

In the United States Court of Federal Claims

No. 08-724V

(Filed Under Seal: January 28, 2015)

(Reissued: February 12, 2015)¹

_____)	
IDA MOSLEY,)	National Childhood Vaccine Injury Act of
)	1986, 42 U.S.C. §§ 300aa-1 to -34 (2006);
Petitioner,)	Tetanus Toxoid Vaccine; Guillain-Barré
)	Syndrome; Transverse Myelitis;
v.)	Causation; <u>Althen v. Sec’y of HHS</u> , 418
)	F.3d 1274 (Fed. Cir. 2005); Medically
SECRETARY OF HEALTH AND HUMAN)	Acceptable Timeframe; Treating
SERVICES,)	Physicians’ Opinions.
)	
Respondent.)	
)	
_____)	

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OPINION AND ORDER

KAPLAN, Judge.

On October 14, 2008, petitioner Ida Mosley filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2006) (“Vaccine Act”), alleging that a tetanus toxoid (“Td”) vaccination had caused her to develop Guillain-Barré Syndrome (“GBS”). On June 23, 2014, a special master issued a decision denying Ms. Mosley compensation and holding that she had failed to establish causation between the vaccination and her injuries. Currently before this Court is Ms. Mosley’s motion for review. For the reasons set

¹ In accord with the Rules of the court of Federal Claims, App. B, Rule 18(b), this opinion was initially filed under seal to afford the parties fourteen days to propose redactions. The parties did not propose any redactions. Accordingly, the opinion is reissued publically in its original form.

forth below, this Court vacates the special master's decision and remands the case for further consideration in light of this opinion.

BACKGROUND²

I. Vaccination and Subsequent Treatment

On the evening of September 6, 2007, after having punctured her thumb with a piece of metal at work earlier in the day, Ms. Mosley went to the Emergency Room ("ER") at Florida Hospital, Heartland Division, Sebring. Mosley v. Sec'y of HHS, No. 08-724V, 2014 WL 3503389 at *3 (Fed. Cl. Spec. Mstr. June 23, 2014); Pet'r's Ex. 5 at 12. There, she received the Td vaccine at 11:10 p.m. Mosley, 2014 WL 3503389 at *3.

Two days later, on September 8, at 6:17 p.m., Ms. Mosley returned to the ER in a wheelchair, complaining of body aches, joint aches, fever, and frequent urination. Id. She gave a history that she had received the Td vaccination on September 6 and had started to feel unwell on September 7. Id. Because urinalysis revealed bacteria in Ms. Mosley's urine, the ER doctor diagnosed her with a urinary tract infection ("UTI") and prescribed an antibiotic. Id. at *1.

The next day, on September 9 at 3:31 p.m., Ms. Mosley returned to the ER, complaining of aching all over with weak legs for three days. Id. at *3. Ms. Mosley was unable to urinate. Id. She complained of suprapubic pain radiating down both legs. Id. She also complained of dull pain and pressure in her abdomen, whose onset had been gradual over four days. Id. The ER doctor noted that the examination of Ms. Mosley resulted in "no objective neurological findings"; her reflexes were normal, and there appeared to be "no sensory loss." Pet'r's Ex. 5 at 76; see also Mosley, 2014 WL 3503389 at *1. Ms. Mosley was admitted to the hospital for further examination and treatment. Id. at *3.

During her hospital stay, several physicians examined Ms. Mosley. On September 10, she was examined by Dr. Luis Duharte, an infectious disease specialist. Pet'r's Ex. 5 at 127. His notes from that examination are largely illegible, but according to Ms. Mosley, he noted that her presentation was "highly suggestive of [an] adverse [reaction] to [the] tetanus toxoid" vaccination. Pet'r's Mem. 2 (citing Pet'r's Ex. 5 at 127). But see Resp't's Mem. 5 n.4 (contending that the same notation reads "highly suspicious of [an] adverse reaction to tetanus toxoid"). On September 11, she was examined by Dr. Miguel Beltre, an internist, who noted his impression that her condition was "probably [a] reaction to [the] tetanus toxoid" vaccination. Pet'r's Ex. 19 at 197.

As it became clear that her symptoms were primarily neurological, the task of diagnosing her illness fell mostly to her neurologist, Dr. Bridglal Ramkissoon. Early in Ms. Mosley's hospitalization, Dr. Ramkissoon tested Ms. Mosley's reflexes, and because they appeared normal, he indicated that he "doubt[ed that] she ha[d] GBS." Pet'r's Ex. 5 at 70. Nevertheless, he ordered tests to rule out GBS as well as a spinal cord lesion. Id. Ms. Mosley underwent a

² The Court recites the background facts as the special master found them, with some details added from Ms. Mosley's medical records.

lumbar puncture on September 12, and an analysis of her cerebrospinal fluid (“CSF”) revealed an elevated protein level and pleocytosis. *Id.* at 60, 112-13. According to Dr. Ramkissoon, such results were inconsistent with GBS and, instead, suggestive of viral meningitis. *Id.* at 59. On September 14, however, Dr. Ramkissoon noted “absent reflexes in the lower extremities,” which “can be seen with [GBS].” *Id.* at 78. Based on these symptoms, Dr. Ramkissoon tentatively diagnosed Ms. Mosley with GBS and recommended that she be transferred to the intensive care unit to receive treatment for that condition. *Id.* at 78-79. He also ordered a repeat lumbar puncture. This time, the lumbar puncture “showed normal protein in her CSF, a [white blood cell count] of 33, and continued pleocytosis.” *Mosley*, 2014 WL 3503389 at *1 (citing Pet’r’s Ex. 5 at 49, 52, 77-79, 81).

Ms. Mosley also underwent MRIs of her brain, cervical spine, thoracic spine, and lumbosacral spine. *Mosley*, 2014 WL 3503389 at *1; Pet’r’s Ex. 5 at 51-53. The images of Ms. Mosley’s spine showed no spinal cord lesion or compression and thus, according to Dr. Ramkissoon, “failed to show . . . any evidence of transverse myelitis.” Pet’r’s Ex. 5 at 78. Additional MRI exams were ordered, but they were canceled because Ms. Mosley complained of claustrophobia. Pet’r’s Ex. 5 at 30-31. On September 15, Dr. Ramkissoon noted absent tibial and peroneal F waves and revised his possible diagnoses to include GBS, viral meningitis, and acute inflammatory demyelinating polyneuropathy (“AIDP”). Pet’r’s Ex. 5 at 45.

On September 20, Ms. Mosley was transferred to an inpatient rehabilitation center at Winter Haven Hospital. *Mosley*, 2014 WL 3503389 at *1 (citing Pet’r’s Ex. 4 at 12-22). There, she was examined by Dr. Alain Delgado, a neurologist, who noted his impression that Ms. Mosley suffered from AIDP “with onset dating back to September 7, 2007.” Pet’r’s Ex. 4 at 13. “What was atypical about this case,” he noted, “was the elevation in white blood cells at 60 without any specific risk factors to suggest other underlying infectious etiologies. It was improvement in white blood cell count which appeared to be 100% lymphocytic, suggesting some sort of viral syndrome.” *Id.* He further noted that some of Ms. Mosley’s symptoms, such as elevated protein, loss of ankle reflexes, and absent F waves, were “more typical of” GBS. *Id.*

After her discharge from Winter Haven on October 3, 2007, Pet’r’s Ex. 4 at 7, Ms. Mosley continued to attend follow-up appointments with her doctors. In one such appointment, her primary care physician, Dr. Audwin Nelson, noted that Ms. Mosley was “in the recovery phase” of “Guillain Barre syndrome secondary to tetanus toxoid booster.” Pet’r’s Ex. 1 at 10.

On October 30, Ms. Mosley began outpatient physical therapy. *Mosley*, 2014 WL 3503389 at *4 (citing Pet’r’s Ex. 6 at 38). She never returned to her job as a mental health counselor after her hospitalization. *Mosley*, 2014 WL 3503389 at *6; see also Pet’r’s Ex. 19 at 913. In March 2008, she began receiving social security disability benefits, Pet’r’s Ex. 23 at 1, and in December 2008, she entered into a worker’s compensation settlement with her employer’s carrier. Pet’r’s Ex. 20 at 11.

II. The Case Before the Special Master

Ms. Mosley filed her petition for compensation in the Office of Special Masters on October 14, 2008. Former Chief Special Master Gary Golkiewicz assigned the case to himself.

Mosley, 2014 WL 3503389 at *1. Between February 2, 2009 and November 30, 2010, the parties attempted to settle the case, but they ultimately failed to reach an agreement. Id.

On June 6, 2011, Ms. Mosley filed the expert report of Dr. William Triggs, a neurologist. Pet'r's Ex. 28. In the report, Dr. Triggs acknowledged that Ms. Mosley's treating physicians had diagnosed her with GBS. Id. at 5-6. He, however, disagreed. In his opinion, her symptoms were more consistent with a diagnosis of transverse myelitis ("TM"), which he described as "an immune-mediated spinal cord lesion." Id. at 6. He further opined that "Ms. Mosley developed transverse myelitis as a consequence of a tetanus vaccination received on September 6, 2007." Id. at 5. He identified the date of onset of Ms. Mosley's TM as September 9, characterizing the symptoms she complained that she had experienced on September 7 and 8 as "urological," not neurological. Pet'r's Ex. 70 at 4. According to Dr. Triggs's report, "[t]he occurrence of a neurological disorder just days after receiving the tetanus vaccination is within a medically appropriate time frame to implicate the vaccine," and "[t]he medical records do not reveal any alternative cause for her condition." Pet'r's Ex. 28 at 7.

On August 4, 2011, the government submitted a report from its expert, Dr. Thomas P. Leist, also a neurologist. Resp't's Ex. B. As he explained in his report, Dr. Leist concluded that Ms. Mosley's neurological symptoms began to manifest on September 7, less than twenty-four hours after she received the Td vaccination. Id. at 8. He opined that this time interval was "too short" for her symptoms to have been caused by the vaccine, "irrespective [of] whether the alleged injury is Guillain-Barre syndrome or meningitis as entertained by Dr. Ramkissoon, or transverse myelitis as indicated in the opinion of Dr. Triggs." Id. "It is furthermore my opinion," he wrote, "that the infection, which was present prior to administration of Td and which caused flu-like symptoms and fever symptoms, has to be considered as a cause of Ms. Mosley's presentation." Id. at 10.

Meanwhile, on June 23, 2011, the case was transferred to former Special Master Daria J. Zane. Mosley, 2014 WL 3503389 at *1. Between October 2011 and February 2012, the parties submitted additional medical records, medical literature, and other exhibits in preparation for trial.

One such exhibit was a letter from Dr. Ramkissoon, which included "a summary of care and treatment provided as well as [his] observations and opinions as a practicing clinical neurologist as to the cause of Mrs. Mosley's neurological injury." Pet'r's Ex. 65 at 1. He stated that it was his "opinion that the neurological injury Mrs. Mosley suffered was caused by the tetanus vaccination, further evidenced by the fact that other causes were not present." Id. Regarding the biological mechanism by which he believed the vaccine caused Ms. Mosley's injury, Dr. Ramkissoon explained that "[v]accination, by design, is intended to stimulate the immune system. In the case of Mrs. Mosley, the tetanus vaccination triggered the immune system, by a process known as molecular mimicry, to destroy segments of the myelin sheath around the nerves, causing weakness, motor dysfunction and sensory issues." Id. at 1-2. In conclusion, he stated, "[t]he fact that Mrs. Mosley had no other precipitating events, coupled with her clinical presentation, and the fact that a tetanus vaccination was given just days prior to her symptoms, I believe it is more likely than not, that the tetanus vaccination was the proximate cause of her injury." Id. at 2.

On February 8, 2012, Ms. Mosley filed a motion to consolidate proceedings, asking that the court consider the issues of both entitlement and damages at the same hearing. Mosley, 2014 WL 3503389 at *2. She also moved to exclude the expert report of Dr. James McCluskey, which was written for her disability claim against her employer. Id. Special Master Zane denied the motion to exclude Dr. McCluskey's report. Id.

Special Master Zane held hearings on July 11 and 20, 2012. Id. Ms. Mosley, Dr. Triggs, and Dr. Leist testified at the hearings. Id.

In his testimony, Dr. Triggs further explained his reasoning for rejecting the diagnosis of GBS and instead adopting the diagnosis of TM. Tr. 169-178, Aug. 8, 2012, ECF No. 88. He also testified regarding the date of the onset of Ms. Mosley's neurological symptoms, which he identified as September 9, 2007. Id. at 166. In his opinion, the symptoms that emerged on September 7 and caused Ms. Mosley to go to the emergency room on September 8—notably, frequent urination—were not neurological symptoms. Tr. 166-68, Aug. 8, 2012, ECF No. 88. Instead, according to Dr. Triggs, they were symptoms of a urinary tract infection, as diagnosed by the ER physicians. Tr. 168, Aug. 8, 2015, ECF No. 88. “[P]roblems urinating ha[ve] to be refined further,” he said. Id. He explained that, in contrast to the urinary frequency that Ms. Mosley reported experiencing on September 7 and 8, an “inability to empty the bladder . . . [or] to control the bladder is neurological. I don't see evidence here that that's the kind of problem Mrs. Mosley was having,” he said, until her emergency room visit on September 9. Id.

When asked about the process by which a vaccine could cause TM, Dr. Triggs testified that a vaccination is an “immunostimulatory event,” and that TM is an autoimmune disorder—in other words, Ms. Mosley's “immune system made a mistake and attacked part of [her] nervous system.” Id. at 179-80. When asked to elaborate, however, he responded that autoimmunity is not well understood. Id. at 180. He testified that it was his “educated speculation” that, “with any robust immune response there is the potential for that immune response to go awry and produce self-disease.” Id. “How or why that happens,” he said, “I don't think anybody understands.” Id. at 181. Dr. Triggs was pressed further about how the vaccine could cause TM, and he responded that he was not an immunologist and could not offer an opinion about whether it was molecular mimicry or some other mechanism at work in her case. Id. at 260.

On cross examination, counsel for the government asked Dr. Triggs to identify the earliest medical interval that might occur between receipt of the vaccine and “injury to the spinal cord resulting in demyelination,” regardless of the mechanism. Id. at 339. He responded that he was “not convinced that the injury to her cord was necessarily demyelination” and stated that, “I think if you're dealing with less than 24 hours, then I'm going to start to squirm a little bit because from my limited knowledge of immunology.” Id. at 340. “But as a clinician,” he explained, “if I don't have any other let's call it immunostimulatory thing going on and my patient gets that and asks me why do you think I had this, I mean, I would implicate what's available to me. If it's 23 hours, I'm not necessarily going to say it absolutely cannot be the vaccine.” Id.

When the government's expert, Dr. Leist, took the stand, he testified that, in his opinion, the best diagnosis for Ms. Mosley's condition was viral meningoradiculitis. Tr. 369, Aug. 8,

2012, ECF No. 90. “Meningoradiculitis,” he explained, “is a process that is kind of in between transverse myelitis and a Guillain-Barre syndrome” because, as in GBS, the nerve roots are affected and, as in TM, the spinal cord is also affected. Id. at 365-66. He further testified that, regardless of the particular diagnosis, id., the shortest period of time in which an immune response could manifest as neurological symptoms “is probably somewhere around five days.” Id. at 378.

On January 14, 2013, the parties filed simultaneous post-hearing briefs, and on April 15, 2013, they filed simultaneous responsive briefs. In her briefs, Ms. Mosley addressed the difference in opinion between her treating physicians (who diagnosed her to be suffering from GBS) and her testifying expert (who identified TM as her diagnosis). See Pet’r’s Post-Hearing Mem. 9-12, ECF No. 94. Citing several decisions from the Court of Federal Claims and Office of Special Masters, she argued that a petitioner has a limited duty to categorize, label, or prove a particular diagnosis of her injury, and there is no duty to distinguish between diagnoses if the distinction bears no significance in the causation analysis, such as when, as here, all proposed diagnoses are autoimmune demyelinating disorders. Id. at 9-12 (citing Kelley v. Sec’y of HHS, 68 Fed. Cl. 84 (2005); Schmidt v. Sec’y of HHS, 2009 U.S. Claims LEXIS 709 (Fed. Cl. Spec. Mstr. Dec. 17, 2009); Whitener v. Sec’y of HHS, 2009 WL 3007380 (Fed. Cl. Spec. Mstr. Sept. 2, 2009); Hawkins v. Sec’y of HHS, 2009 U.S. Claims LEXIS 169 (Fed. Cl. Spec. Mstr. Feb. 27, 2009)).

On August 31, 2013, Special Master Zane retired. Mosley, 2014 WL 3503389 at *2. Chief Special Master Denise K. Vowell assigned the case to herself to explore the possibility of settlement. Id. The parties again failed to settle, and on November 6, 2013, the case was transferred to Special Master Laura Millman. Id. Special Master Millman held a status conference and ordered Ms. Mosley to obtain a supplemental expert report from Dr. Triggs, which Ms. Mosley filed on May 19, 2014.³

³ Special Master Millman requested a supplemental report from Dr. Triggs “[b]ecause of the difference between his expert report and his testimony” at the hearing. Mosley, 2014 WL 3503389 at *14. In particular, Dr. Triggs had changed his opinion regarding whether Ms. Mosley’s disorder involved demyelination, and “[h]e did not know what the medical theory was connecting Td vaccine to transverse myelitis.” Id. In the supplemental report, Dr. Triggs explained his equivocation at the hearing regarding demyelination and the mechanism by which the vaccine could cause TM:

In my testimony, I was reluctant to commit to molecular mimicry as the actual mechanism whereby vaccination resulted in Mrs. Mosley’s myelitis. This reluctance was based on my knowledge, as a clinician, that the mechanism of transverse myelitis is incompletely understood. I do not reject molecular mimicry as an operant mechanism in this case. It is the viable mechanism, more likely than not, at work. However, the practice of medicine is not in absolutes and scientific certainty. I cannot say with absolute certainty the specific mechanism (or mechanisms) or autoimmunity at work. We cannot always identify and distinguish demyelination from axonal or cellular injury in an inflammatory process like transverse myelitis, and without specific pathology, we do not know if the neuronal targets are myelin, interneurons or axons. What we do know, is

III. The Special Master's Decision

Special Master Millman issued her decision denying compensation on June 23, 2014. While she had “no difficulty accepting that tetanus vaccine can cause transverse myelitis” (thereby satisfying prong one of the standard set forth in Althen v. Secretary of Health and Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005)), she concluded that Ms. Mosley had failed to demonstrate causation. Mosley, 2014 WL 3503389 at *14. Specifically, she concluded that Ms. Mosley failed to establish by preponderant evidence “a proximate temporal relationship between vaccination and injury,” as required by prong three of Althen. Mosley, 2014 WL 3503389 at *14.

First, the special master identified what she viewed as inconsistencies in Dr. Triggs's testimony. For instance, Special Master Millman observed, Dr. Triggs had focused on Ms. Mosley's urinary dysfunction as proof that she had TM and not GBS, but he had ignored that Ms. Mosley began experiencing urinary dysfunction on September 7, 2007, less than twenty-four hours after her Td vaccination. Id. Furthermore, “[a]lthough 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.” Id. at *15.

After expressing a lack of confidence in Dr. Triggs's opinion regarding the possibility of a one-day onset between the vaccine and Ms. Mosley's injuries, Special Master Millman cited Bazan v. Secretary of Health and Human Services, 539 F.3d 1347 (Fed. Cir. 2008). Mosley, 2014 WL 3503389 at *15. In that case, the Federal Circuit had affirmed a special master's finding that the alleged eleven-hour onset of a demyelinating central nervous system disease was too short. Id. She further found that “[m]edical literature, even in the form of case reports, does not support a one-day onset of TM.” Id. She cited one of the articles submitted by the petitioner (Pet'r's Ex. 47), which “describes a woman who had TM three weeks after tetanus toxoid vaccine.” Mosley, 2014 WL 3503389 at *15. Special Master Millman noted that the authors of the article “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,” and that “[t]hey report cases involving neurologic illness after vaccination ranging from three to twenty days.” Id. at *15. Similarly, she noted, “[t]he case reports petitioner filed in the instant action list onset of TM from two days to weeks after vaccination.” Id.

In short, Special Master Millman held that Ms. Mosley had “failed to satisfy the third prong of Althen because an onset of TM one day after [a] tetanus vaccination is too soon to support vaccine causation.” Id. at *16. Further, she stated, “because petitioner has failed to satisfy the third prong of Althen, she has also failed to satisfy the second prong of Althen, i.e.,

the process of immunization, specifically the tetanus vaccination, can stimulate a cross-reactivity of immune cells from the initial immune-stimulatory challenge and transmute an inadvertent immune response against self-cells.

Pet'r's Ex. 70.

that tetanus vaccine did cause her TM in this case.” Id. Accordingly, the special master dismissed Ms. Mosley’s petition.

IV. Ms. Mosley’s Motion for Review

On July 23, 2014, Ms. Mosley filed a motion for review in this Court pursuant to Appendix B of the Rules of the United States Court of Federal Claims, Vaccine Rule 23. She grounds her motion on a single argument: that the special master committed error when she failed to consider or discuss the opinions of Ms. Mosley’s treating physicians finding that the Td vaccination caused her neurological disorder. Pet’r’s Mem. Supp. Mot. for Review (“Pet’r’s Mem.”) 5. Ms. Mosley argues that the Federal Circuit has found error in decisions in which the special master did not consider the opinions of the petitioner’s treating physicians when analyzing causation. Pet’r’s Mem. 6-9 (citing, e.g., Capizzano v. Sec’y of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006); Andreu v. Sec’y of HHS, 569 F.3d 1367, 1375-76 (Fed. Cir. 2009)). Here, Ms. Mosley argues, “the Special Master’s Decision neglected to acknowledge, much less weigh” the numerous notations of her treating physicians linking her injury to the vaccine or Dr. Ramkissoon’s letter detailing his opinion, as Ms. Mosley’s neurologist, that her injury was caused by the tetanus vaccination. Pet’r’s Mem. 6; see, e.g., Pet’r’s Ex. 1 at 10; Ex. 3 at 13; Ex. 19 at 197; Ex. 65 at 1.

For the reasons set forth below, the Court agrees with Ms. Mosley that the special master committed legal error when she failed to consider and discuss the opinions of Ms. Mosley’s four treating physicians as set forth in chart notations and/or written reports. While the Court expresses no opinion regarding the weight that should be ascribed to this evidence and whether it is sufficient to change the result the special master has reached, it agrees with Ms. Mosley that those opinions were relevant to the determination of whether petitioner made out her prima facie case under prong three of Althen. For that reason, the Court vacates the special master’s decision and remands this case back to her, to allow her to apply her special expertise to these issues. See 42 U.S.C. § 300aa-12(e)(2)(C) (providing that, upon review of a special master’s decision, “the United States Court of Federal Claims . . . may . . . remand the petition to the special master for further action in accordance with the court’s direction”); Doe 93 v. Sec’y of HHS, 98 Fed. Cl. 553, 571 (2011) (finding that special master improperly elevated burden of proving causation and remanding to special master for application of appropriate burden); Boley v. Sec’y of HHS, 82 Fed. Cl. 407, 414-15 (2008) (finding multiple errors in special master’s decision, including that special master failed to consider all relevant evidence in the record, and remanding to the special master for reevaluation, while expressing no view on whether petitioner was entitled to recover).

DISCUSSION

I. Legal Standards

A. Standard of Review

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:

- (A) uphold the findings of fact and conclusions of law [of the special master] and sustain the special master’s decision;
- (B) set aside any findings of fact or conclusions of law found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue a separate decision; or
- (C) remand the case to the special master for further action [in accordance with the court’s direction].

RCFC App. B, Rule 27; Flores v. Sec’y of HHS, 115 Fed. Cl. 157, 161 (2014) (citing 42 U.S.C. § 300aa-12(e)(2)). On review, 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,” which “are all matters within the purview of the fact finder.” Porter v. Sec’y of HHS, 663 F.3d 1242, 1249 (Fed. Cir. 2011).

B. Causation

Under the Vaccine Act, a claim for compensation proceeds through one of two tracks. In what is known as a “table claim,” “a claimant who shows that . . . she received a vaccination listed in the Vaccine Injury Table (“table”), 42 U.S.C. § 300aa-14, and suffered an injury listed in the table within a prescribed period is afforded a presumption of causation.” Andreu, 569 F.3d at 1374 (citing 42 U.S.C. § 300aa-11(c)(1)(C)(i)). On the other hand, in an off-table claim, like Ms. Mosley’s, the petitioner must establish that her injury was “caused in fact” by the vaccine; that is, she must establish “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.” Mosley, 2014 WL 3503389 at *14 (citing Shyface v. Sec’y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999)).

In Althen, the Federal Circuit delineated three requirements for a prima facie case of causation:

[The petitioner’s] burden is to show by preponderant evidence⁴ that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

418 F.3d at 1278. Regarding prong three, the main requirement at issue in this case, a petitioner must provide “preponderant proof that the onset of symptoms occurred within a timeframe for

⁴ “The burden of showing something by a ‘preponderance of the evidence,’ the most common standard in the civil law, simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact’s existence.” Moberly v. Sec’y of HHS, 592 F.3d 1315, 1322 n.2 (quoting Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal., 508 U.S. 602, 622 (1993)).

which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." De Bazan, 539 F.3d at 1351.

II. Merits Analysis

A. The special master committed legal error when she failed to address the evidence in the record showing that several of Ms. Mosley's treating physicians ascribed her injuries to the Td vaccination.

As described above, the special master found that the onset of Ms. Mosley's neurological disorder occurred less than twenty-four hours after she received her vaccination on September 6. Thus, as the special master observed, the record shows that Ms. Mosley reported to her treating physicians that she had started feeling sick on September 7, the day after her vaccination. Mosley, 2014 WL 3503389 at *1, 3-7, 11-14. Furthermore, the special master relied on the report and testimony of the government's expert, Dr. Leist, who explained that Ms. Mosley's bladder presentation on September 7 and 8 and her bladder presentation on September 9 were not separate events, but that rather, they were parts of the same complex of neurological symptoms. Mosley, 2014 WL 3503389 at *13; Tr. 379-80, Aug. 8, 2012, ECF No. 90. Although Ms. Mosley's expert, Dr. Triggs, had distinguished between these two presentations and concluded that only the urinary retention arising on September 9 was neurological, the special master acted within her discretion when she found that Dr. Leist's opinion in this regard was more credible than Dr. Triggs's. See Porter, 663 F.3d at 1250 ("[S]pecial masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act.").

While Ms. Mosley continues to express disagreement with the special master's conclusion regarding the timing of the onset of her neurological symptoms, she does not argue that the special master's finding on this issue was arbitrary, capricious, or contrary to law. Instead, her challenge to the special master's decision focuses on the special master's finding that a one-day onset was not a medically appropriate timeframe for establishing causation and that, accordingly, Ms. Mosley failed to make out her prima facie case under Althen prong three. Pet'r's Mem. 5-13.

In reaching this conclusion, as described above, the special master first noted that "[t]he Federal Circuit has addressed the short onset of a demyelinating central nervous system disease after tetanus vaccination"—specifically, an eleven-hour onset—"as preventing a petitioner from satisfying her burden of proof," Mosley, 2014 WL 3503389 at *15 (citing de Bazan, 539 F.3d at 1353-54).⁵ She also cited case reports that "list onset of TM from two days to weeks after

⁵ It is not clear from the special master's decision whether she was citing de Bazan for the legal principle that prong three of Althen is not met where the interval between the vaccine and injury is too short, or whether she was using de Bazan to support a factual finding that a period of less than twenty four hours (eleven hours in de Bazan) between the vaccination and the onset of the injury "was not sufficient time to produce molecules responsible for myelin destruction." 2014 WL 3503389 at *15. While it is, of course, perfectly appropriate (in fact, necessary) to consider and follow de Bazan for purposes of the legal analysis, "[a]s a general rule, a special master should not base his findings on causation-in-fact in one case on other Vaccine Act cases."

vaccination,” as well as a 1994 article from the Italian Journal of Neurological Sciences, in which “[t]he 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.” Id. (citing Pet’r’s Ex. 47).

Notwithstanding the foregoing, as Ms. Mosley observes, her treating physicians concluded that the Td vaccination caused her neurological disorder. Implicit in those conclusions, Ms. Mosely argues, is their opinion that a one-day interval for the onset of symptoms was a medically appropriate time period within which to infer causation. Pet’r’s Mem. 11. She contends that the special master’s failure to even discuss their opinions in her analysis of prong three constituted legal error. Id. at 5-12.

The Court agrees with Ms. Mosley. The Federal Circuit has underscored the value of medical records as evidence in Vaccine Act cases, observing that “[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.” Curcuras v. Sec’y of HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Furthermore, the court of appeals has noted, “[w]ith proper treatment hanging in the balance, accuracy has an extra premium.” Id. Such records have particular importance, the court observed, because they are “generally contemporaneous to the medical events.” Id.

Similarly, the opinions of treating physicians are highly relevant in vaccine cases. As the Federal Circuit observed in Capizzano and Andreu, because “treating physicians are likely to be in the best position” to detect a link between a petitioner’s vaccination and her injury, the opinions of a petitioner’s treating physicians are “quite probative” of causation. Andreu, 569 F.3d at 1375; Capizzano, 440 F.3d at 1326. Indeed, in Capizzano, the Federal Circuit held that the special master committed legal error by failing to consider such evidence, warranting vacation of the special master’s judgment. Capizzano, 440 F.3d at 1326.

In this case, it may well be that the special master concluded that the treating physicians’ general notations and opinions regarding the etiology of Ms. Mosley’s injuries should be discounted in favor of the medical literature and/or other expert opinion (such as Dr. Leist’s) that specifically addressed the time frame within which causation could be inferred. But the Court has no way of knowing whether that was the conclusion that the special master reached and if so, the basis for such conclusion, because the special master did not mention the treating physicians’ opinions that the vaccine caused Ms. Mosley’s injury at all in her analysis of causation. See Mosley, 2014 WL 3503389 at *14-15. In fact, there is barely any citation of those opinions in the special master’s recitation of the facts. See id. at *1-6.

Contreras v. Sec’y of HHS, 107 Fed. Cl. 280, 308 (2012) (citing Moberly, 592 F.3d at 1325; Caves v. Sec’y of HHS, 100 Fed. Cl. 119, 129 n.11 (2011); Hanlon v. Sec’y of HHS, 40 Fed. Cl. 625, 630 (1998), aff’d, 191 F.3d 1344 (Fed. Cir. 1999)).

Of course, a “special master [is] not required to discuss every piece of evidence or testimony in her decision.” Snyder v. Sec’y of HHS, 88 Fed. Cl. 706, 728 (2009) (citing Maza v. Sec’y of HHS, 67 Fed. Cl. 36, 38 (2005)). But the opinions of treating physicians on the ultimate issue of causation can hardly be characterized as mere “minutiae.” See Moreno v. Sec’y of HHS, 65 Fed. Cl. 13, 26 (2005). To the contrary, they are highly relevant and warrant thorough analysis and discussion. Capizzano, 440 F.3d at 1326. The special master’s failure to engage in such analysis and discussion in this case, the Court concludes, constitutes reversible error.

B. The government’s arguments are without merit.

The government does not dispute that the special master did not address the opinions of Ms. Mosley’s treating physicians in her causation analysis. Instead, it points out that Capizzano and Andreu addressed the relevance of treating physicians’ opinions in the context of Althen prong two analysis. Resp’t’s Mem. 13-14. The government contends that, therefore, the Federal Circuit’s statements regarding the probative value of these opinions are not relevant to Althen prong three. Resp’t’s Mem. 13-14.

This argument is unpersuasive. The government has offered no reason why treating physicians’ opinions regarding the cause of Ms. Mosley’s injuries would be considered relevant in the context of a prong-two, but not a prong-three analysis. In fact, the court of appeals in Capizzano noted that evidence used to satisfy one of the Althen prongs can “overlap to satisfy another prong.” Capizzano, 440 F.3d at 1326. Here, a number of Ms. Mosley’s treating physicians explicitly noted their impression that her injuries resulted from her Td vaccination. See, e.g., Pet’r’s Ex. 1 at 10; Ex. 3 at 13; Ex. 19 at 197; Ex. 65 at 1. Each of these physicians recorded Ms. Mosley’s medical history and had access to her medical records. Id. Arguably, therefore, implicit in their opinions that the vaccine caused Ms. Mosley’s injury is a finding that Ms. Mosley’s neurological symptoms appeared within a medically appropriate timeframe to suggest a causal connection. Cf. Contreras, 107 Fed. Cl. at 299 (observing that “it is difficult to conceive of a treating physician who would conclude that a vaccine caused the petitioner’s illness without also concluding that the onset of the illness was within a medically-acceptable time-frame”).

There is similarly no merit to the government’s arguments that the opinions of Ms. Mosley’s treating physicians are irrelevant because they believed that Ms. Mosley suffered from GBS while plaintiff’s expert, Dr. Triggs, testified that she suffered from TM. See Resp’t’s Mem. 1, 15-16. First, the Court finds unpersuasive the government’s argument that in her case in front of the special master, Ms. Mosley “abandoned her GBS claim” by presenting Dr. Triggs as her expert. Id. at 1. In fact, in her first post-hearing brief, Ms. Mosley acknowledged the discrepancy between her treating physicians’ diagnosis and her expert’s, and she argued that, under the circumstances of her case, it was irrelevant whether her condition was characterized as GBS or TM. Pet’r’s Post-Hearing Mem. 9-12. Ms. Mosley’s position—that it is immaterial whether her condition was classified as GBS or TM—has support in prior decisions in which the two conditions are characterized as not materially different for purposes of determining causation. See, e.g., Contreras, 107 Fed. Cl. at 293; Whitener, 2009 WL 3007380 at *19.

Further, in general, there is no requirement to ascribe a diagnosis to a petitioner's injury in a Vaccine Act case. See Porter, 663 F.3d at 1249; Lombardi v. Sec'y of HHS, 656 F.3d 1343, 1351 (Fed. Cir. 2011); Andreu, 569 F.3d at 1382. The government's reliance upon Broekelschen v. Secretary of Health and Human Services, 618 F.3d 1339 (Fed. Cir. 2010), for a contrary proposition is misplaced. To be sure, in that case, the Federal Circuit confronted a record that contained evidence supporting two different diagnoses and held that "it was appropriate for the special master to first find which of [the petitioner's] diagnoses was best supported by the evidence presented in the record before applying the Althen test." 618 F.3d at 1342-44, 1346. But as the Federal Circuit noted in Broekelschen, the case before it was "atypical because the injury itself [was] in dispute, the proposed injuries differ significantly in their pathology, and the question of causation turns on which injury [petitioner] suffered." Id. at 1346. Thus, the court reasoned, Broekelschen differed from other, more typical cases where, for example, "competing diagnoses were variants of the same disorder." Id. (citing Kelley v. Sec'y of HHS, 68 Fed. Cl. 84, 100-01 (2005)).

In short, under Broekelschen, the opinions of Ms. Mosley's treating physicians who diagnosed her with GBS would become irrelevant to the analysis of causation only upon a finding that "the question of causation turns on which injury [Ms. Mosley] suffered" and that the injury she suffered was TM. Broekelschen, 618 F.3d at 1346. Here, the special master did not make such a finding. Because the special master's opinion is silent on the issue, the Court cannot assume that the opinions of Ms. Mosley's treating physicians were entitled to no weight because they characterized her condition as GBS rather than TM.

CONCLUSION

Based on the foregoing, the Court concludes that it is necessary to remand this case back to the special master to allow her to consider and explain the impact, if any, of the opinions of Ms. Mosley's treating physicians on her conclusion that Ms. Mosley failed to make out her prima facie case under Althen. Accordingly, the special master's decision denying compensation to petitioner is **VACATED** and **REMANDED** for 120 days for further consideration in light of this opinion.

Pursuant to Vaccine Rule 18(b), this opinion will be held for fourteen days to afford each party an opportunity to object to the public disclosure of any financial or medical information furnished by that party. An objecting party must provide the court with a proposed redacted version of the decision. In the absence of an objection, the entire decision will be made public.

IT IS SO ORDERED.

s/ Elaine D. Kaplan
ELAINE D. KAPLAN
Judge