes that the word appears to be "suspicious."

Duharte thought a neurologist could rule out petitioner's GBS diagnosis or a causal relationship to the Td vaccine. When Dr. Duharte followed up with petitioner on September 17, 2007, he suspected that petitioner suffered from a viral infection, probably enterovirus 71, because of her symptoms. Id. at 129.

On October 9, 2007, petitioner's personal care physician, Dr. Nelson, saw petitioner and wrote that petitioner received Td vaccine after cutting her finger on September 6, 2007, followed by weakness in her legs a day later. Med. recs. Ex. 1, at 8. His impression was that she had GBS "secondary to tetanus toxoid booster." Id. at 10.[7] Dr. Nelson noted in his subsequent records that petitioner had an allergy to tetanus toxoid.[8] Med. recs. Ex. 39, at 34. On October 26, 2009, he again noted petitioner had an allergy to tetanus toxoid and recommended that she not receive further vaccinations. Med. recs. Ex. 40, at 16. Dr. Nelson is an internist, not a neurologist. He does not give a basis for his impression that petitioner had GBS secondary to tetanus toxoid booster, although he appears to believe that petitioner's onset was one day after her vaccination. In addition, he does not give a basis for his recommendation that petitioner not receive vaccines.

On October 18, 2007, petitioner saw Dr. Ramkissoon, who recounted petitioner's history and noted, "[A] precipitating cause was a tetanus toxoid injection." Med. recs. Ex. 3, at 13. He also noted that a lumbar puncture (spinal tap) showed evidence for viral meningitis as well. Id. Under the "Impression" section, Dr. Ramkissoon wrote that petitioner's GBS began "soon after" her tetanus toxoid injection. Id. at 17. He concluded, "The Patient most likely developed Guillian [sic]-Barre Syndrome as a result of the tetanus toxoid injection." Id. Although clearly attributing petitioner's neurologic condition to Td vaccine, Dr. Ramkissoon does not specify what amount of hours or days "soon after" is. Therefore, it is hard to state that his opinion encompasses a one-day onset.

Petitioner filed a statement from her treating neurologist, Dr. Ramkissoon, dated January 31, 2012, as Exhibit 65. Dr. Ramkissoon states that he first saw petitioner on September 9, 2007, at Florida Hospital Heartland. Ex. 65, at 1. She was unable to urinate and had lower extremity weakness but preserved reflexes. Id. He gave her a presumed diagnosis of GBS. Id. He writes, "On the basis of the clinical findings and observations and my expertise and knowledge as a practicing neurologist, it is my opinion that the neurological injury Mrs. Mosley suffered was caused by the tetanus vaccination, further evidenced by the fact that other causes were not

[7] Dr. Nelson wrote petitioner had GBS secondary to tetanus toxoid booster in his notes for follow-up visits on November 12, 2007 (Med. recs. Ex. 1 at 14), December 12, 2007 (Id. at 17), February 26, 2008 (Id. at 26), August 12, 2008 (Med. recs. Ex. 9, at 4), November 18, 2008 (Id. at 8), December 31, 2008 (Id. at 12), January 7, 2009 (Id. at 16), and February 18, 2009 (Id. at 20).

[8] See also Med. recs. Ex. 39, at 34 (February 2, 2010 visit); Id. at 30 (May 19, 2010 visit); Id. at 28–29 (July 12, 2010 visit); Id. at 25–26 (August 24, 2010 visit); Id. at 23–24, 205–206 (September 28, 2010 visit); Id. at 209 (November 24, 2010 visit); Id. at 212 (January 13, 2011 visit); Id. at 215 (January 28, 2011 visit); Id. at 218 (February 21, 2011 visit); Id. at 221 (March 30, 2011 visit).

present." Id. Dr. Ramkissoon opines that petitioner's vaccination triggered molecular mimicry to destroy segments of the myelin sheath around her nerves. Id. at 1–2. He also relies on "the fact that tetanus vaccination was given just *days* prior to her symptoms." Id. at 2 (emphasis added). He does not specify how many days he thinks there were between vaccination and the onset of petitioner's neurological condition, but his use of "days" in the plural conveys his belief that petitioner did not have a one-day onset.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]"

In addition, petitioner must show not only that but for her Td vaccination, she would not have had TM, but also that the vaccine was a substantial factor in causing her TM. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Vaccine Act does not permit the undersigned to rule in favor of petitioner based solely on her allegations unsupported by medical records or credible medical opinion. 42 U.S.C. § 300aa-13(a)(1). Nor is mere temporal association sufficient to prove causation in fact. Grant, 956 F.2d at 1148. Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Id. at 1149.

With regard to Althen prong one, the undersigned has no difficulty accepting that tetanus vaccine can cause transverse myelitis. Petitioners have prevailed in cases in which they alleged that tetanus vaccine caused their TM. See, e.g., Roberts v. Sec'y of HHS, No. 09-427V, 2013 WL 5314698, at *1 (Fed. Cl. Spec. Mstr. Aug. 29, 2013) (four-week onset); Helman v. Sec'y of HHS, No. 10-813V, 2012 WL 1607142, at *3 (Fed. Cl. Spec. Mstr. Apr. 5, 2012) (three-week onset; respondent elected not to defend the case); Bowes v. Sec'y of HHS, No. 01-481V, 2006 WL 2849816, at *3 (Fed. Cl. Spec. Mstr. Sept. 8, 2006) (two-week onset). The medical literature filed in this case also supports a finding that tetanus vaccine can cause TM. Petitioner has satisfied prong one of Althen.

Before discussing prong two of Althen, it is essential to discuss prong three because this case hinges on timing. Petitioner's expert, Dr. Triggs, states in his initial expert report that petitioner had transverse myelitis, which he describes as an "immune-mediated demyelinating disorder." Ex. 28, at 5. He later changed his opinion, testifying at the hearing that petitioner had an inflammatory lesion of her spinal cord, a partial myelitis. Tr. at 316. He also testified he was "hanging up on demyelination" because he was not convinced petitioner had demyelination. Tr. at 339. He did not know what the medical theory was connecting Td vaccine to transverse myelitis. Because of the difference between his expert report and his testimony, the undersigned ordered petitioner to file a supplemental expert report from Dr. Triggs. In this supplemental report, Dr. Triggs identifies the onset of petitioner's TM as 54 hours after vaccination, or just over two days. Ex. 70, at 4.

However, numerous records, including contemporaneous records, show that petitioner experienced urinary dysfunction, leg weakness, difficulty ambulating, and numbness and tingling in her legs within one day of receiving her tetanus vaccination. Petitioner received the tetanus vaccination on Thursday, September 6, 2007, at around 11:10 p.m. Med. recs. Ex. 5, at 11–12; Ex. 19, at 903. When she presented to the emergency room on Saturday, September 8, 2007, at 6:17 p.m., she reported fever, urinary frequency, problems urinating, body aches, joint aches, and generalized weakness. Med. recs. Ex. 5, at 141, 148–49. She reported that she started not feeling well on Friday, September 7, 2007. Id. at 149. On September 9, 2007, she gave a history that she had been aching all over and had weak legs for the past three days. Id. at 15. Numerous other histories within the next month document that her onset of symptoms, including progressive lower extremity weakness, malaise, polyarthralgia, polymyalgia, fever, tremor, and difficulty moving around, occurred the day after her vaccination. Id. at 15, 68, 127; Med. recs. Ex. 1, at 8; Ex. 4, at 12; Ex. 6, at 38. Dr. Delgado, a neurologist who saw petitioner on October 3, 2007, opined that her onset of acute inflammatory demyelinating polyneuropathy was on September 7, 2007. Med. recs. Ex. 4, at 13. Additionally, petitioner gave an extremely detailed history to Dr. McCluskey, in which she reported tingling in her toes and feet beginning at 4:00 a.m. on September 7, 2007. Med. recs. Ex. 19, at 911.

In her brief regarding the treating doctors' opinions, petitioner distinguishes between petitioner's urinary frequency on September 8, 2007, and her inability to urinate on September 9, 2007. Pet'r's Memo. at 11. Petitioner gave a history on September 8, 2007, at the Florida Hospital ER of bodily aching, generalized weakness, frequent urination, fever, and chills since September 7, 2007. Med. recs. Ex. 5, at 141, 148–49. This September 8, 2007 history of urinary dysfunction starting on September 7, 2007 is petitioner's earliest contemporaneous recounting of her symptomatology and its onset. Interestingly, in Dr. Triggs' initial expert report, he emphasizes that petitioner had early manifestation of her TM with urinary bladder dysfunction as one of the bases for his opinion that she had TM and not GBS. Ex. 28, at 5. But he ignores in his expert report that the onset of petitioner's urinary bladder dysfunction was on September 7, 2007, within one day of her receipt of Td vaccine. Med. recs. Ex. 5, at 141. Dr. Triggs then testified at the hearing that petitioner was having a vaccine reaction on September 8, 2007, when she complained of urinary frequency for the past day. Tr. at 297. His rationale for this was that

although she may have had a urinary tract infection based on the evidence of a bacterial infection, she was also having a vaccine reaction at the time because her primary complaints were pain and fever, which is not typical of a UTI. Id. at 298. He later changed his position in his supplemental expert report, stating that petitioner's urological complaints (as opposed to neurological complaints) and diagnostic tests on September 7, 2007, indicated she had a urinary tract infection, and her onset of TM was not until September 9, 2007. Ex. 70, at 4. On the one hand, Dr. Triggs focuses on petitioner's urinary dysfunction as proof in his initial expert report that petitioner had TM, not GBS, but on the other hand, he ignores that this proof includes a one-day onset from the Td vaccination. Furthermore, at the hearing, Dr. Triggs pinpointed the location of petitioner's lesion as in her conus medullaris, which is at the bottom part of the spinal cord, where the neural structures that control bladder function are and where the nerve roots for the lower extremities originate. Tr. at 330. This very location indicates that the lesion led to petitioner's urinary dysfunction, the onset of her TM.

Respondent's expert Dr. Leist testified that petitioner's urinary dysfunction was basic to her evolving neurologic disease, which he opines is due to a viral infection. He terms her neurologic disease as meningoradiculitis (involving both the spinal cord and the nerve roots). In focusing on the bladder dysfunction, Dr. Leist's opinion is consonant with Dr. Triggs' opinion in his initial report (before Dr. Triggs changed his opinion to view the bladder dysfunction as unrelated to petitioner's TM).

Like Dr. Triggs' testimony about petitioner's urinary dysfunction, Dr. Triggs' testimony about onset is similarly discordant. Although he testified that he would be unlikely to support a one-day onset based on his understanding of animal studies, he then concluded that a one-day onset was acceptable because there was no other factor that could have caused petitioner's TM. This opinion is legally insufficient, as the absence of other causes does not meet petitioner's affirmative duty to prove vaccine causation. Grant, 956 F.2d at 1148–49. Furthermore, Dr. Triggs omitted the possibility of an alternative cause—a urinary tract infection unrelated to her vaccination, which he had previously mentioned in his testimony. In contrast to Dr. Triggs' conclusion that there was no other factor that could have caused petitioner's TM, respondent's expert Dr. Leist opined there was a factor unrelated to the tetanus vaccine that caused petitioner's illness. Dr. Leist noted that petitioner had a significantly elevated white blood count consisting of lymphocytes and an elevated erythrocyte sedimentation rate, which are not indicia of TM but are indicia of a viral infection. In fact, two of petitioner's treating physicians opined that she had a viral meningitis or enterovirus 71 infection. However, the initial burden is on petitioner, not respondent. Because the undersigned does not hold that petitioner has satisfied her burden of proving an appropriate causal interval between tetanus vaccination and her neurologic illness, the burden does not shift to respondent to prove a known factor unrelated to the vaccine caused petitioner's illness.

Consonant with this view that an autoimmune mechanism takes time to manifest is the Tezzon article (Ex. 47), which describes a woman who had TM three weeks after tetanus toxoid vaccine. Ex. 47, at 2. The authors state that the process for the vaccine injury should take days

to manifest in order to enable the antibody movement or cell-mediated mechanism to result in the neurologic illness. They report cases involving neurologic illness after vaccination ranging from three to twenty days. Id. at 3. The case reports petitioner filed in the instant action list onset of TM from two days to weeks after vaccination. Medical literature, even in the form of case reports, does not support a one-day onset of TM.

In the remand instructions of the Opinion and Order, Judge Kaplan instructed the undersigned to evaluate and consider the opinions of the treating doctors as to whether or not petitioner proved her allegations.

Petitioner's treating neurologist, Dr. Ramkissoon, did not indicate in any of his records or his 2012 opinion letter that he considered petitioner's onset to be one day. He specifically wrote "days" in his opinion letter, showing that he apparently believed petitioner's onset was greater than 24 hours. This factual assertion that petitioner's onset was "days" is not borne out after a full review of the medical records, expert reports, and hearing testimony. Petitioner's urinary dysfunction, which Dr. Leist testified is related to her neurological disease, began on September 7, 2007, within one day of her vaccination. Moreover, Dr. Ramkissoon cites as one of the bases for his opinion a lack of other precipitating events. As previously stated, however, the absence of other causes does not meet petitioner's affirmative duty to prove vaccine causation. Grant, 956 F.2d at 1148–49. The fact that Dr. Ramkissoon could not find another reason for petitioner's supposed GBS days after her Td vaccination except the vaccine is not legally sufficient to establish causation.

The other treating doctors had various specialties, including infectious diseases, and are thus less qualified to opine on causation of a neurologic injury than a neurologist would be. The undersigned considers the opinion of a neurologist to be significantly more important than that of an internist in evaluating what is the appropriate time interval between Td vaccination and onset of neurologic disease. See Contreras v. Sec'y of HHS, No. 05-626V, 2013 WL 6698382, at *33–34 (Fed. Cl. Spec. Mstr. Nov. 19, 2013) (discussing that a treating neurologist's opinion is more credible in determining the cause of a neurological illness than the opinions of a treating emergency medicine specialist and a treating pediatric specialist), vacated and remanded on other grounds, 116 Fed. Cl. 472 (Fed. Cl. 2014), on remand, 2014 WL 8098606 (Fed. Cl. Spec. Mstr. Oct. 24, 2014), aff'd, slip op. (Fed. Cl. Apr. 17, 2015). Moreover, those who petitioner argues opine in favor of vaccine causation (Dr. Nelson, Dr. Beltre, and Dr. Duharte) either do not give a specific onset or do not explain the basis for their opinion. For example, Dr. Nelson, an internist, opined that petitioner's neurologic condition occurred one day after her vaccination and was caused by the vaccination. However, Dr. Nelson did not explain his reasoning for his diagnosis and did not address whether a one-day onset was a medically appropriate timeframe for Td vaccination to cause a demyelinating disorder. Dr. Beltre, another internist, noted that petitioner had acute febrile illness and a probable reaction to tetanus toxoid. He did not opine that petitioner had a demyelinating disease, did not clarify in his note when he thought

petitioner's onset was, and relied on an inaccurate history from petitioner.[9] The notes of Dr. Duharte (an infectious disease specialist arguably more qualified than an internist to opine on vaccine causation) are unclear as to whether he believed petitioner had GBS caused by Td vaccination. His notes suggest he was suspicious of such a causal relationship since he ordered a neurology consultation to "rule it out." But Dr. Duharte did not specifically discuss the temporal relationship between petitioner's vaccination and the onset of her demyelinating illness.

Dr. Nelson also recommended that petitioner not receive further vaccines. He did not, however, give an explanation or a basis for this recommendation. The Federal Circuit noted in Andreu v. Secretary of Health and Human Services, 569 F.3d 1367, 1376 (Fed. Cir. 2009), that, "[a] treating doctor's recommendation to withhold a particular vaccination can provide probative evidence of a causal link between the vaccination and an injury a claimant has sustained." However, "there is nothing in Andreu that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted." Snyder ex rel. Snyder v. Sec'y of HHS, 88 Fed. Cl. 706, 745 n.67 (Fed. Cl. 2009). In Andreu, the petitioner's admitting neurologist testified that he "thought it would be 'safer' for [the petitioner] not to receive additional pertussis inoculations because there was 'some evidence' to indicate that [the petitioner's] initial seizure was a 'reaction'" to the vaccine. 569 F.3d at 1376, 1377 n.3. In contrast to Andreu, Dr. Nelson offers no explanation for his recommendation, and his specialty (internal medicine) is not apposite to the disease at issue. As an internist, Dr. Nelson would not be as informed about the risk from and the type of reactions to tetanus toxoid vaccines as a neurologist. Dr. Nelson's opinion is therefore less probative of causation than the opinion of an expert witness in the appropriate specialty (neurology).

In drafting the Vaccine Act, Congress directed that the special masters consider the "entire record" in concluding whether or not to compensate a petitioner, but also specified that "[a]ny . . . diagnosis, conclusion, judgment, test result, report, or summary *shall not be binding* on the special master." 42 U.S.C. § 300aa-13(b)(1) (emphasis added). The undersigned has had the benefit of reading the expert reports, the transcripts of the expert testimony in this case, and numerous medical articles written that discuss the very subject matter concerning this case. The treating doctors have not. The undersigned relies, therefore, on the testimony of Dr. Leist rather than the testimony of Dr. Triggs or the opinions of petitioner's treating doctors. The undersigned also relies on conclusions and information in the medical literature filed into evidence in this case to conclude that one day is too soon for a vaccine to cause transverse myelitis.

Petitioner has failed to satisfy the third prong of Althen because an onset of TM one day after tetanus vaccination is too soon to support vaccine causation. The Federal Circuit has addressed the failure of a petitioner to satisfy prong three of Althen in De Bazan v. Sec'y of

[9] As the Federal Circuit has noted, a factfinder may properly reject an expert's opinion when the expert "assumes facts that are not supported by a preponderance of the evidence." Dobrydnev v. Sec'y of HHS, 566 Fed. Appx. at 982–83 (quoting Dobrydnev, 2010 WL 816881, at *9, n.12 (Fed. Cl. Spec. Mstr. Oct. 27, 2010)).

HHS, 539 F.3d 1347 (Fed. Cir. 2008) (11-hour onset of acute disseminated encephalomyelitis after tetanus vaccination). The Federal Circuit stated that a petitioner must provide "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." Id. at 1352. Since eleven hours was not sufficient time to produce molecules responsible for myelin destruction, the onset interval in De Bazan was inappropriate for causation. Id. at 1353, 1354. If any petitioner fails to satisfy the third prong of Althen, i.e., prove appropriate timing for credible causation from the vaccine, that petitioner will similarly fail to prevail on entitlement.

Because petitioner has failed to satisfy the third prong of Althen, she has also failed to satisfy the second prong of Althen, i.e., that tetanus vaccine did cause her TM in this case. This petition is hereby **DISMISSED**.

CONCLUSION

Petitioner's petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.[10]

IT IS SO ORDERED.

April 27, 2015
DATE

s/Laura D. Millman
Laura D. Millman
Special Master

[10] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.