In the United States Court of Federal Claims

No. 07-443 V
(Filed June 24, 2011)[1]

* * * * * * * * * * * * * * * * *	*	
JOAN CAVES,	*	National Childhood Vaccine
	*	Injury Act of 1986, 42 U.S.C.
Petitioner,	*	§§ 300aa-1 to -34 (2006); Proof
	*	of Causation; Reliability of
v.	*	Expert Testimony.
	*	
SECRETARY OF	*	
DEPARTMENT OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
* * * * * * * * * * * * * * * * *	*	

Ronald C. Homer, Boston, MA, for petitioner.

Michael P. Milmoe, United States Department of Justice, with whom were *Tony West*, Assistant Attorney General, *Timothy P. Garren*, Director, *Mark W. Rogers*, Deputy Director, *Catharine E. Reeves*, Assistant Director, Washington, DC, for respondent.

OPINION AND ORDER

---

[1]/ Pursuant to Rule 18(b) of Appendix B of the Rules of the United States Court of Federal Claims, this Opinion and Order was initially filed under seal on May 18, 2011. Pursuant to ¶ 4 of the ordering language, the parties were to propose redactions of the information contained therein on or before June 15, 2011. No proposed redactions were submitted to the court. Thus, with the exception of the publication date, this footnote, and the correction of two minor typographical errors on page 31 of the opinion, the sealed and public versions of this opinion are identical.

Bush, *Judge*.

Now pending before the court is petitioner's motion for review of the special master's November 29, 2010 final decision (Opin.) denying her petition for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2006) (the Vaccine Act). For the reasons stated below, the court denies petitioner's motion for review and affirms the decision of the special master.

BACKGROUND[2]

I. Factual History

Petitioner Joan Caves received her annual influenza vaccination on November 18, 2005.[3] Ex. 10 at 5; Ex. 11 ¶ 4. When she received that vaccine, petitioner was fifty-two years old and was employed as a registered nurse at Raulerson Hospital in Okeechobee, Florida.[4] Ex. 10 at 1, 5; Ex. 11 ¶¶ 1, 3.

On or about December 4, 2005, Mrs. Caves experienced a minor illness that is described variously in the record as a "very mild sinus cold," Ex. 5 at 741, "mild sinus congestion symptoms," Ex. 5 at 32, "a flu-like syndrome," Ex. 9 at 3, and "some flu-like symptoms," Ex. 5 at 35.

On the morning of December 11, 2005, approximately three weeks after she

---

[2]/ Petitioner's exhibits in this case are numbered (*e.g.*, Ex. 1), while respondent's exhibits are marked alphabetically (*e.g.*, Ex. A).

[3]/ According to her employee health records, Mrs. Caves received influenza vaccinations in 2002, 2003 and 2004 as well. *See* Ex. 10 at 4, 6-7.

[4]/ Prior to her vaccination, Mrs. Caves had been treated for hypertension, mitral valve prolapse, and parasthesias over the left supraorbital region with associated redness in her left eye, the latter of which petitioner's physician believed to be consistent with an ocular migraine. Ex. 1 at 7. The parties appear to agree that none of those conditions is relevant to petitioner's subsequent development of transverse myelitis. Although petitioner's medical records do make reference to a prior onset of shingles, *see id.* at 5, petitioner did not provide any records related to an initial diagnosis of shingles.

received the vaccination and one week following her minor illness, Mrs. Caves experienced pain and weakness in her legs and lower back while sitting in a chair at home. Ex. 11 ¶ 5. Although her discomfort subsided when she began to walk around, *id.*, petitioner experienced severe pain on the way home from church later that day, *id.* ¶ 6. When she returned home, Mrs. Caves went to bed, which temporarily relieved some of her pain. *Id.* When she got out of bed later that afternoon, however, her legs were numb and she was completely unable to walk. *Id.* ¶ 7. Mrs. Caves was transported to the emergency room at Raulerson Hospital by the Okeechobee County Fire Rescue Department at approximately 6:00 p.m. that evening. *See* Ex. 4 at 1.

Upon petitioner's arrival in the emergency room, a registered nurse prepared a triage report to assess her condition. *See* Ex. 5 at 843-45. The patient complaint section of the report noted the following:

> [Patient states] that she was sitting having coffee and her legs started cramping both legs, went to church and about 1100 more cramping and weakness in her legs in the bed until 1500, was unable to walk or stand, right leg numb. Pain in butt and leg when the pain gets worse to numbness increases. Right leg numb up to hip area. Denies any injury. Had a flu shot 2 weeks ago.

Id. at 843. The assessment section of the triage report noted that petitioner was "awake and alert," and had some limited sensation in her left leg. *Id.* However, the report further stated that petitioner could not move her right leg or foot at all, and was numb up to her right hip. *Id.* at 844.

During her initial stay at Raulerson Hospital, Mrs. Caves underwent a number of laboratory tests and other diagnostic procedures. *See* Ex. 5 at 860-62, 866-69 (noting that the hospital performed lab work, including various blood tests, as well as an x-ray of petitioner's spine and a computerized tomography (CT) scan of her head). The CT scan of petitioner's head revealed "no acute intracranial pathology." Ex. 1 at 38; Ex. 14 at 1. Similarly, the x-rays of petitioner's lumbosacral spine did not reveal any acute abnormalities. Ex. 1 at 40; Ex. 5 at 868 (noting a chronic degenerative narrowing of the disk space between the fifth lumbar vertebra and the sacrum, but no acute injury).

Early the next morning, petitioner was transferred to the Shands Medical Center (Shands) at the University of Florida in Gainesville, Florida. *See* Ex. 5 at 856-57. According to the physicians' notes for her stay at Shands, Mrs. Caves received a tentative diagnosis of Guillain-Barré syndrome, an inflammatory demyelinating disorder of the peripheral nervous system, *see* Ex. 6 at 47, but that diagnosis was later changed to transverse myelitis (TM), an inflammatory demyelinating disorder of the spinal cord, *see id.* at 49. Petitioner was subjected to extensive testing at Shands for the purpose of reaching a definite diagnosis based on an initial differential diagnosis that included both Guillain-Barré syndrome and TM. *See* Ex. 6 at 15.

Upon her arrival at Shands, petitioner was examined by a resident and the attending physician, Dr. Ramon Rodriguez. The resident prepared a patient history and physical report, which was reviewed and approved by Dr. Rodriguez. *See* Ex. 6 at 14-16. In describing the history of petitioner's current illness, the report observed that Mrs. Caves "does note having taken a flu shot two weeks before the onset of symptoms and a very mild sinus cold recently with no flu-like symptoms." *Id.* at 14. In assessing petitioner's condition, the report noted that

> Ms. Caves is a 52-year-old with the acute onset of severe posterior leg pain and paraparesis. She has loss of some of the lower extremity reflexes. Interestingly, she did obtain a flu shot two weeks ago. The differential diagnosis includes Guillain-[Barré] syndrome, transverse myelitis which could be idiopathic or autoimmune, or less likely a vascular event in the spinal cord. Guillain-[Barré] syndrome certainly could produce her weakness and loss of reflexes with paresthesias and sensory loss, particularly two weeks after an influenza immunization; however, the strikingly abrupt onset of her symptoms would be atypical for this disorder making transverse myelitis highly suspect.

Id. at 15. In his statement at the end of the report, Dr. Rodriguez noted that petitioner "very likely has transverse myelitis and work up is to try to find potential etiologies." *Id.* at 16.

Mrs. Caves underwent CT scans of her chest, abdomen, and pelvis during

her stay at Shands. *See* Ex. 6 at 35-40. While the CT scans did not indicate any compression of the spinal cord or other abnormalities, the resident radiologist recommended that petitioner undergo magnetic resonance imaging (MRI) due to her neurological symptoms. *Id.* at 35, 37, 39. The resident radiologist identified Guillain-Barré syndrome as a likely diagnosis. *Id.*

Mrs. Caves then received MRIs of her brain and the cervical, thoracic, and lumbar regions of her spine. Ex. 6 at 2. The resident radiologist who examined the MRI images of petitioner's lumbar spine noted the presence of a conus edema (a swelling of the distal end of the spinal cord) without evidence of vasculopathy or a compressive lesion. *Id.* at 41. He further noted that the "basis for the cord swelling is not apparent." *Id.* A different resident radiologist who examined the MRI images of the cervical and thoracic regions of petitioner's spine did not detect any abnormalities in those regions, but did make note of the conus edema revealed by the earlier MRI of petitioner's lumbar spine. *Id.* at 32, 34. In addition, this resident radiologist suggested a vascular insult, an inflammatory process such as acute disseminated encephalomyelitis, or an infectious etiology as potential diagnoses of petitioner's condition. *Id.* The MRI of petitioner's brain did not reveal any abnormalities. *Id.* at 45.

In a progress note prepared on December 13, 2005, TM was described as the "most likely" diagnosis of petitioner's condition. Ex. 6 at 17. In addition, the progress note stated that Mrs. Caves had responded well to steroid treatment and was regaining both muscle strength and sensation in her legs, and recommended that petitioner continue with steroid treatment and begin physical or occupational therapy. *Id.* In another progress note prepared the same day, the attending neurologist stated that "we don't know the etiology[,]" and further predicted that "we probably will not . . . ." *Id.* at 19.

Petitioner was discharged from Shands and returned to Raulerson Hospital on December 14, 2005.[5] Ex. 6 at 1. A progress note prepared at Shands that day noted that the strength in petitioner's legs had improved, but also reported that she was still unable to bear any weight on her feet. *Id.* at 20. Although the Shands discharge summary for petitioner indicated a diagnosis of TM, it further noted that

[5]/ Mrs. Caves requested that she be transferred back to Raulerson Hospital because Shands was not within her insurance network. *See* Ex. 6 at 5.

the hospital staff "did not know the etiology of her transverse myelitis." *Id.* at 5.

On December 15, 2005, Mrs. Caves was examined by Dr. Abul Ali, a neurologist at Raulerson Hospital. *See* Ex. 5 at 31-34. In his report, Dr. Ali noted that petitioner suffered from

> [p]araplegia relatively acute onset, which has improved to paretic stage, with significant distal weakness in both lower extremities, neurogenic bladder and incontinence of bowels, which has shown significant response to high dose steroids. This is most likely in favor of transverse myelitis terminal cord which was also noted on MRI of the lumbosacral spine as edema of the terminal spinal cord and [conus].

Id. at 33. Dr. Ali further noted that the "[c]linical course does not go in favor of Guillain-Barr[é] syndrome, [and] does not appear to be multiple sclerosis or related myelitis." *Id.* In his report, Dr. Ali also mentioned petitioner's influenza vaccination and her subsequent minor illness: "interestingly, she had received a flu vaccination about two weeks prior to her onset of symptoms and a week prior to the onset of symptoms she had mild sinus congestion symptoms . . . [but] did not report any frank flu like symptoms." *Id.* at 32.

Mrs. Caves met with Dr. Marvin Young, a urologist, on the same day to discuss her urinary incontinence and her inability to fully void her bladder. *See* Ex. 9 at 3-4. In his report, Dr. Young stated that petitioner suffered from impaired bladder and bowel function due to TM at the level of the second lumbar (L2) vertebra. *Id.* at 4. While he did not mention her influenza vaccination, Dr. Young did note that petitioner "had a flu-like syndrome about a week or so prior to her present neurological problems." *Id.* at 3.

On December 16, 2005, Mrs. Caves was examined by Dr. John Chang, a gastroenterologist. *See* Ex. 5 at 35-36. Dr. Chang noted that Mrs. Caves "has been having some flu-like symptoms, had a flu shot earlier and developed decreased paralysis and acute exacerbation of the lower extremities, as well as transverse

myelitis at the level of L2."[6] *Id.* at 35. Dr. Chang recommended "gastrointestinal prophylaxis with proton pump inhibitor (PPI) and also consider motility agent for the bowel activity, and also add Colace as indicated at this time." *Id.*

Petitioner was examined by Dr. Frank Nami on December 23, 2005 to assess the need for an inferior vena cava filter due to her immobility. *See* Ex. 5 at 39-41. Dr. Nami accepted the diagnosis of TM and noted that because Mrs. Caves

> will require long-term rehabilitation and she is immobile she is at high very risk [*sic*] for developing deep venous thrombosis and possible pulmonary embolism. I explained this to the patient, including the possibility of placing an inferior vena cava filter which will protect her against the fatal pulmonary embolism.

Id. at 40. After discussing the risks and benefits of the procedure with Dr. Nami, Mrs. Caves agreed to the placement of an inferior vena cava filter. *Id.* Dr. Nami indicated that he would schedule Mrs. Caves for the surgery later that day. *Id.* Subsequent medical records indicate that the surgery was successful.

Mrs. Caves continued to undergo physical therapy on an inpatient basis at Raulerson Hospital until she was discharged on December 24, 2005. Petitioner's primary care physician, Dr. Saeed Khan, indicated on her discharge form that she had been diagnosed with "transverse myelitis, status post flu shot." Ex. 5 at 20. However, in response to a question regarding the cause of petitioner's TM, Dr. Khan checked a box indicating that he was "unable to determine" its cause. *Id.* Mrs. Caves was directed to spend the weekend at home before checking herself into another hospital for rehabilitation. Ex. 26.

On December 28, 2005, Mrs. Caves was admitted as an inpatient at the

---

[6]/ In his report, Dr. Chang also states that the "patient [has] transverse myelitis at the level of T11 and T12." Ex. 5 at 35. Similarly, Dr. Jimmy Lockhart at HealthSouth Treasure Coast Rehabilitation Hospital diagnosed petitioner with a "spinal cord injury at thoracic 12, . . . secondary to transverse myelitis." Ex. 7 at 14. Because most of petitioner's treating physicians, as well as the parties in this case, appear to agree that petitioner suffers from TM at the level of L2, the court will assume that is the correct diagnosis. In any event, the precise location of petitioner's TM does not appear to be relevant to any of the disputed issues in this case.

HealthSouth Treasure Coast Rehabilitation Hospital (HealthSouth) with an initial diagnosis of TM at the L2 level. *See* Ex. 7 at 1. Mrs. Caves required significant assistance from the staff upon her admission to the facility:

> On admission she [received] supervision with eating and grooming; moderate assistance with bathing; minimal assistance with upper extremity dressing; maximum assistance with lower extremity dressing; total assistance with toileting, bladder and bowel management; total assistance with bed-chair-wheelchair transfers, toilet transfers, tub/shower transfers; total assistance with ambulation. She [received] minimal assistance [with] wheelchair mobility; total assistance with stairs.

Id. at 13.

Mrs. Caves was discharged from HealthSouth on February 2, 2006. *See id.* at 13-14. In the discharge report he prepared for Mrs. Caves, Dr. Jimmy Lockhart noted that petitioner had made significant progress during her stay there, and was now

> independent with eating; modified independent with grooming; supervision with bathing; modified independent with upper and lower extremity dressing, toileting; supervision with bladder management; modified independent with bowel management; modified independent with bed-chair-wheelchair transfers, toilet transfers; supervision with shower transfers; total dependent with ambulation; modified independent with wheelchair mobility for unlimited distance.

Id. at 13. Despite this progress, Dr. Lockhart noted that Mrs. Caves had achieved "no real neurologic recovery." *Id.* Furthermore, the discharge report stated that "no real etiology [has been] found for [petitioner's] transverse myelitis." *Id.* at 13.

Mrs. Caves met with Dr. Lockhart again for an initial outpatient evaluation on March 7, 2006. *See* Ex. 21 at 7-9. Although Dr. Lockhart stated that petitioner's condition had improved considerably, he also noted that she had begun

to develop pain in both shoulders as a consequence of her confinement to a wheelchair. *Id.* at 7. Following her discharge from HealthSouth, Mrs. Caves attended physical therapy as an outpatient at Raulerson Hospital five times per week. *See* Ex. 5 at 1.

Mrs. Caves had a follow-up appointment with Dr. Khan on March 27, 2006. *See* Ex. 1 at 2. Dr. Khan noted that petitioner had experienced some improvement in her left lower extremities, but that she was still very weak on her right side. *Id.* Dr. Khan observed that Mrs. Caves was now able to take a few steps with her walker, and instructed her to follow up with her neurologist and urologist. *Id.*

Mrs. Caves was examined by Dr. Young, her urologist, on April 17, 2006. *See* Ex. 9 at 1-2. Dr. Young noted that petitioner had regained some function in her bladder and bowels, and was now able to void her bladder spontaneously. *Id.* at 1. Although Mrs. Caves was still experiencing some urinary incontinence at night and when she waited too long before voiding, she was now able to move her bowels without the use of suppositories or digital manipulation. *Id.* Dr. Young recommended that Mrs. Caves follow up with him in three months, and suggested an ultrasound and frequent urinalysis in the event that her neurogenic bladder had not improved by that time. *Id.* at 2.

Mrs. Caves met with Dr. Ali, her neurologist, on May 3, 2006. *See* Ex. 8. Dr. Ali noted that Mrs. Caves still suffered from TM and paraplegia, but that her condition was improving. *Id.* at 1.

On June 6, 2006, Mrs. Caves had a follow-up appointment with her primary care physician, Dr. Khan. *See* Ex. 1 at 1. In his progress notes, Dr. Khan noted that Mrs. Caves had "myelitis with a resultant paraplegia and minimal muscle function." *Id.* According to Dr. Khan, petitioner's neurological condition remained essentially unchanged, and he further stated that "[t]he underlying factor has not been determined." *Id.* Dr. Khan recommended that Mrs. Caves obtain a walker and continue with her rehabilitation. *Id.*

Mrs. Caves continued with her physical therapy until April 10, 2007. *See* Ex. 21 at 1; Ex. 22 at 17. In her affidavit, petitioner states that she continues to

suffer from pain, reduced mobility, and urinary incontinence.[7] Ex. 11 ¶¶ 9-11. Although she returned to work on a part-time basis for a short period of time, she was forced to take additional time off due to exhaustion. *Id.* ¶ 12.

II. Procedural History

Mrs. Caves filed a petition under the Vaccine Act on June 28, 2007, alleging that the influenza vaccination she received on November 18, 2005 caused her to develop TM. On July 12, 2007, Mrs. Caves filed some of her medical records, *see* Exs. 1-12, and she filed additional medical records between November 2007 and February 2008, *see* Exs. 13-28, and again in October and November 2009, *see* Exs. 41-44.

Respondent filed her report on the petition, pursuant to Vaccine Rule 4(c), on September 28, 2007. In that report, respondent contended that petitioner was not entitled to compensation because the petition was not supported by any expert testimony, and none of petitioner's treating physicians identified the influenza vaccine as the likely cause of her TM. On the contrary, according to respondent, petitioner's physicians merely noted the temporal relationship between petitioner's vaccination and her subsequent development of TM. In the absence of both expert testimony and probative statements by her treating physicians, respondent argued that petitioner failed to meet the burden of demonstrating that the influenza vaccination she received in November 2005 was the cause of her TM.

On January 7, 2008, petitioner filed an amended petition and motion for a ruling on the existing record. Therein, Mrs. Caves argued that she was entitled to compensation because her treating physicians had concluded that her TM was caused by the influenza vaccination she received in November 2005. Mrs. Caves further asserted that her treating physicians did not identify any other potential causes of her TM. Finally, Mrs. Caves argued that her physicians' determination that her TM was caused by the influenza vaccine necessarily implies a medical theory that the vaccine is capable of causing TM.

On April 23, 2008, respondent filed a response to the amended petition and

---

[7]/ In October 2007, after she had filed her petition for compensation, Mrs. Caves underwent surgery on tendons in her right foot to correct a neurogenic hammertoe deformity, presumably a complication of her TM. *See* Exs. 20, 24.

motion for a ruling on the existing record. In addition, respondent also filed the curriculum vitae and report of the government's expert, Dr. Arthur P. Safran. *See* Exs. A-B. In its response, the government contended that petitioner's medical records provide no support for her assertion that the influenza vaccine caused her TM. At most, according to respondent, the statements of petitioner's treating physicians simply recognize the temporal association between those two occurrences. In his report, Dr. Safran stated that he did not believe the flu vaccine caused petitioner's TM because such a relationship is not supported by epidemiological studies. In fact, according to Dr. Safran, there is some evidence to suggest that the incidence of TM among individuals who receive the influenza vaccine is lower than the background rate of TM in the population. Dr. Safran suggested cytomegalovirus (CMV) or petitioner's sinus infection as potential alternative causes of her TM.

The special master held a status conference with the parties on June 11, 2008. *See* Order of June 11, 2008. During that conference, petitioner requested that she be afforded an opportunity to cross-examine respondent's expert witness. *Id.* The special master directed petitioner to file a motion requesting a hearing for that purpose. *Id.* At the time of the status conference, petitioner had not yet filed an expert report in support of her petition.

Petitioner filed a motion requesting a hearing to cross-examine respondent's expert witness on July 16, 2008, and respondent responded to that motion on August 22, 2008. In her motion for a hearing, Mrs. Caves argued that the opinion proffered by Dr. Safran was in direct contradiction to statements made by her treating physicians. Mrs. Caves further asserted that she was entitled to an opportunity to examine the bases of Dr. Safran's opinion, particularly with respect to the issue of multiple, independent causes of TM. In her response, respondent argued that cross examination of Dr. Safran was not warranted because petitioner had not made out a prima facie case, nor had she presented any reliable evidence on the issue of causation.

In a published order dated November 25, 2008, the special master denied the motions for a ruling on the record and for cross examination of respondent's expert. Order, 2008 WL 5970976 (Fed. Cl. Spec. Mstr. Nov. 25, 2008). In that order, the special master concluded that petitioner had failed to produce preponderant evidence with respect to the first two prongs of the three-part test articulated by the United States Court of Appeals for the Federal Circuit in *Althen*

v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). In the view of the special master, the statements of petitioner's treating physicians did not demonstrate a logical sequence of cause and effect between the influenza vaccine and petitioner's subsequent development of TM. Furthermore, the special master held that the medical records submitted by petitioner did not contain any medical theory to support a causal relationship between the influenza vaccine and TM. Because petitioner had failed to establish a prima facie case under *Althen*, and because she had failed to present her own expert, the special master held that cross examination of Dr. Safran would be unnecessary and inappropriate.

On April 2, 2009, Mrs. Caves filed the curriculum vitae and report of her expert, Dr. Derek Smith, along with two supporting articles, *see* Exs. 29-30, and she filed several additional articles in support of her petition on April 14, 2009, *see* Exs. 31-40. In his expert report, Dr. Smith provided a theory to explain how the influenza vaccine may have triggered an autoimmune response that led to the development of TM in petitioner. According to Dr. Smith, the influenza vaccine could have activated self-reactive T-cells, which in turn entered petitioner's central nervous system and recognized myelin in petitioner's spinal cord as an influenza antigen. Dr. Smith described this autoimmune process, also known as molecular mimicry, as the "consensus immunopathogenic model for transverse myelitis and multiple sclerosis." Ex. 29 at 2 (citation omitted). Dr. Smith agreed with Dr. Safran's statement that the epidemiological studies do not support a causal relationship between the influenza vaccine and TM. He noted, however, that the absence of epidemiological evidence of a causal relationship cannot refute the existence of such a relationship because of the variability in flu vaccines and human immune systems, as well as the rarity of TM in the population.

Respondent filed a supplemental report prepared by Dr. Safran and supporting references on June 15, 2009.[8] *See* Exs. C-D. In his supplemental expert report, Dr. Safran argued that while the theory of molecular mimicry is a plausible autoimmune mechanism, it applies equally to any number of other antigens, including viruses and other infectious agents. For that reason, the theory of molecular mimicry, according to Dr. Safran, does not make it any more or less likely that the influenza vaccine caused petitioner's TM. Dr. Safran noted that the

[8]/ The special master directed respondent to file the articles cited in Dr. Safran's report, *see* Order of June 25, 2009, and respondent filed those articles on July 24, 2009, *see* Exs. F-J.

literature submitted with Dr. Smith's report discusses the relationship between the influenza vaccine and Guillain-Barré syndrome, a disorder of the peripheral nervous system, rather than TM, a disorder of the central nervous system. Finally, Dr. Safran surmised that it is more likely that any autoimmune response leading to petitioner's TM was triggered by the infection she experienced between the time of her vaccination and the onset of her neurological symptoms.

On August 27, 2009, Mrs. Caves filed a renewed motion for a ruling on the record, in which she argued that she had demonstrated by a preponderance of the evidence that the influenza vaccination she received in November 2005 was the cause of her TM. Respondent filed a response to that motion on October 28, 2009, in which she incorporated by reference the arguments raised in her response to petitioner's first motion for judgment on the record and further argued that the expert testimony of Dr. Smith was unreliable and contradicted by the testimony of Dr. Safran.

The special master submitted into evidence several articles he believed might be relevant to the issues in this case. *See* Order of December 1, 2009 and Special Master Exs. 1-5. These articles addressed the issue of whether certain vaccines can cause or exacerbate multiple sclerosis and other similar demyelinating disorders of the nervous system. None of the submitted articles discussed the possibility of a causal relationship between the influenza vaccine and TM.

The special master conducted an evidentiary hearing on petitioner's motion in Boston, Massachusetts on December 9, 2009. During that hearing, the parties' respective experts testified as to whether the influenza vaccine is capable of causing TM and whether petitioner's TM was caused by her vaccination. Following the hearing, the parties filed post-hearing briefs, and the special master heard oral argument on those briefs on June 16, 2010.

III. The Special Master's Decision

On November 29, 2010, the special master issued a decision holding that petitioner was not entitled to compensation under the Vaccine Act because she had failed to meet her burden of demonstrating by a preponderance of the evidence that the influenza vaccine is capable of causing TM, and that the vaccine had in fact

caused her TM in this particular case.[9] For each of the three prongs of the *Althen* test, the special master examined the various types of evidence submitted by petitioner in support of her claim and concluded that Mrs. Caves had failed to present a prima facie case.

A. *Althen* Prong One

The special master concluded that Mrs. Caves did not present preponderant evidence on the issue of whether the influenza vaccine is capable of causing TM. The special master first noted that the principal support for petitioner's assertion that the flu vaccine can cause TM was the testimony of Dr. Smith on that issue.[10] However, the special master went on to hold that Dr. Smith's expert testimony on this point was unreliable because it was not supported by any of the other evidence presented by petitioner.

First, the special master found that none of petitioner's treating physicians concluded that petitioner's influenza vaccination was the cause of her TM. Next, the special master determined that petitioner's asserted elimination of any alternative causes of TM was of limited probative value because the etiology of the vast majority of cases of TM is never discovered. The special master also noted that while Mrs. Caves claimed her theory was supported by case studies and animal models, she submitted neither case studies nor animal models into evidence in this case. Next, the special master rejected the probative value of two scientific articles

---

[9]/ The special master here adopted a formulation of the first two prongs of *Althen* that was upheld by the Federal Circuit in *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). In the decision of the special master reviewed in *Pafford*, the special master described the first prong of *Althen, i.e.*, a medical theory causally connecting the vaccine and the injury, as essentially "whether the vaccine in question is capable of causing the injury." In addition, the special master in that case described the second prong of *Althen, i.e.*, a logical sequence of cause and effect showing that the vaccine was the reason for the injury, as essentially "whether the vaccine actually caused the petitioner's injury in that particular case." The Federal Circuit held that the tests applied by the special master in that case were consistent with *Althen*. *See Pafford*, 451 F.3d at 1355-56; *see also Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326-27 (Fed. Cir. 2006) (holding that the first prong of *Althen* "was satisfied by the finding that the hepatitis B vaccine can cause" rheumatoid arthritis).

[10]/ The special master noted that petitioner also sought support in the testimony of respondent's expert, Dr. Safran, but held that petitioner had taken the referenced testimony out of context. Opin. at 18.

cited by petitioner in support of her argument that the influenza vaccine can cause TM. While the special master acknowledged that the submitted articles supported the general theory of molecular mimicry – the validity of which is not disputed by the parties in this case – he further held that the articles do not provide any support for the more specific theory that the influenza vaccine can serve as the antigenic trigger that sets that autoimmune process into motion.

The special master held that the testimony of Dr. Smith, in the absence of any other supporting evidence, was essentially based on no more than the temporal proximity between petitioner's vaccination and the subsequent onset of her TM, as well as the absence of any other identified cause. The special master noted that the Federal Circuit had rejected similar reasoning in *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1323 (Fed. Cir. 2010), and held that Dr. Smith's extrapolation from the existing data in this case was "too great to be persuasive." Opin. at 19 (citing *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010)).

Because the special master concluded that petitioner had failed to establish prong one of the *Althen* test, he also held that it was unnecessary to examine the evidence presented by respondent. Nonetheless, the special master proceeded to evaluate that evidence and held that it in fact undermined petitioner's assertions. The special master credited the testimony of Dr. Safran, who stated that there is no empirical evidence of a causal relationship between the influenza vaccine and TM. Dr. Safran's testimony, as the special master noted, was based on epidemiological studies that showed no correlation between the administration of the influenza vaccine and the incidence of TM. While the special master noted that the epidemiological evidence failed to support petitioner's claim, he also emphasized the limited import of such studies when a disease is as rare as TM. However, the special master concluded that Mrs. Caves would have failed to meet her burden even if respondent had not presented any evidence at all. For that reason, the special master concluded that Mrs. Caves had failed to carry her burden on the first prong of *Althen*.[11]

---

[11]/ Before the special master, and in her motion for review, Mrs. Caves also argues that the special master should award her compensation on the grounds that other petitioners have been compensated in similar circumstances. The special master held that he was not bound by the decisions of other special masters, particularly in those cases where an award of

continue...

B. *Althen* Prong Two

With respect to the second prong of *Althen*, the special master held that petitioner failed to demonstrate by a preponderance of the evidence that the influenza vaccine she received in November 2005 was the cause of her TM. Once again, the special master concluded that none of petitioner's treating physicians stated that the influenza vaccine was the cause of her TM. The special master also noted that the parties' experts offered competing interpretations of the physician statements cited by petitioner. Dr. Smith testified that the mention of the influenza vaccine in the medical records implies that the physicians believed there was a causal relationship. Dr. Safran, in contrast, testified that those physicians were merely describing petitioner's medical history as recounted to them by petitioner. In resolving those conflicting interpretations, the special master determined that the statements cited by petitioner noted a mere temporal association between the vaccine and petitioner's TM, and further held that the recognition of such an association does not constitute a determination on the issue of causation. Opin. at 23 (citing *Cedillo*, 617 F.3d at 1347). The special master also held that, under *Moberly*, the testimony of Dr. Smith lacked a sufficient evidentiary foundation. Finally, the special master rejected petitioner's assertion that the other potential causes of her TM – CMV, herpes zoster virus, and a sinus cold virus – had been eliminated. However, the special master further noted that an extensive discussion of that issue was unnecessary because Mrs. Caves had failed to meet her burden of proof on either prong one or prong two of the *Althen* test.

C. *Althen* Prong Three

The parties' experts agreed that the interval of time between petitioner's influenza vaccination and the initial onset of her neurological symptoms was medically appropriate and consistent with what is known about the progression of

---

[11]/ ...continue
compensation was the result of a voluntary settlement agreement between the parties. The special master further noted that the cases cited by Mrs. Caves are distinguishable on the facts. The court agrees that the special master was not bound by the decisions cited by petitioner, *see Hanlon ex rel. Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998) ("Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand."), and it will not disturb the decision of the special master based on any failure to follow those cases.

autoimmune injuries and disorders. The special master concluded that petitioner satisfied her burden of proof with respect to prong three of *Althen*, but held that she was not entitled to compensation because she failed to meet the first two prongs of the test.

IV. Petitioner's Motion for Review

On December 29, 2010, petitioner filed a motion for review of the special master's final decision denying compensation, along with a supporting memorandum. In her motion, Mrs. Caves contends that the special master committed four distinct legal errors in declining to award her compensation under the Vaccine Act. First, petitioner argues that the special master misapplied the framework set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Second, petitioner claims that the special master erred in failing to credit the statements of her treating physicians as evidence of a reliable causal theory and a logical sequence of cause and effect. Third, petitioner argues that the special master should have considered the absence of alternative causes for her TM as circumstantial evidence of causation, and that his failure to do so was legal error. Finally, Mrs. Caves argues that the special master committed legal error in failing to consider the temporal relationship between petitioner's vaccination and her subsequent development of TM as evidence relevant to the first two prongs of *Althen*, rather than viewing that evidence as relevant only with respect to the third prong of the test.

On January 28, 2011, respondent filed a response to petitioner's motion for review. Respondent first argues that the special master was correct in his holding that petitioner failed to present a persuasive medical theory establishing a causal connection between the influenza vaccine and TM. In that regard, respondent asserts that a medical theory must be supported by reliable evidence, and that the theory proposed by petitioner's expert witness was not supported by such evidence. In addition, respondent contends that petitioner failed to demonstrate that her TM was caused by the influenza vaccine in this particular case. Respondent contends that none of the physician statements cited by petitioner amount to a conclusion that the influenza vaccine caused her TM. In addition, respondent asserts that the special master's application of the *Daubert* factors to assess the reliability of Dr. Smith's testimony was entirely proper. According to respondent, the decision of the special master should be affirmed because it was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance

with law.

DISCUSSION

I. Standard of Review

This court has jurisdiction to review the decision of a special master in a Vaccine Act case. 42 U.S.C. § 300aa-12(e)(2). "Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]'" *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1350 (Fed. Cir. 2008) (quoting 42 U.S.C. § 300aa-12(e)(2)(B) and citing *Althen*, 418 F.3d at 1277) (alteration in original); *see also Hanlon v. Sec'y of Health & Human Servs.*, 191 F.3d 1344, 1348 (Fed. Cir. 1999) ("Under the Vaccine Act, the Court of Federal Claims may not disturb the factual findings of the special master unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" (quoting 42 U.S.C. § 300aa-12(e)(2)(B))). This court uses three distinct standards of review in Vaccine Act cases, depending upon which aspect of a special master's judgment is under scrutiny:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard.

Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

The arbitrary and capricious standard of review is used to consider factual findings by the special master. *Id.* The scope of this review is limited, and highly deferential. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000); *Burns by Burns v. Sec'y of the Dep't of Health & Human Servs.*, 3 F.3d 415, 416 (Fed. Cir. 1993). "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines ex rel. Sevier v. Sec'y of the Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528

(Fed. Cir. 1991); *see also Burns*, 3 F.3d at 416. This court's arbitrary and capricious review of the fact findings of a special master is "well understood to be the most deferential possible." *Munn*, 970 F.2d at 870 (citations omitted). When the court's review of a special master's decision involves statutory construction or other legal issues, the "not in accordance with law" standard is applied. *Hines*, 940 F.2d at 1527. The third standard of review, abuse of discretion, is applicable when the special master excludes evidence or otherwise limits the record upon which he relies. *See Munn*, 970 F.2d at 870 n.10.

II. Burden of Proof in an Off-Table Vaccine Injury Case

There are two distinct avenues for recovery under the Vaccine Act. *See* 42 U.S.C. § 300aa-11(c). First, a petitioner who has received a vaccination listed on the Act's Vaccine Injury Table (Table) may recover for any resulting illness, disability, injury or condition that is also listed on the Table, or a significant aggravation thereof. *Id*. § 300aa-11(c)(1)(C)(I); *see also id.* § 300aa-14(a); 42 C.F.R. § 100.3 (2010) (current version of the Vaccine Injury Table). Second, a petitioner who has received a vaccination listed on the Table, but whose vaccine-related injuries do not meet Table requirements, may recover under the "off-Table" theory of recovery. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A). Under this theory, a petitioner may make out a prima facie case of entitlement to compensation by showing, by a preponderance of the evidence, that a Table vaccine actually caused the petitioner to sustain an illness, disability, injury or condition which is not listed on the Table, or that first appeared outside the time limits set by the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii); *Pafford*, 451 F.3d at 1355.

A petitioner who hopes to recover for an off-Table claim must establish causation-in-fact. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1); *Pafford*, 451 F.3d at 1355. This requires "preponderant evidence both that [the] vaccination[] [was] a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford*, 451 F.3d at 1355 (citing *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)). The vaccination "must be a 'substantial factor'" in bringing about the injury, but "it need not be the sole factor or even the predominant factor." *Id.* at 1357 (quoting *Shyface*, 165 F.3d at 1352-53).

The Federal Circuit has further explained the evidentiary burden associated with causation in off-Table cases. That court explained that a petitioner who wishes to demonstrate that a vaccination brought about his or her injury must present:

> (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, 418 F.3d at 1278 (explaining that "[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'") (quoting *Grant v. Sec'y of the Dep't of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)); *see also Pafford*, 451 F.3d at 1355; *Capizzano*, 440 F.3d at 1324.

As to the evidence related to the three factors, "these prongs must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford*, 451 F.3d at 1355. Further, "[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278 (citing *Grant*, 956 F.2d at 1149). It is likewise critical to recognize that the special master may not make a finding of causation that is based on the claims of a petitioner alone, which are not substantiated by medical records or by medical opinion. *See* 42 U.S.C. § 300aa-13(a)(1). Thus, the presentation of medical records or medical opinion supporting a claim is a prerequisite to recovery. *Id.* Only if a petitioner presents adequate evidence on the three essential aspects of causation, and thus makes a prima facie case for liability, does the burden shift to the Secretary to prove, also by a preponderance of the evidence, an alternate cause of the alleged injury. *Althen*, 418 F.3d at 1278; *de Bazan*, 539 F.3d at 1352 (citations omitted). When a petitioner seeks to demonstrate causation in fact by meeting the three *Althen* requirements, each of those requirements must be proven by a preponderance of the evidence. *See de Bazan*, 539 F.3d at 1351-52.

III. Petitioner's Specific Allegations of Error

A. The Special Master's Application of *Daubert* Was Not in Error

Mrs. Caves argues that the special master committed legal error in that he applied an overly rigid version of the *Daubert* analysis. While Mrs. Caves concedes the general applicability of *Daubert* in Vaccine Act cases, she contends that the special master's alleged transformation of the factors set forth in that case into absolute requirements was a misapplication of the *Daubert* analysis. As discussed below, the court holds that the special master did not commit any legal error in his use of the *Daubert* analysis to evaluate the evidence presented by petitioner.

In *Daubert*, the United States Supreme Court held that trial court judges are required to evaluate the reliability of expert testimony on scientific subjects. According to the Court, this judicial gatekeeping function is embodied in Rule 702 of the Federal Rules of Evidence (FREs), which provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702. The Court later confirmed that the rule established in *Daubert* applies not only to scientific testimony, but to any other technical or specialized expert testimony as well. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

The Supreme Court discussed a number of factors to be considered by the trial court in determining whether to exclude the testimony of an expert witness as unreliable. First, the Court noted that the trial court should consider whether the proffered scientific theory or technique has been subjected to empirical testing, or whether such testing is possible. *Daubert*, 509 U.S. at 593. Next, the trial court should determine whether the theory or technique has been subjected to peer review and publication. *Id.* Third, the trial court should examine the known or

potential rate of error for the theory or technique. *Id.* at 594. Finally, the trial court should consider the general acceptance of the theory or technique within the relevant scientific community. *Id.*

As noted above, the Supreme Court held in *Daubert* that trial courts must evaluate the reliability of scientific and other technical evidence, thus preventing the presentation of unreliable evidence to a jury. The Court further held that this gatekeeping role is required by Rule 702. In Vaccine Act proceedings before the special masters, of course, there are no jury trials, and the FREs do not generally apply in Vaccine Act cases. *See Munn*, 970 F.2d at 873 ("Congress clearly determined that the Federal Rules of Evidence shall not be applied in vaccine-injury proceedings before a special master."). However, Vaccine Rule 8 provides that the special master "must consider all relevant *and reliable* evidence governed by fundamental principles of fairness to both parties." Rules of the United States Court of Federal Claims (RCFC) App. B, Rule 8(b)(1) (emphasis added). *See Moberly*, 592 F.3d at 1325 ("Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases."). Furthermore, the Federal Circuit has held that the use of the *Daubert* framework to evaluate the reliability of expert testimony is entirely appropriate in Vaccine Act cases. *See Cedillo*, 617 F.3d at 1338-39 ("We have previously held that Special Masters may look to the *Daubert* standards in evaluating expert testimony.") (footnote omitted); *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) ("Thus, the Special Master did not err in analyzing the proffered testimony according to *Daubert*.").

Petitioner argues that the special master treated the four guideposts discussed in *Daubert* as necessary prerequisites to a showing of legal causation, and contends that such an application of *Daubert* is not in accordance with law. The court concludes that petitioner's reading of *Daubert* is correct, but holds that her characterization of the special master's analysis is not.

While the Supreme Court identified the four factors listed above as useful criteria in evaluating the reliability of scientific testimony, it emphasized that those considerations should not be viewed as rigid requirements for admissibility:

> The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. Its overarching subject is the scientific

> validity and thus the evidentiary reliability of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.

Daubert, 509 U.S. at 594-95 (footnote omitted); *see also Kumho Tire*, 526 U.S. at 151 ("[*Daubert*] made clear that its list of factors was meant to be helpful, not definitive."). Indeed, in *Daubert*, the Court vacated the judgment of the lower court, which had held that general acceptance in the relevant scientific community was a prerequisite to admissibility. In other words, the failure to establish one of the *Daubert* factors does not necessarily preclude the admissibility of a scientific theory or technique presented by an expert witness.

Here, the special master did not exclude the testimony of Dr. Smith on the basis of a simple disagreement with his conclusions, nor did he disregard his theories based on their failure to meet any one of the four *Daubert* factors. On the contrary, the special master examined Dr. Smith's theory and reached the reasonable conclusion that, in the absence of supporting studies or other evidence, his expert testimony was unreliable. Such an application of the *Daubert* analysis is not erroneous. *See Terran*, 195 F.3d at 1316 (upholding the special master's use of the *Daubert* factors "as a tool or framework for conducting an inquiry into the reliability of the evidence"); *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66 (2010) (noting that "uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted, at least in bench proceedings conducted by special masters in vaccine cases").

There is no indication that the special master excluded any of the evidence presented by petitioner. Indeed, although the special master spent several pages of his decision discussing *Daubert*, it does not appear that he applied its specific factors to the evidence in this case in a rigid or rote fashion. Rather, the special master engaged in a flexible examination of the parties' expert testimony to determine whether that testimony was supported by sufficient indicia of reliability, as he was allowed – and, indeed, required – to do under the rules of this court. *See* RCFC App. B, Rule 8(b)(1) (providing that the special master "must consider all relevant *and reliable* evidence governed by fundamental principles of fairness to both parties") (emphasis added); *see also Moberly*, 592 F.3d at 1326 (noting that the special masters "are entitled – indeed, expected – to make determinations as to

the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence"); *Terran*, 195 F.3d at 1316 (rejecting the argument that "the *Daubert* framework is narrowly intended to prevent the introduction of 'junk science' into trials, rather than as a broader tool for analyzing the admissibility of scientific testimony").

With respect to the first two prongs of *Althen*, the parties' experts provided conflicting testimony. Dr. Smith, on behalf of petitioner, stated that the influenza vaccine is capable of causing TM and that the vaccine caused petitioner's TM in this case. Dr. Safran, on behalf of respondent, stated that there is no evidence that the influenza vaccine is capable of causing TM. He further testified that since there were other, more likely, potential causes of petitioner's TM, the onset of her TM could not be specifically ascribed to the influenza vaccine. In order to resolve these material disputes, the special master was required to assess the persuasiveness and reliability of the parties' expert witnesses.

Petitioner first argues that a scientific theory does not have to be tested or objectively confirmed in order to meet the first prong of *Althen*. The court agrees with petitioner that such objective confirmation is not an absolute prerequisite for reliability. *See Althen*, 418 F.3d at 1274 ("We see no 'objective confirmation' requirement in the Vaccine Act's preponderant evidence standard."). However, it should be obvious to petitioner that a scientific theory that lacks any empirical support will have limited persuasive force. *See Moberly*, 592 F.3d at 1325-26 ("Assessments as to the reliability of expert testimony often turn on credibility determinations, particularly in cases such as this one where there is little supporting evidence for the expert's opinion."); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (holding that *Daubert* does not require a trial court "to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").

The Federal Circuit has held that a special master may discount the reliability of expert opinion when that opinion is not supported by the evidence:

> Here, the Special Master found the petitioner's evidence of causation unpersuasive. There is nothing in the case to suggest that the Special Master failed to comprehend the value or effect of the medical evidence. The fact that the opinion of petitioner's doctors was rejected does not

> mean that the Special Master was demanding scientific certainty; he might simply have been demanding some degree of acceptable scientific support when concluding that the [petitioner's] claim for causation in-fact was not supported by a preponderance of the evidence.

Hodges v. Sec'y of the Dep't of Health & Human Servs., 9 F.3d 958, 961-62 (Fed. Cir. 1993) (footnote omitted). In addition, a determination by the special master that evidence presented by a petitioner fails to meet the statutory burden of proof "is not the same as refusing to consider it." *Id.* at 961 n.4.

In this case, moreover, the causal theory posited by Dr. Smith was not merely lacking in empirical support; rather, it was inconsistent with the available epidemiological evidence. Although a special master cannot require a petitioner to submit epidemiological evidence in support of his or her petition, *see Capizzano*, 440 F.3d at 1325 (holding that special masters cannot require petitioners to submit epidemiological studies and other specific types of evidence in support of their petition), the submission of such evidence is relevant to the issue of causation, *see Grant*, 956 F.2d at 1144 (noting that "epidemiological studies are probative medical evidence relevant to causation"). In light of the apparent conflict between Dr. Smith's theory and the available empirical evidence, the special master committed no legal error in concluding that Dr. Smith's theory was less reliable, and thus less persuasive, than the competing causal theory offered by Dr. Safran. As the Supreme Court has explained, the "overarching subject [of the *Daubert* analysis] is the scientific validity and evidentiary reliability of the principles that underlie a proposed submission." *Daubert*, 509 U.S. at 594-95.

Petitioner asserts that the causal theory presented by Dr. Smith is supported by substantial empirical evidence, and contends that its validity was essentially conceded by respondent's expert, Dr. Safran. However, as the special master noted, there is an important difference between the general theory of molecular mimicry – *i.e.*, the theory that a foreign antigen can trigger an autoimmune response due to certain similarities between peptides on the surface of that antigen and peptides in the body – and the more specific theory that the influenza vaccine is capable of triggering an autoimmune response that culminates in the development of TM in the vaccinee. While there is significant support for the general theory, the special master properly concluded that the more specific theory proposed by Dr. Smith was not supported by any of the evidence presented in this

case. *See Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation *that pertains specifically to the petitioner's case* . . . .") (emphasis added). The theory of molecular mimicry does not apply specifically to petitioner's case; on the contrary, that general theory could be used to demonstrate an association between virtually any combination of antigens and autoimmune injuries. Without any empirical evidence that the theory actually applies to the influenza vaccine and TM, the first prong of *Althen* would be rendered meaningless.

The same can be said for the special master's evaluation of the experts' testimony with respect to the second prong of *Althen*. The special master noted that Dr. Smith's conclusion on this issue, *i.e.*, that the influenza vaccine was the cause of petitioner's TM, was based on no more than a temporal association between those two occurrences and the absence of any other apparent cause. In the eyes of the special master, such a conclusion based only on that evidence was foreclosed by the Federal Circuit's decision in *Moberly*. The special master did not exclude or disregard Dr. Smith's testimony on the second prong of *Althen* based on the failure of that testimony to meet any single factor of the *Daubert* analysis. Instead, the special master held, based on *Moberly*, that an expert witness cannot reach the conclusion that a vaccine caused an injury based on no more than the temporal relationship between those occurrences and the absence of other potential causes. That determination was not erroneous.[12] *See Moberly*, 592 F.3d at 1315

---

[12]/ Although petitioner asserts that her expert testimony demonstrates that the influenza vaccination she received in November 2005 was the cause of her subsequent development of TM, the court notes that Dr. Smith appeared to concede during his testimony that he could not conclude that it is more likely than not that the vaccination, rather than an infection, caused her TM. In his direct testimony, Dr. Smith opined that the influenza vaccine caused Mrs. Caves to develop TM. During respondent's cross examination of Dr. Smith, however, the following exchange occurred:

> [Counsel]: Okay. Now, you mentioned on – so, how can you tell that it is – it is more likely than not the vaccination, as opposed to a virus or infection that caused Mrs. Caves's transverse myelitis?
>
> [Dr. Smith]: You can't. If the dates that you're presenting me

continue...

("As this court has stated, 'neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.'") (quoting *Althen*, 418 F.3d at 1278); *Grant*, 956 F.2d at 1148 (noting that "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury").

Finally, petitioner argues that the special master misapplied *Daubert* in that he purported to evaluate the reliability of Dr. Smith's conclusions, rather than his methods. While the *Daubert* analysis is focused primarily on the soundness and scientific validity of an expert witness's proposed methods or techniques, the Federal Circuit has noted that an expert's ultimate conclusions may be held to be unreliable when they are not supported by the evidence:

> While *Daubert* does not require that the experts' ultimate conclusions be generally accepted in the scientific community, and the focus of a *Daubert* inquiry must generally be "on principles and methodology, not on the conclusions they generate," "conclusions and methodology are not entirely distinct from one another . . . . A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."

Cedillo, 617 F.3d at 1339 (quoting *Joiner*, 522 U.S. at 146) (internal quotations omitted). Here, the special master concluded that both the theory presented by Dr. Smith, as well as the conclusions generated by that theory, were too far removed from the other evidence in this case to be deemed reliable. That determination was

---

[12]/ ...continue

> with are correct, then I would agree that it makes it less likely that the vaccine is the cause.

Tr. at 50. The question posed to Dr. Smith was based on the assumption that petitioner experienced a minor illness one week before the onset of her neurological symptoms, a fact that is supported by petitioner's medical records, and which has not been challenged by Mrs. Caves in this court. In other words, even if the special master were to accept the testimony of Dr. Smith as reliable, that testimony does not provide substantial support for petitioner's case.

not erroneous.

B. The Special Master Did Not Fail to Consider the Statements of Petitioner's Treating Physicians in Determining that Petitioner Failed to Meet Her Burden on the Issue of Causation

Petitioner asserts that the special master disregarded the statements of her treating physicians in determining that she had failed to meet her burden of demonstrating a logical sequence of cause and effect between petitioner's vaccination and her subsequent development of TM. The special master reviewed petitioner's medical records and concluded that "the treating doctors generally presented a sequence of events in which the flu vaccination preceded the onset of Ms. Caves's transverse myelitis." Opin. at 15. While the special master concluded that those statements indicated no more than the physicians' recognition of a temporal association between the vaccine and subsequent injury, petitioner contends that there was a "clear consensus" among her treating physicians that the influenza vaccine is capable of causing TM, and that the particular vaccine received by petitioner on November 18, 2005 did in fact cause her TM. The court concludes that the special master did not err in according little weight to the referenced notations in petitioner's medical records.

The special master is required to consider recorded statements by treating physicians in determining whether a petitioner's injury was caused by a vaccination. 42 U.S.C. § 300aa-13(b)(1)(A) (requiring the special master to consider "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death"). When a treating physician concludes that an injury or illness was caused by a vaccine, that conclusion is circumstantial evidence that the vaccine did in fact cause that injury or illness. *See Capizzano*, 440 F.3d at 1326 (explaining that "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect shows that the vaccination was the reason for the injury"). However, the special master is not bound by the conclusions of treating physicians on the issue of causation. 42 U.S.C. § 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *see Broekelschen*, 618 F.3d at 1346-49 (affirming the special master's finding that a petitioner

suffered from anterior spinal artery syndrome, rather than TM, even though the petitioner's treating physicians had diagnosed that petitioner with TM).

In this case, the special master properly found that none of petitioner's treating physicians concluded that her TM was caused by the influenza vaccine. The special master held that the medical statements referenced by petitioner, whether viewed alone or within the context of the entire record, fail to satisfy her burden of proof in this case. The court holds that the special master's conclusion was not unreasonable or contrary to law.

1. Dr. Rodriguez

Following her admission to Shands Medical Center, petitioner was seen by Dr. Ramon Rodriguez. In reviewing petitioner's medical history, Dr. Rodriguez observed that Mrs. Caves "does note having taken a flu shot two weeks before the onset of symptoms and a very mild sinus cold recently with no flu-like symptoms." Ex. 6 at 14. Dr. Rodriguez went on to describe the temporal association between petitioner's influenza vaccination and the onset of her neurological symptoms as "interesting[.]" *Id.* at 15. While Dr. Rodriguez did not render a final diagnosis, he strongly suspected that Mrs. Caves suffered from TM:

> The differential diagnosis includes Guillain-[Barré] syndrome, transverse myelitis which could be idiopathic or autoimmune, or less likely a vascular event in the spinal cord. Guillain-[Barré] syndrome certainly could produce her weakness and loss of reflexes with paresthesias and sensory loss, particularly two weeks after an influenza immunization; however, the strikingly abrupt onset of her symptoms would be atypical for this disorder making transverse myelitis highly suspect.

Id. While Dr. Rodriguez notes the significance of an influenza vaccination in his differential diagnosis, it is important to emphasize that he considered it only in the context of an evaluation as to the possible presence of Guillain-Barré syndrome.

Petitioner views the statements contained in Dr. Rodriguez's report as providing support for her contention that the influenza vaccine caused her TM. However, as noted by the special master, Dr. Rodriguez did not discern a causal

relationship between the vaccination and petitioner's subsequent development of TM. Rather, the statements quoted above are most reasonably read to describe a temporal association that was reported to Dr. Rodriguez by petitioner. The only language that might be interpreted to suggest that the vaccine could have caused petitioner's symptoms is in reference to a possible diagnosis of Guillain-Barré syndrome, which – unlike TM – has been actually linked to the influenza vaccine in epidemiological studies. *See* Tr. at 155-56; Exs. 31-37, 39-40.

If the mere mention of the influenza vaccine is to be viewed as evidence that the vaccine caused petitioner's TM, there is no reason that the special master should not have viewed the report's mention of a "sinus cold" in the same manner. *See* Ex. 6 at 14. Furthermore, the report prepared by Dr. Rodriguez stated that Mrs. Caves "very likely has transverse myelitis and work up is to try to find potential etiologies." *Id.* at 16. In other words, Dr. Rodriguez had not yet identified a cause of petitioner's TM and ordered several lab tests and other diagnostic procedures for that very purpose. Even if the mention of the vaccination and the sinus cold could be taken as a discussion of causation, the statements of Dr. Rodriguez point to at least two potential causes of petitioner's neurological symptoms and do not indicate that either of those potential causes is a more likely culprit than the other.

2. Dr. Ali

On December 15, 2005, petitioner was examined by Dr. Abul Ali, a neurologist. In his report, Dr. Ali noted petitioner's influenza shot and subsequent illness: "interestingly, she had received a flu vaccination about two weeks prior to her onset of symptoms and a week prior to the onset of symptoms she had mild sinus congestions symptoms." Ex. 5 at 32. While noting that they were "interesting[,]" Dr. Ali did not indicate that he suspected either the vaccination or sinus congestion as potential causes of petitioner's symptoms. To the extent that his statement is interpreted to suggest a causal relationship, he does not indicate that he considered either of those suspects to be a more likely cause than the other.

3. Dr. Young

Mrs. Caves also asserts that Dr. Young concluded that the influenza vaccine caused her TM. The particular statement referenced by petitioner, however, does not support such a reading. In his report on their initial consultation, Dr. Young

stated that petitioner suffered from impaired bladder and bowel function due to TM at the level of the L2 vertebra. Ex. 9 at 4. Dr. Young did not mention the vaccine that petitioner had received in November 2005. However, Dr. Young did point out that petitioner "had a flu-like syndrome about a week or so prior to her present neurological problems." *Id.* at 3. As noted above, respondent has argued that the minor illness experienced by Mrs. Caves approximately one week before the onset of her neurological symptoms is a logical and more likely cause of her TM than the influenza vaccination.

Whether the minor illness experienced by Mrs. Caves is best described as a "flu-like syndrome," *id.*, a "very mild sinus cold," Ex. 6 at 14, "mild sinus congestion symptoms," Ex. 5 at 32, or "some flu like symptoms," *id.* at 35, there does not appear to be any dispute that Mrs. Caves suffered from some type of infection or sinusitis between the time she was vaccinated and the onset of her neurological symptoms. Moreover, following his initial assertion that the minor illness was a side effect of the vaccine, *see* Tr. at 45, Dr. Smith later testified that it was unlikely that the minor illness she experienced was caused by the vaccination due to the period of time between the vaccine and her minor illness, *see id.* at 49.[13] With the understanding that the minor illness was more likely an independent occurrence that was not caused by the vaccine, Dr. Smith further testified that he could not state that the influenza vaccine was more likely than not the cause of petitioner's TM. *Id.* at 50. In short, to the extent that the statements of Dr. Young are relevant to the issue of causation at all, those statements undermine petitioner's case in that they point to the "flu-like syndrome" as a potential cause of her TM.

4. Dr. Chang

Dr. Chang noted that Mrs. Caves "has been having some flu-like symptoms,

---

[13]/ In his testimony, Dr. Smith expressed his understanding that petitioner experienced flu-like symptoms "several days after the vaccination[,]" and stated that such symptoms are "not uncommon after a vaccination." Tr. at 45. *See also* Ex. 29 at 1 ("As is often the case, [petitioner] developed some mild symptoms suggestive of a viral syndrome after her vaccination."), 2 ("[I]t is perhaps more likely that her viral symptoms were a result of the vaccine itself."). When he was informed that Mrs. Caves experienced her minor illness approximately two weeks after the vaccination, Dr. Smith stated that the vaccine was probably not the cause of that minor illness because such effects typically occur within a matter of days rather than weeks. *See* Tr. at 49.

had a flu shot earlier and developed decreased paralysis and acute exacerbation of the lower extremities, as well as transverse myelitis at the level of L2." Ex. 5 at 35. Once again, there is no express language in the report prepared by Dr. Chang to suggest that he believed the influenza vaccine caused petitioner's TM. Much like the statements of Drs. Rodriguez and Ali, the statements of Dr. Chang might be interpreted, at best, to suggest two alternative causes of petitioner's TM, and those statements do not indicate that either of those causes is more likely than the other.

5. Dr. Khan

Next, Mrs. Caves points to the discharge form prepared by Dr. Khan at Raulerson Hospital, which provides a diagnosis of "transverse myelitis, status post flu shot." Ex. 5 at 20. In the view of petitioner, that diagnosis implies that her TM was caused by the influenza vaccine. However, on the same form, Dr. Khan responded to a question regarding the cause of petitioner's TM by checking a box that stated he was "unable to determine" the cause of the disorder. Rather than concluding that Dr. Khan provided two contradictory responses on the discharge form, the special master interpreted the first response as a mere observation of the temporal relationship between the vaccine and the injury, instead of a determination that one caused the other.

Furthermore, petitioner's interpretation of the discharge form is also inconsistent with a later statement made by Dr. Khan. On June 6, 2006, Mrs. Caves had a follow-up appointment with Dr. Khan. In his notes on that appointment, Dr. Khan noted that "[t]he underlying factor [of petitioner's TM] has not been determined." Ex. 1 at 1.

6. Other Statements in Petitioner's Medical Records

In determining whether petitioner demonstrated that the influenza vaccine caused her TM, the special master was required to base his decision on the "record as a whole." 42 U.S.C. § 300aa-13(a). When viewed in isolation, the physician statements cited by petitioner do not meet her burden of proof on the issue of causation; when viewed in context, those statements have even less persuasive force. Mrs. Caves was transported to Raulerson Hospital by the Okeechobee County Fire Rescue Department on December 11, 2005. At that time, she informed the emergency medical personnel that her symptoms might be a reaction to an influenza shot. Ex. 4 at 1. Based on that initial statement to emergency

personnel, it would be reasonable to assume that she also communicated her belief regarding the cause of her symptoms to her treating physicians. Similarly, the triage report prepared for Mrs. Caves upon her admission to Raulerson Hospital stated that she "[h]ad a flu shot two weeks ago." Ex. 5 at 843. That observation, however, was contained in the section of the report entitled "patient complaints." *Id.* These two statements provide useful context for evaluating the import of the later statements made by her treating physicians.

Petitioner's medical records are replete with statements indicating the uncertainty of her treating physicians with respect to the etiology of her TM. As noted above, the report prepared by Dr. Rodriguez, which petitioner argues contains a clear conclusion that the influenza vaccine caused her TM, also states that he was ordering a work-up "to find potential etiologies." Ex. 6 at 16. Similarly, a progress note on December 13, 2005 stated that "we don't know the etiology[,]" and surmised that "we probably will not . . . ." *Id.* at 19. When petitioner was discharged from Shands, her discharge report indicated a diagnosis of TM. However, the report further noted that hospital personnel were still waiting on some of petitioner's lab results and "did not know the etiology of her transverse myelitis." Ex. 5 at 744. In the discharge report from the HealthSouth Treasure Coast Rehabilitation Hospital, Dr. Lockhart stated that "no real etiology [has been] found for [petitioner's] transverse myelitis." Ex. 7 at 13. In light of these statements, it was not unreasonable for the special master to reject petitioner's assertion that there was a "clear consensus" among her treating physicians that the influenza vaccine caused her TM.

In short, petitioner asserts that her treating physicians concluded that the influenza vaccine was the cause of her TM based on the observation of those physicians that she received the vaccine approximately three weeks before the onset of her neurological symptoms. The Federal Circuit has held that notations in medical records concerning the temporal relationship between a vaccine and an injury, without any express discussion of causation, are entitled to little weight:

> The Special Master did not err in failing to afford significant weight to the opinions of [petitioner's] treating physicians. As the Special Master observed in his decision, in seven of the nine notations, the physician was simply indicating an awareness of a temporal, not causal, relationship between the fever [petitioner] experienced after her MMR vaccine and the emergence

of her autistic symptoms sometime thereafter.

Cedillo, 617 F.3d at 1348; *see also Moberly*, 592 F.3d at 1324-25 (denying compensation and distinguishing an earlier case in which there was direct testimony from a treating physician "unequivocally" stating that there was a causal relationship between the vaccine and subsequent injury). In light of this binding precedent, and based on the record as a whole, the court cannot conclude that the special master's decision to afford little weight to the probative value of the statements of petitioner's treating physicians was arbitrary, capricious, an abuse of discretion, or otherwise contrary to law.

C. The Special Master Did Not Fail to Consider the Elimination of Alternative Causes as Circumstantial Evidence of Causation

Petitioner also asserts that the special master erred in dismissing the probative value of the absence of any apparent alternative causes for her TM. While the court agrees with petitioner that the elimination of alternative etiologies increases the likelihood that the influenza vaccine caused her illness, the court does not read the decision of the special master as holding that the elimination of such alternatives has no probative value at all. Rather, the special master held that the elimination of alternative causes, without more, does not demonstrate a logical sequence of cause and effect between the vaccine and petitioner's TM.[14]

---

[14]/ The special master discusses the probative value of excluding alternative etiologies in two different sections of his decision. In one of those sections, the special master appears to reach the conclusion that, due to the high percentage of cases of TM that are idiopathic, the elimination of alternative causes through a differential diagnosis has no probative value. *See* Opin. at 15. However, the special master reached that conclusion in his analysis of whether petitioner had demonstrated that the influenza vaccine is capable of causing TM (*i.e.*, the first prong of *Althen*). While the court agrees that the exclusion of alternative etiologies is not relevant to the issue of whether the influenza vaccine is capable of causing TM, the court's conclusion is not based on the frequently idiopathic nature of TM. Rather, the court believes that the issue of whether the influenza vaccine is *capable* of causing TM would not be affected by whether a petitioner's TM might have been caused by something else in a particular case. In his second discussion of the probative value of ruling out alternative causes, the special master merely holds that excluding such alternatives, without more, is insufficient to meet the second prong of *Althen*. The court notes that petitioner does not have the affirmative burden of eliminating other potential causes for her TM, and is not generally required to exclude such causes in order to make out a prima facie case. *See Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1149-50 (Fed. Cir. 2007).

First, the special master rejected petitioner's assertion that she eliminated the other potential causes of her TM, and he concluded there was still a dispute between the parties with respect to whether any of the three alternative causes proposed by respondent – CMV, the zoster virus, and a sinus cold virus – had been ruled out. Opin. at 24. While there is conflicting evidence in the record as to whether CMV and the zoster virus had been excluded as potential causes of petitioner's TM, the court does not discern any evidence in the record – aside from Dr. Smith's testimony – that the minor illness experienced by Mrs. Caves had been eliminated as a potential cause of her TM.[15]

In addition, the special master held that, even if those alternative causes had in fact been eliminated by petitioner, that fact alone would not establish that the influenza vaccine was the cause of petitioner's TM. *See* Opin. at 24-25 (noting that "the 'simplistic elimination of other potential causes of the injury [does not] suffice[], without more, to meet the burden of showing actual causation'") (quoting *Moberly*, 592 F.3d at 1323). In short, the special master did not hold that the elimination of alternative causes is irrelevant; rather, he held that such a showing is insufficient to meet petitioner's burden without other supporting evidence. That conclusion was not erroneous. *See Moberly*, 592 F.3d at 1323 ("As this court has stated, 'neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.'") (quoting *Althen*, 418 F.3d at 1278); *Grant*, 956 F.2d at 1149 (noting that "evidence

---

[15]/ The lab results for Mrs. Caves indicated that she had been previously exposed to CMV, Ex. 5 at 146, but that she did not have an active CMV infection at the time of her hospitalization, Ex. 6 at 27-29. Similarly, petitioner's medical records indicate that she had experienced at least one previous outbreak of shingles, Ex. 1 at 5, but her lab tests indicated that she did not have an active zoster virus infection at the time her lab tests were performed, Ex. 6 at 30. Dr. Safran provided a theory to reconcile those test results with his assertion that petitioner's TM could have been caused by either CMV or the zoster virus. Tr. at 132-34. Dr. Smith conceded that shingles, which he described as a "dermatomal reactivation of the zoster virus[,]" "is very, very commonly associated with transverse myelitis, and central nervous system complications." Tr. at 58. Dr. Smith also testified that CMV can cause TM, but noted that CMV-caused TM is rare in immunocompetent individuals. Tr. at 217. The minor illness experienced by Mrs. Caves one week before the onset of her neurological symptoms was not definitively diagnosed, but Dr. Smith testified that it is rare for TM to follow a sinus infection. Tr. at 56. Dr. Safran, in contrast, testified that approximately thirty-seven percent of cases of TM are preceded by an antecedent respiratory infection. Tr. at 103. In short, the special master was correct in his assessment that there is a significant dispute between the parties with respect to whether other potential causes of petitioner's TM have been ruled out in this case.

showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation").

The Federal Circuit has observed that preponderant evidence demonstrating that a particular vaccine caused a particular injury will, as a practical matter, eliminate other potential etiologies. *See Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007). From that premise, petitioner reaches the conclusion that the converse must also be true, *i.e.*, that the elimination of an alternative cause proves that the vaccine caused the injury. However, the only situation in which the elimination of alternative causes would prove that the vaccine was in fact the cause of the injury is when all potential causes of the injury are known and all, or at least most, of those causes other than the vaccine have been eliminated. That is not the case here. The experts for both parties agreed that, in the majority of cases of TM, the underlying cause is never known or discovered. *See* Ex. 29 at 1; Tr. at 51-52, 103. For that reason, while the elimination of alternative causes might marginally increase the likelihood that a vaccine caused an injury, such a showing would be insufficient in most cases to meet the second prong of *Althen*. Because the majority of cases of TM are idiopathic, in other words, the elimination of other identified causes would have limited probative value in establishing the influenza vaccine as the actual cause of petitioner's TM.

D. The Special Master Did Not Disregard the Temporal Relationship between the Petitioner's Vaccination and Her Subsequent Development of Transverse Myelitis in Evaluating the Evidence of Causation

In her final assignment of error, Mrs. Caves argues that the special master failed to consider the evidence of an appropriate temporal relationship between petitioner's influenza vaccination and her subsequent development of TM with respect to the first two prongs of *Althen*. In other words, petitioner argues that the close temporal proximity between the inoculation and the injury is probative with respect to whether the influenza vaccine is capable of causing TM and whether this particular vaccination caused petitioner's TM. In support of that assertion, petitioner cites the Federal Circuit's decision in *Capizzano*, which held that evidence may be probative with respect to more than one prong of the *Althen* analysis:

> We see no reason why evidence used to satisfy one of the

> *Althen III* prongs cannot overlap to satisfy another prong. In other words, if close temporal proximity, combined with the finding that hepatitis B vaccine can cause [rheumatoid arthritis], demonstrates that it is logical to conclude that the vaccine was the cause of the injury (the effect), then medical opinions to this effect are quite probative.

440 F.3d at 1326. While petitioner is correct that evidence may be relevant with respect to more than one prong of the *Althen* analysis, there is no question that the temporal relationship between petitioner's vaccination and her TM, without more, is insufficient to satisfy the first or second prong of the analysis. There is no indication that the special master did not consider the temporal relationship between the administration of the vaccine and the later development of petitioner's TM. Rather, the special master merely held that a temporal relationship and an absence of other apparent causes, without more, is insufficient to meet a petitioner's burden of proof. As already noted above, the Federal Circuit has held that "'neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.'" *Moberly*, 592 F.3d at 1323 (quoting *Althen*, 418 F.3d at 1278); *see also Grant*, 956 F.2d at 1148 ("When a petitioner relies upon proof of causation in fact rather than proof of a Table injury, a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury.").

IV. Petitioner's Characterization of the Standard of Proof

In addition to the specific allegations of error she raised in her motion for review, Mrs. Caves generally asserts that she met her burden of proof on the issue of causation and argues that the special master improperly heightened that burden. However, it appears that petitioner contends she is required to establish causation by something less than the preponderant evidence standard that applies in tort law. That contention is incorrect.

In an off-Table case, the petitioner has the burden of demonstrating, by a preponderance of the evidence, that a listed vaccine caused the petitioner's injury or illness. In order to meet the standard of preponderant evidence, the party with the burden of establishing a disputed fact must demonstrate that the existence of that fact is more likely than its nonexistence. *Concrete Pipe & Prod. of Cal., Inc.*

v. Constr. Laborers Pension Trust for So. Cal., 508 U.S. 602, 622 (1993). This is a probabilistic standard, under which a petitioner must prove that there is a greater than fifty percent probability that a vaccine caused the asserted injury. *See Althen v. Sec'y of the Dep't of Health & Human Servs.*, 58 Fed. Cl. 270, 283 (2003) (stating that, under the preponderant evidence standard, a plaintiff must prove each fact necessary to its case by a probability of greater than 0.5), *aff'd*, 418 F.3d 1274 (Fed. Cir. 2005); *see also Hellebrand v. Sec'y of the Dep't of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993) (noting that "[w]ith the aid of statistical analysis it is possible to ascertain where the preponderance lies") (Newman, J., concurring in the judgment).

The Federal Circuit has consistently held that the standard of proof for causation in an off-Table Vaccine Act case is the exact same as that applied in the tort context. *See Walther*, 485 F.3d at 1151 ("Moreover, under the Restatement (Second) of Torts, which is controlling in off-Table cases, for purposes of the causation analysis the petitioner is treated as the equivalent of the tort plaintiff and the government is treated as the equivalent of the tort defendant."); *Shyface*, 165 F.3d at 1344 ("We adopt the Restatement rule for purposes of determining vaccine injury, that an action is the 'legal cause' of the harm if that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action."); *Grant*, 956 F.2d at 1148 (noting that the Vaccine Act "does not relax proof of causation in fact for non-Table injuries").

In her motion for review, petitioner discusses the legislative history of the Vaccine Act for the apparent purpose of demonstrating that Congress expected that a lower standard of proof would apply in Vaccine Act cases to ensure that petitioners are compensated "quickly, easily, and with certainty and generosity." *See* Motion for Review at 20 (quoting H.R. Rep. No. 99-908, at 3 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344). That argument was squarely rejected by the Federal Circuit in *Moberly*:

> The petitioners also invoke legislative intent and the purposes of the federal Vaccine Program to argue that a standard less demanding than the tort standard of causation is applicable. In doing so, however, they conflate the burden of proof imposed for off-Table injuries with the lenient presumptions applicable to Table injuries.

Moberly, 592 F.3d at 1322. Although Mrs. Caves discusses the legislative history of the Vaccine Act in the context of her opposition to the special master's application of the *Daubert* analysis, it appears that her entire motion for review is organized around the assumption that petitioners in off-Table cases must be held to a lower standard than their counterparts in tort actions. While it is true that "close calls regarding causation are resolved in favor of injured claimants[,]" *Althen*, 418 F.3d at 1280, that rule applies only when the evidence on the issue of causation is in equipoise, or nearly so. Here, in contrast, the special master concluded that Mrs. Caves fell far short of meeting her burden of proof.

Petitioner also appears to argue that a lower burden of proof should apply because there is a dearth of scientific evidence connecting the influenza vaccine to TM. However, the Federal Circuit has rejected the argument that a petitioner can be relieved of her burden by virtue of the limitations of scientific knowledge. In an off-Table case,

> the heavy lifting must be done by the petitioner, and it is heavy indeed. Given the statutory burden of persuasion placed on petitioner, and the general state of knowledge about the causes of infant illness and death, it is not surprising that petitioners have a difficult time proving cases such as this.

Hodges, 9 F.3d at 961 (citation omitted). While petitioners in Vaccine Act cases are not required to provide conclusive scientific evidence to demonstrate "a sequence hitherto unproven in medicine," *Althen*, 418 F.3d 1280, particularly in "a field bereft of complete and direct proof of how vaccines affect the human body[,]" *id.*, they are nonetheless required to demonstrate each element of their case by a preponderance of the evidence in off-Table cases. The standard of proof does not operate as a sliding scale that varies depending upon the quantity and quality of the scientific evidence that is available.

The petitioners in *Moberly* raised many of the same arguments raised by petitioner here.[16] The Federal Circuit rejected those arguments:

> While the petitioners acknowledge that the statute

[16]/ This similarity is not merely a coincidence. The petitioners in *Moberly* were represented by the same law firm as the petitioner in this case.

> requires proof of causation by a preponderance of the evidence, they appear to be arguing for a more relaxed standard. They repeatedly characterize the test as whether [petitioner's] condition was "likely caused" by the DPT vaccine. By that formulation, however, they appear to mean not proof of causation by the traditional "more likely than not" standard, but something closer to proof of a "plausible" or "possible" causal link between the vaccine and the injury, which is not the statutory standard.

Moberly, 592 F.3d at 1322 (citation and footnote omitted). Here, Mrs. Caves argues that she has met prong one of the *Althen* test because her expert presented a "plausible" medical theory connecting the influenza vaccine to TM, and she asserts that she has met prong two of that test because the vaccine must be viewed as the "most likely" cause of her TM in the absence of any other identified cause.[17] The special master held that the evidence presented by petitioner was insufficient to carry her burden under the preponderant evidence standard applicable in Vaccine Act cases. That conclusion was not arbitrary or capricious.

Mrs. Caves asserts that the special master applied a heightened burden of proof on the first prong of the *Althen* test by requiring her to present scientific evidence related to the precise biological mechanism through which the influenza vaccine caused her TM. Mot. for Review at 15, 19-24. According to petitioner, the appropriate inquiry was whether she had described a "biologically plausible" medical theory connecting the vaccine to her injury. Mrs. Caves asserts that she met that standard in this case.

---

[17]/ The court notes that it is imprecise to describe the preponderant evidence standard as whether a vaccine is the "most likely" cause of an injury. There are circumstances in which a vaccine may be the most likely identified cause of an injury, but nonetheless fails to meet the standard of "more likely than not." Assume, for example, that there are five potential causes for an asserted injury – A, B, C, D, and E – and further assume that the evidence demonstrates that there is a forty-percent probability that A caused the injury, while there is a fifteen-percent probability for each of causes B, C, D, and E. While A would be the "most likely" cause of the injury in that scenario, the evidence would not support a conclusion that A "more likely than not" caused the injury. Instead, assuming the five potential causes are both collectively exhaustive and mutually exclusive, there would be a forty-percent likelihood that A caused the injury, while there would be a sixty-percent probability (a preponderance) that either B, C, D, or E caused the injury.

The court notes that the special master did not require Mrs. Caves to demonstrate the precise biological mechanism through which the influenza vaccine allegedly caused her TM. Rather, the special master held that petitioner had failed to advance a "persuasive" medical theory to demonstrate that the influenza vaccine is capable of causing TM at all. Put another way, the special master properly concluded that petitioner was required to satisfy the first prong of the *Althen* test by a preponderance of the evidence, *i.e.*, whether it is more likely than not that the influenza vaccine is capable of causing TM.[18] *See Broekelschen*, 618 F.3d at 1350 (holding that petitioners must meet the first prong of *Althen* by a preponderance of the evidence); *Moberly*, 592 F.3d at 1322 (noting that a medical theory of causation must be "probable"); *Althen*, 418 F.3d at 1278 (holding that petitioners must establish a "persuasive" medical theory that is supported by a "reputable medical or scientific explanation"). In requiring petitioner to advance a medical theory explaining how the influenza vaccine is capable of causing TM in general, the special master did not impose upon petitioner the additional burden of demonstrating that the proffered theory was at work in this particular case.[19]

While this court has determined that petitioner has failed to carry her burden of proof in this case, and while the undersigned has upheld the ultimate decision of the special master, the court does recognize some problems with the special master's analytical process, particularly with respect to prong one of *Althen*. The court notes that the special master's analysis, to some degree, has conflated the relevant evidence required for an analysis of prong two with that required for prong one of *Althen*.

---

[18]/ The court recognizes that a very recent decision by another judge of this court disapproves of the same analytical framework employed by the special master in this case. In addition to the factual distinctions between the two cases, this court notes that the undersigned is not bound by the decision in *Doe 93 v. Sec'y of Health & Human Servs.*, No. 07-448, 2011 WL 1615238 (Fed. Cl. Apr. 29, 2011), and respectfully declines to adopt the analysis contained therein.

[19]/ In some cases, for example, expert witnesses for petitioners have provided multiple theories of causation without claiming to know which of the proposed biological mechanisms was actually responsible for the asserted injury. *See, e.g., Adams v. Sec'y of the Dep't of Health & Human Servs.*, 76 Fed. Cl. 23, 36-40 (2007) (holding that a petitioner met prong one of *Althen* because two of the three medical theories presented by her expert "were not persuasively rebutted" by respondent). As long as a petitioner demonstrates, by a preponderance of the evidence, that a particular vaccine is capable of causing a particular type of injury, it does not matter whether the petitioner can demonstrate the precise biological mechanism that caused the injury in that particular case.

First, the elimination of alternative causes for petitioner's TM has no direct relevance to prong one of the *Althen* analysis. *See supra* note 14. While the exclusion of alternative etiologies is usually quite probative with respect to prong two of the *Althen* analysis – *i.e.*, whether the vaccine caused the injury in a particular case – it does not make it any more or less likely that the influenza vaccine is *capable* of causing TM in general. Although the special master properly discussed whether Mrs. Caves had excluded alternative causes of her TM in his analysis of prong two of *Althen*, he should not have addressed that issue in his analysis of prong one. The special master's reason for rejecting the probative value of that evidence, moreover, misses the mark. Evidence that tends to exclude alternative etiologies is not irrelevant with respect to *Althen* prong one because of the idiopathic nature of most cases of TM; rather, such evidence is irrelevant because there is no direct logical connection between whether the influenza vaccine is capable of causing TM and whether something else might have caused petitioner's TM in this case.

Second, it appears that most of the analysis contained on page 19 of the special master's decision concerns Dr. Smith's testimony regarding whether the influenza vaccine actually caused petitioner's TM in this case, as opposed to whether the vaccine is capable of causing TM as a general matter. While the special master's discussion purports to evaluate the reliability of Dr. Smith's "theory," it is clear that much of the testimony under consideration addressed his assertion that the vaccine actually caused petitioner's TM, not the logically antecedent issue of whether the vaccine is capable of causing TM at all. Because the special master's negative assessment of Dr. Smith's reliability appears to have been based, at least in part, on testimony addressed to prong two of the *Althen* test, the court cannot disregard the possibility that the special master's analysis of the first prong of *Althen* was based in part on evidence that was not relevant to whether the influenza vaccine is capable of causing TM.

The court recognizes that evidence that is relevant to whether a particular vaccine actually caused a particular injury may be ultimately relevant to whether that vaccine is capable of causing that type of injury. Indeed, as noted by the special master, a statement that a vaccine did in fact cause an injury presupposes that the vaccine is capable of causing that injury. *See* Opin. at 15. In addition, the court also notes that the special master's analysis of the evidence in this case was determined in large part by the manner in which petitioner argued her case. However, the court believes that it is important to maintain an analytical demarcation between the evaluation of evidence that tends to demonstrate that a

vaccine caused an asserted injury in a particular case, and evidence that tends to demonstrate that a specific vaccine is capable of causing a certain injury or illness as a general matter. Because the special master conflated those issues in his analysis, the court cannot dismiss outright petitioner's contention that the special master heightened her burden of proof on prong one of the *Althen* test.

However, to the extent that the special master's analysis of the evidence on the first prong of the *Althen* test was flawed in this respect, the court is convinced that any resulting errors were harmless because Mrs. Caves failed to meet her burden of proof on the second prong of the *Althen* test. In determining whether petitioner carried her burden of demonstrating a logical sequence of cause and effect between the influenza vaccination she received in November 2005 and her subsequent development of TM, the special master evaluated the statements of petitioner's treating physicians, the expert testimony of Dr. Smith, and the probative value of eliminating alternative causes of TM. First, the special master concluded, based on petitioner's medical records and the interpretation of those records offered by the parties' experts, that none of petitioner's treating physicians concluded that her TM was caused by the vaccine. Next, the special master rejected Dr. Smith's assertion that the vaccine caused petitioner's TM because that assertion was based on no more than the temporal association between the vaccine and the injury, and an absence of other apparent causes. Finally, the special master held that there was still a genuine dispute between the parties with respect to whether petitioner had excluded other potential causes of her TM. The special master also noted that, even if Mrs. Caves had conclusively eliminated the three alternative causes proposed by respondent, the exclusion of such causes would be insufficient to meet her burden of proof on prong two of *Althen* because the majority of cases of TM are idiopathic.

The court discerns no error in the special master's analysis of the second prong of *Althen*, and his findings of fact on that issue were neither arbitrary nor capricious. Because Mrs. Caves failed to meet her burden of proof on prong two of *Althen*, she is not entitled to compensation under the Vaccine Act. *See Broekelschen*, 618 F.3d at 1350 (noting that a Vaccine Act petitioner must prove each of the three elements of the *Althen* test by a preponderance of the evidence).

CONCLUSION

For all of the above reasons, the court holds that the special master's decision in this case was not arbitrary, capricious, an abuse of discretion, or

otherwise not in accordance with law.

Accordingly, it is hereby **ORDERED** that

(1) Petitioner's Motion for Review, filed on December 29, 2010, is **DENIED**;

(2) The decision of the special master, filed on November 29, 2010, is **SUSTAINED**;

(3) The Clerk's Office is directed to **ENTER** judgment dismissing the petition; and

(4) The parties shall separately **FILE** any proposed redactions to this opinion, with the text to be redacted clearly marked out or otherwise indicated in brackets, on or before **June 15, 2011**.

/s/ Lynn J. Bush
LYNN J. BUSH
Judge