



expert disagreed. The weight of the evidence, considered as a whole, does not support her expert's theory. Thus, Ms. Caves is not entitled to compensation.

## **I. Factual Background**

Ms. Caves was born in 1953. Amend. Pet. ¶ 1; exhibit 10 at 5. Her medical history, prior to the vaccination at issue, does not appear to be relevant. Respondent has not argued that any illness in Ms. Caves's medical history is relevant to her claim for compensation. See Resp't Rep't at 2, 19.

Before her influenza vaccination, Ms. Caves worked as a registered nurse at Raulerson Hospital, a position she held for 30 years. Exhibit 11 (affidavit of Joan Caves dated June 27, 2007) ¶ 3. Her duties at the time of the vaccination included working in an operating room as a circulator and taking calls for after hours cases. Ms. Caves was also the nurse manager supervising 20 employees. Id.

Ms. Caves received an influenza vaccination on November 18, 2005. Exhibit 10 at 5. In an affidavit, Ms. Caves states that approximately three weeks later, on December 11, 2005, she noticed pain and weakness in her legs and back. Some of the pain was relieved when Ms. Caves got up and walked around. However, Ms. Caves continued to experience pain in her lower back and legs later that day while returning home from church. When she arrived home, Ms. Caves went to bed which gave her some additional pain relief. Exhibit 11 ¶ 5-6.

At approximately 3 o'clock that afternoon, Ms. Caves's condition quickly deteriorated. Ms. Caves states that her legs were numb and she was completely unable to walk. She was transported to the emergency room at Raulerson Hospital by the Okeechobee County Fire Rescue Department. Exhibit 4 at 1.

At Raulerson Hospital, Ms. Caves underwent a series of laboratory tests including a complete blood count and erythrocyte sedimentation rate. The Raulerson Hospital Emergency Room triage note reports:

[P]atient [states] that she was sitting having coffee and her legs starting cramping both legs, went to church 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. [Patient] awake and alert. [Patient] able to feel touch on left leg [slightly] different, right leg very num[b], unable to move right leg or foot. Numbness on right up to hip.

Exhibit 5 at 843-44. An x-ray of the spine and a CT (computerized tomography) scan of the brain were performed. The results were negative. Exhibit 5 at 860-62, 866, 868.

The next day, Ms. Caves was transferred to the Shands Medical Center at the University of Florida in Gainesville, Florida. While at Shands, Ms. Caves was evaluated by Dr. Ramon Rodriguez. In reviewing Ms. Caves's medical history, Dr. Rodriguez notes that:

Ms. Caves has never experienced such severe leg pain or any focal weakness or numbness in the past. She has had no associated symptoms prior to those described above. She 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.

Exhibit 5 at 741.

In conducting the physical examination, Dr. Rodriguez also notes:

Sensory exam reveals decreased sensation in pin prick circumferentially up to the knee on the right lower extremity and half-way up to the pelvic shin on the left lower extremity . . . She has significant allodynia of both lower extremities, right greater than left. This is particularly notable in her right proximal thigh laterally.

Id. at 742.

In the assessment plan, Dr. Rodriguez notes, "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 could certainly 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.

A December 13, 2005 progress note indicates that Ms. Caves began steroid treatment, which brought some improvement. Exhibit 5 at 736. Ms. Caves was discharged from Shands Hospital on December 14, 2005, with a diagnosis of transverse myelitis. Id. She was transferred back to Raulerson Hospital for inpatient rehabilitation.

On December 15, 2005, Ms. Caves was evaluated by Dr. Abu Ali, a neurologist. Dr. Ali notes that Ms. Caves was still experiencing significant weakness in her legs although she could move her legs bilaterally and proximally. Dr. Ali also notes that Ms. Caves's problems with bowel incontinence and bladder retention did not show improvement. Exhibit 5 at 32. In recounting Ms. Caves's medical history, Dr. Ali notes "interestingly she had received a flu vaccination about two weeks prior to the onset of symptoms and a week prior to the onset of symptoms she had mild sinus congestion symptoms. She did not report any frank flu like symptoms." Id. Dr. Ali's impressions included "paraplegia relatively acute onset, which has improved to paretic stage, with significant weakness in both lower extremities . . . This is most likely in favor of transverse myelitis terminal cord." Id.

That same day, Ms. Caves was also evaluated by Dr. Marvin Young, a urologist, for issues with her bladder. Exhibit 9 at 3-4; exhibit 5 at 37-38. Dr. Young notes in Ms. Caves's medical history that she "had a flu like syndrome about a week or so prior to her present neurologic problems." Id. Dr. Young's impression of Ms. Caves was "transverse myelitis resulting in compromised bladder and bowel function." Dr. Young recommended that Ms. Caves continue with intermittent catheterization as well as a bowel regime with Dulcolax. Id.

On December 16, 2005, Ms. Caves was evaluated by Dr. John Chang, a gastroenterologist. Dr. Chang notes in Ms. Caves's medical history, "[t]he patient 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 the L2." Exhibit 5 at 35. Dr. Chang's treatment plan included following "with gastrointestinal prophylaxis with proton pump inhibitor (PPI) and also consider motility agent for the bowel activity, and also add Colace at this time." Id.

Ms. Caves continued her physical therapy at Raulerson Hospital until she was discharged on December 24, 2005. On the discharge form, Dr. Khan noted that Ms. Caves's diagnosis was "transverse myelitis, status post flu shot." However, Dr. Khan checked the box "Unable to determine" indicating that the cause of Ms. Caves's transverse myelitis was unknown. Exhibit 5 at 20.

Ms. Caves was admitted to Health South Treasure Coast Rehabilitation Hospital on December 28, 2005, for further rehabilitation. Exhibit 7 at 1. At this time, Ms. Caves's care included supervision with eating and grooming, assistance with dressing, toileting, bladder and bowel management and total assistance with ambulation. She required no assistance with comprehension, expression, social interaction, problem solving and memory. Exhibit 7 at 13.

Ms. Caves was discharged from Health South on February 2, 2006. At that time, Ms. Caves required no assistance with eating, required moderate supervision with grooming and bathing, and required moderate assistance with bowel management, transfers and wheelchair mobility. Ms. Caves still required total assistance with ambulation. The discharge summary, signed by Dr. Jimmy Lockhart (the admitting physician), noted that Ms. Caves did well throughout her hospitalization, but with "no real neurologic recovery." It was also noted that there was "no real etiology found for her transverse myelitis." Id. at 14.

On March 27, 2006, Ms. Caves presented to Dr. Khan for a follow-up examination and treatment. Exhibit 1 at 2. Dr. Khan noted that Ms. Caves had some improvement in "movement in her lower left extremities," but that her "right side is still extremely weak." Ms. Caves was, however, able to take some steps with her walker. Id.

On April 17, 2006, Ms. Caves presented to Dr. Young. Exhibit 9 at 1. Dr. Young notes that he was "happy to see that [Ms. Caves] is in fact regaining some function." Dr. Young also notes that her "bowel movements have also regularized and she is able to move her bowels without the use of suppositories or digital manipulation." Dr. Young's impression at that time

was that Ms. Caves “is doing quite well managing herself with timed voiding and is also moving her bowels daily. She clearly has a neurologic bladder. Fortunately, I think she has a low-pressure system with diminished pressure outlet.” Id.

On May 3, 2006, Ms. Caves presented to Dr. Ali for a follow-up evaluation. Exhibit 8 at 1-4. Dr. Ali concluded that Ms. Caves had transverse myelitis and paraplegia, which was slowly improving. Id.

On June 6, 2006, Ms. Caves followed-up again with Dr. Khan. Exhibit 1 at 1. Dr. Khan notes that an “underlying factor has not been determined” for Ms. Caves’s transverse myelitis. Dr. Khan recommended that Ms. Caves continue with her current treatment plan. Id.

Ms. Caves continued with physical therapy until she was discharged on April 10, 2007. Exhibit 21 at 1; Exhibit 22 at 17. In her June 27, 2007 affidavit, Ms. Caves described her condition as:

I am no longer able to work as an operating room nurse. Much of my daughter’s care has been transferred to my husband, as [he] has all of the management of the house. Much of my energy is consumed with my own daily needs. Activities of daily life that used to take minutes now take hours . . . The worst part of all of this has been that I have had to become so focused on myself. My life has been about caring for others, my family, my patients, and my mission work.

Exhibit 11 ¶ 10-11, 13.

Transverse myelitis, the condition that afflicts Ms. Caves, is a rare condition. Tr. 54 (testimony of Dr. Smith); tr. 94 (testimony of Dr. Safran, estimating incidence rate to be approximately 8 cases per million); tr. 156 (same). The term “transverse myelitis” means that there is dysfunction in the spinal cord. Tr. 17. A precise definition is that there is inflammation in the spinal cord because the suffix “-itis” indicates inflammation. Tr. 71; Dorland’s Illustrated Medical Dictionary (30th ed. 2003) at 960.<sup>2</sup> Inflammation in transverse myelitis can be triggered by an infectious agent. Tr. 17; tr. 49; tr. 72. The ultimate cause of most cases of transverse myelitis is not identified. Exhibit 29 (report of Dr. Smith) at 1; tr. 50-51 (testimony of Dr. Smith); tr. 102 (testimony of Dr. Safran). One reason that the ultimate cause of transverse myelitis is not identified is that scientists do not have perfect ability to detect infectious agents. Tr. 215 (testimony of Dr. Smith).

The medical community believes that some cases of transverse myelitis are autoimmune. Tr. 18 (testimony of Dr. Smith); tr. 126 (testimony of Dr. Safran). An autoimmune condition is

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<sup>2</sup> When a vascular event damages the spinal cord, the precise diagnosis is transverse myelopathy (not myelitis). Tr. 71. Ms. Caves was diagnosed with transverse myelitis in part because doctors ruled out any vascular causes for the damage to her spinal cord. See tr. 18 (testimony of Dr. Smith); tr. 89-90 (testimony of Dr. Safran).

one in which the body's immune system, which usually is protective, becomes confused and attacks self. An autoimmune attack on the central nervous system may lead to a type of damage to the nerves in the spinal cord, known as demyelination. Tr. 18-19. This theory — that the flu vaccine can cause an autoimmune attack, leading to demyelination and, ultimately, to transverse myelitis — underlies Ms. Caves's claim for compensation.

## **II. Procedural History**

Ms. Caves filed her petition seeking compensation on June 28, 2007. She filed a collection of the medical records approximately two weeks later. Additional records were filed between November 2007 and February 2008.

Respondent filed her report, pursuant to Vaccine Rule 4, on September 28, 2007. Respondent asserted that Ms. Caves was not entitled to compensation. In particular, respondent stated that a review of Ms. Caves's medical records demonstrates that her "treating physicians never concluded that [Ms. Caves's] vaccine was the likely cause of her [transverse myelitis]." Resp't Rep't at 10. Respondent also noted that "petitioner has not submitted any expert opinion in support of her position. Instead, petitioner attempts to rely on statements made by her treating physicians." Id. at 10.

Ms. Caves filed an amended petition and a motion for ruling on the existing record. In the motion, Ms. Caves argued that "her medical records and the medical opinions of her treating physicians demonstrate preponderant evidence that the flu vaccine, not something else, caused her symptoms." Pet'r Mot. for Ruling on the Record, filed Jan. 7, 2008, at 14. In particular, Ms. Caves cited passages from Dr. Abul Ali, a neurologist; Dr. Marvin Young, a urologist; Dr. John Chang, a gastroenterologist; and Dr. Saeed Khan, Ms. Caves's primary care physician. Id. at 15. During this time, respondent also requested additional medical records from Ms. Caves, which were filed in January and February 2008.

On April 23, 2008, respondent filed a response to petitioner's motion for ruling on the record as well as the curriculum vitae and expert report of Dr. Arthur P. Safran. Dr. Safran's report discounted any association between Ms. Caves's influenza vaccination and her onset of transverse myelitis stating that "[t]here is no reason to suspect the influenza inoculation given that [transverse myelitis's] background does not appear to be above expected in the population." Exhibit A at 4.

A status conference was held on June 11, 2008. During that status conference, petitioner conceded that she was unlikely to prevail on her Motion for Ruling on the Record and requested the opportunity for a hearing to cross-examine respondent's expert, Dr. Safran. Petitioner was ordered to file a motion requesting such a hearing. As of June 11, 2008, Ms. Caves had not filed an expert report.

Ms. Caves filed her motion requesting a hearing to cross-examine Dr. Safran on July 16, 2008. Respondent filed a response on August 22, 2008, arguing that Ms. Caves has

“misunderst[ood] what she must prove to demonstrate actual causation” by attempting to prove her case through Dr. Safran. Respondent argued that the evidence presented by Ms. Caves fails to establish a prima facie case and therefore her case must fail and her motion to cross-examine Dr. Safran should be denied.

Ms. Caves’s motions were denied. The statements of the treating doctors identified by Ms. Caves did not support a finding that Ms. Caves had established that she was entitled to compensation. Ms. Caves’s argument was lacking for two of the elements that she is required to establish: a medical theory causally connecting the flu vaccine to transverse myelitis and a logical sequence of cause and effect between the flu vaccine and her development of transverse myelitis. See Order, 2008 WL5970976, at \*8-9 (Fed. Cl. Spec. Mstr. Nov. 25, 2008) (citing Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Additionally, Ms. Caves had not established that she was entitled to a hearing to cross-examine respondent’s expert when she had not presented an expert. Id. at \*10.

Ms. Caves obtained an expert report from Dr. Derek Smith, which was filed as exhibit 29. Dr. Smith opined that the flu vaccine caused Ms. Caves’s transverse myelitis. Dr. Smith proposed that the influenza vaccine antigen activated self-reactive T-cells. According to Dr. Smith, the “consensus model” for the pathogenesis of transverse myelitis involves an interaction between activated T-cells and part of the central nervous system. Dr. Smith acknowledged that the “‘scarce’ epidemiologic data . . . do not support ‘a relationship between influenza vaccine and transverse myelitis.’” This recognition did not dissuade Dr. Smith from opining that the flu vaccine caused Ms. Caves’s transverse myelitis because “the same data do very little to reject a rare relationship.”

Respondent filed another report from Dr. Safran, which addressed Dr. Smith’s report. Dr. Safran maintained that the immunologic mechanisms proposed by Dr. Smith “apply to various foreign agents including various viral infections.” Dr. Safran also stated that statistical analyses “demonstrate no association [between] influenza vaccine and transverse myelitis.” Finally, Dr. Safran suggested that a virus was the more likely cause of Ms. Caves’s transverse myelitis. Exhibit C.

Approximately one week before the hearing, the undersigned submitted five articles into the record. Order, filed Dec. 1, 2009 (citing Hines v. Sec’y of Health & Human Servs., 940 F.2d 1518, 1526 (Fed. Cir. 1991), and Wittner v. Sec’y of Health & Human Servs., 43 Fed. Cl. 199, 205 (1999)). The source of these articles was another case in which the petitioner happened to be represented by the same attorney who represents Ms. Caves.

A hearing was held in Boston, Massachusetts. The witnesses were Dr. Smith and Dr. Safran. Citations to this hearing are abbreviated “Tr.” Following the hearing, both parties filed

briefs.<sup>3</sup> After the written submissions, an oral argument was conducted. The completion of oral argument makes this case ready for adjudication.<sup>4</sup>

### **III. Standards for Adjudication**

There are at least three distinct parts to evaluating whether a petitioner is entitled to compensation. One part is to articulate the elements of the petitioner's case. These elements are "what" petitioner must establish. A separate part of the analysis is the quantum of evidence that a petitioner must introduce, which is the burden of proof. A final aspect is the process of weighing or evaluating the evidence that is submitted. These three portions are discussed separately.

#### **A. Elements of Petitioner's Case**

To receive compensation under the Program, Ms. Caves must prove either: (1) that she suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding to the influenza vaccination, or (2) that she suffered an injury that was actually caused by the influenza vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, no injuries are associated with the influenza vaccine on the Vaccine Injury Table. Thus, Ms. Caves must prove causation in fact.

When a petitioner proceeds on a causation-in-fact theory, a petitioner must establish three elements. The petitioner's

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

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<sup>3</sup> Ms. Caves filed her initial brief ("Pet'r Br.") on March 18, 2010. Respondent's brief ("Resp't Br.") was filed on April 19, 2010. Ms. Caves's reply brief (Pet'r Reply.) was submitted on May 3, 2010.

<sup>4</sup> With consent of the parties, the oral argument was held in conjunction with another case in which the petitioner alleged that the flu vaccine caused her to develop transverse myelitis. Doe 93 v. Sec'y of Health & Human Servs., No. [redacted], 2010 WL 4205677 (Fed. Cl. Spec. Mstr. Oct. 20, 2010), motion for review filed (Nov. 8, 2010). The oral arguments were consolidated as a matter of convenience because the two petitioners were represented by attorneys from the same law firm. Although the oral argument is part of the record in each case, each case has been decided upon the evidence presented in that case alone. See Althen, 418 F.3d at 1281 (stating that special masters make decisions on a case-by-case basis).

Althen, 418 F.3d at 1278.

## **B. Burden of Proof**

For the elements that petitioners are required to prove, their burden of proof is a preponderance of the evidence. 42 U.S.C. § 300aa–13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master’s decision that petitioners were not entitled to compensation); see also Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357 (2000); Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge’s contention that the special master confused preponderance of the evidence with medical certainty). In this regard, “close calls regarding causation are resolved in favor of injured claimants.” Althen, 418 F.3d at 1280.

## **C. How to Weigh Evidence**

The preceding sections explain what a petitioner is required to establish and what level of proof satisfies the petitioner’s obligation. The remaining issue is how to evaluate evidence submitted to meet the standard of proof on those elements. Three authorities generally instruct special masters in how to evaluate evidence. They are Congress, the United States Court of Federal Claims, and the United States Court of Appeals for the Federal Circuit.

Congress is the first authority for instructions about how to weigh evidence. In enacting the National Vaccine Injury Compensation Act, specifically section 13, Congress provided some instructions about how special masters should analyze the evidence. Among other provisions, section 13 dictates that the special master should consider “the record as a whole.” Section 13 also provides that the special master shall 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.” Nevertheless, “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court.”

The second authority is the United States Court of Federal Claims, in its capacity as rule maker. Congress authorized the Court of Federal Claims to promulgate rules of procedure for cases in the Vaccine Program. 42 U.S.C. § 300aa–12(d)(2). Collectively, the judges of the Court of Federal Claims have issued the Vaccine Rules. The Vaccine Rules, in turn, provide

that the special master “must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.” Vaccine Rule 8(b)(1).

The third authority is the United States Court of Appeals for the Federal Circuit. Decisions by the Federal Circuit are binding precedent. 42 U.S.C. § 300aa–12(e). Within the Vaccine Program, the Federal Circuit expected that special masters would “consider[] the relevant evidence of record, draw[] plausible inferences and articulate[] a rational basis for the decision.” Hines, 940 F.2d at 1528.

A particular topic on which the Federal Circuit has guided special masters is the process for evaluating the testimony of expert witnesses. In the Vaccine Program, an expert’s opinion may be evaluated according to the factors identified by the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999). As recognized in Terran, the Daubert factors for analyzing the reliability of testimony are:

- (1) whether a theory or technique can be (and has been) tested;
- (2) whether the theory or technique has been subjected to peer review and publication;
- (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and,
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2, citing Daubert, 509 U.S. at 592-95.

After Terran, decisions from judges of the Court of Federal Claims have consistently cited to Daubert. E.g. Snyder v. Sec’y of Health & Human Servs., 88 Fed. Cl. 706, 742-45 (2009); Cedillo v. Sec’y of Health & Human Servs., 89 Fed. Cl. 158, 182 (2009), aff’d, 617 F.3d 1328, 1347 (Fed. Cir. 2010); De Bazan v. Sec’y of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2006) (“A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness’s testimony regarding causation.”), rev’d on other grounds, 539 F.3d 1347 (Fed. Cir. 2008); Campbell v. Sec’y of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006); Piscopo v. Sec’y of Health & Human Servs., 66 Fed. Cl. 49, 54 (2005).

The reliability of the expert’s theory is not presumed. A “special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” Moberly, 592 F.3d at 1324. Furthermore, the reliability of an expert’s theory affects the persuasiveness of the evidence. Special masters may “inquir[e] into the reliability of testimony from expert witnesses. 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.” Id. at 1325.

In evaluating expert testimony and scientific literature, special masters should analyze scientific literature “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” Andreu, 569 F.3d at 1379. “In other words, a finding of causation in the medical community may require a much higher level of certainty than that required by the Vaccine Act to establish a prima facie case. The special master must take these differences into account when reviewing the scientific evidence.” Broekelschen v. Sec’y of Health & Human Servs., 89 Fed. Cl. 336, 343 (2009), aff’d, 618 F.3d 1339 (Fed. Cir. 2010).

Generally, the Federal Circuit expects that a special master will present a reasonable basis for rejecting the opinion of an expert. Lampe, 219 F.3d 1361; Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

These standards will be used to determine whether Ms. Caves has established that she is entitled to compensation. For reasons explained in the following section, Ms. Caves has not met her burden of proof. Therefore, she is not entitled to compensation.

#### **IV. Analysis**

Among the three prongs from the test in Althen, the primary conflict is with the first prong, which requires a medical theory causally connecting the flu vaccine to Ms. Caves’s injury (transverse myelitis). There is relatively less, although still some, dispute with regard to the second prong, which requires a logical sequence of cause and effect. On the third prong, there is no dispute because respondent has conceded that if Ms. Caves were to have established the first and second prongs, then she has also established the third prong. Because the first prong is the central dispute in this case, the analysis begins with it.

##### **A. Althen Prong One**

###### **1. Legal Standard**

The first prong of Althen requires “a medical theory causally connecting the vaccination and the injury.” Althen, 418 F.3d at 1278. In the context of Althen prong one, Ms. Caves argues that “A medical theory is nothing more than biologic plausibility.” Pet’r Br. at 19. To the extent that “plausibility” suggests that a petitioner may satisfy prong one in absence of “reliable” evidence, Ms. Caves has not described her burden of proof accurately.

Parties advance their positions by submitting “reliable” evidence. Vaccine Rule 8(b)(1) directs special masters to “consider all relevant and reliable evidence.” Although the term “reliable evidence” was not defined by the Court when the Vaccine Rules were initially promulgated in 1989, see 16 Cl. Ct. XXL-LXI (1989); the reliability of an expert’s opinion in the context of Federal Rule of Evidence 702 was subsequently discussed by the Supreme Court in Daubert, 509 U.S. at 589-90. The Federal Circuit approved the use of Daubert in the Vaccine Program, even though the Federal Rules of Evidence do not set the standards for the admission

of evidence in these cases. Terran, 195 F.3d at 1316 (affirming special master’s use of Daubert in vaccine program cases).

In Daubert, the Supreme Court also stated that Federal Rule of Evidence 702 clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify. “‘If scientific, technical or other specialized *knowledge will assist the trier of fact* to understand the evidence or to determine a fact in issue’ an expert ‘may testify thereto.’” (emphasis in original). Daubert, 594 U.S. at 589. The Court stated that the subject of an expert’s testimony must be “scientific knowledge,” that is, the word “scientific” implied a grounding in the methods and procedure of science and the word “knowledge” implies more than subjective belief or unsupported speculation. To qualify as “scientific knowledge,” the Court stated that “an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation - i.e, ‘good grounds,’ based on what is known. In short, the requirement that an expert’s testimony pertain to ‘scientific knowledge’ establishes a standard of evidentiary reliability.” Id. at 590.

Decisions from the Federal Circuit support the idea that evidence must be reliable. “In the context of an off-table case, where a petitioner is attempting to prove that a certain vaccine in fact actually caused a particular injury, . . . [petitioner’s proof] must be supported by a sound and reliable medical or scientific explanation.” Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). One of the cases cited by Knudsen for this proposition was Daubert. Before the Supreme Court decided Daubert, the Federal Circuit stated that “A reputable medical or scientific explanation must support this logical sequence of cause and effect.” Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

Ms. Caves does not rely upon either Knudsen or Grant. Instead, Ms. Caves cites Althen, 418 F.3d at 1279, which states that “objective confirmation” of the medical theory is not needed. Pet’r Br. at 8. To the extent that Althen’s statement is in tension with earlier Federal Circuit decisions, the Federal Circuit’s decision in Moberly resolves any tension. In Moberly, the petitioner-appellant advanced the argument that because petitioners are not required to establish their case with a scientific certainty, petitioners prevail when they establish that a condition was “‘likely caused’ by the . . . vaccine . . . something closer to proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury.” Moberly, 592 F.3d at 1322. The Federal Circuit rejected this argument. In off-Table cases, “the applicable level of proof is . . . the traditional tort standard of ‘preponderant evidence.’” Id. Thus, Moberly makes clear that the opinion advanced by petitioners in support of their case must be reliable, although this reliability may be established in a variety of ways according to Althen, 418 F.3d at 1279.

Reliable evidence is the foundation for presenting a persuasive case. Reliable evidence is what the Court of Federal Claims requires special masters to consider. Vaccine Rule 8(b)(1). By implication, special masters should not consider evidence that is not reliable. In some cases within the Vaccine Program, evidence may be reliable (and, therefore, worthy of consideration) but fall short of meeting the preponderance of the evidence standard. See Lampe, 219 F.3d at 1362 (finding that the special master did not abuse his discretion in denying compensation and

stating “the special master credited Dr. Snyder’s evidence, but found the testimony given by Dr. Conkling and Dr. Lewis ‘unpersuasive.’”). The Court of Federal Claims has distinguished the submission of evidence from the crediting of evidence:

Merely because a party offers a huge volume of evidence does not mean that the special master is duty bound to accept any of that material as persuasive. It is hardly unusual for diametrically opposed expert views to be admitted as evidence at hearing. However, it is up to the trier of fact to weigh and credit that evidence.

Snyder, 88 Fed. Cl. at 742 n.63. In another case, the Court of Federal Claims explained that “As fact-finders, Special Masters, like juries, are often faced with the ‘battle of the experts’ when it comes to interpreting facts. . . . Expert opinion testimony is just opinion, and the fact-finder may weigh and assess that opinion in coming to her own conclusions.” Sword v. United States, 44 Fed. Cl. 183, 188 (1999).

The difference between reliable evidence and preponderant (or persuasive) evidence is implicit in cases discussing a district court’s role as a gatekeeper preventing unreliable evidence from reaching a jury. See Micro Chemical, Inc. v. Lextron, Inc., 317 F.3d 1387, 1392-93 (Fed. Cir. 2003) (holding that district court properly admitted expert’s opinion and holding that, “in a classic example of competing experts,” substantial evidence supported the jury’s choice of which expert to believe); Biotec Biologishche Natuverpacjungen GmbH & Co. v. Biocorp, Inc., 249 F.3d 1341, 1349-50 (Fed. Cir. 2001) (stating “the court’s obligation was to assure that evidence was reliable and relevant” and stating that when the evidence was in conflict, the “jury’s evaluation of the evidence could include determinations of the reliability of the data.”). These cases indicate that reliability differs from persuasiveness because, in traditional civil litigation, the evaluations are performed by different entities – judges evaluate the reliability of an expert’s opinion and the jury evaluates the persuasiveness.

This division of duties is not present in the Vaccine Program because special masters decide the case without a jury. In practice, the special master’s role means that Daubert motions to exclude an expert’s opinion are rarely filed because, among other reasons, the concern about allowing an unreliable opinion to reach the finder of fact is not present. See Snyder, 88 Fed. Cl. at 744-45; Veryzer v. Sec’y of Health & Human Servs., No. 06-522V, 2010 WL 2507791, at \*21 (Fed. Cl. Spec. Mstr. June 15, 2010). Rather than resolve separately the questions of whether the expert’s opinion is reliable and whether the expert’s opinion is persuasive, these two tasks are undertaken simultaneously. See Garcia v. Sec’y of Health & Human Servs., No. 05-720V, 2010 WL 2507793, at \*5 (Fed. Cl. Spec. Mstr. May 19, 2010). For example, in Terran, the opinion of the petitioner’s expert was admitted and then the special master evaluated that opinion with reference to the four factors listed in Daubert. Terran v. Sec’y of Health & Human Servs., No.95-451V, 1998 WL 55290, at \*11 (Fed. Cl. Spec. Mstr. Jan. 23, 1998). The Federal Circuit approved this procedure. Terran, 195 F.3d at 1316.

Terran, therefore, supports the notion that a Daubert analysis, which, strictly speaking, district courts use to determine the reliability of an expert’s opinion, may be used to evaluate the persuasiveness of an expert’s opinion. See Davis v. Sec’y of Health & Human Servs., 94 Fed. Cl. 53, 66 (2010) (stating “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” and citing Terran, 195 F.3d at 1316, and Moberly, 592 F.3d at 1324); Snyder, 88 Fed. Cl. at 744 (stating, “the special master considered all of the relevant evidence submitted by both parties, using the Daubert factors only to determine the reliability of that evidence and, hence, the weight it should be assigned.”), appeal docketed, No. 2101-5159 (Fed. Cir. Oct. 26, 2010). The overlapping criteria were also recognized by the Federal Circuit in a patent case: “disputes about the degree of relevance or accuracy (above this minimum threshold [of reliability]) may go to the testimony’s weight.” i4i Ltd. Partnership v. Microsoft Corp., 598 F.3d 831, 852 (Fed. Cir. 2010).

For petitioners to meet their burden of proof on any particular element of their case, the preponderance of evidence must support the proposition advanced by the petitioners. By statute, the petitioner’s burden is to present a preponderance of the evidence. 42 U.S.C. § 300aa–13(a)(1); Moberly, 592 F.3d at 1321-22; see also Grant, 956 F.2d at 1148 (stating “[t]he [Vaccine] Act relaxes proof of causation for injuries satisfying the Table . . . but does not relax proof of causation in fact for non-Table injuries.”). With regard to the first prong of Althen, petitioners bear the burden of showing “preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury.” Althen, 418 F.3d 1278.

Collectively, these precedents demonstrate that the petitioner’s burden is to present an opinion that is both reliable and persuasive. The way that Ms. Caves has attempted to meet this burden of proof is by presenting various pieces of evidence to support Dr. Smith’s opinion. The analysis of this evidence is taken up in the following section.

## **2. Evidence Regarding Can the Flu Vaccine Cause Transverse Myelitis**

Ms. Caves argues that she satisfies Althen prong one “by demonstrating a scientifically acceptable plausible mechanism.” Ms. Caves contends that she meets her burden of proof “by presenting the circumstantial evidence contained in the medical records regarding timing, alternative causes, . . . the opinions of treating doctors, . . . case reports, animal studies, and supporting statements in the scientific literature.” Pet’r Br. at 19. If this list is expanded to include the testimony of experts retained for the purposes of testifying in litigation, Ms. Caves’s list is a relatively comprehensive description of the types of evidence that may be relevant in considering whether a preponderance of reliable evidence supports a petitioner’s claim that a medical theory causally connects a vaccine to an injury.

These individual elements that Ms. Caves has identified will be evaluated one by one. A close examination of the evidence actually presented (as opposed to argument by counsel)

shows that Ms. Caves has presented relatively little persuasive proof for any of the factors that she has identified. Her claim, therefore, fails due to the absence of “indicia of reliability.” Moberly, 592 F.3d at 1324.

**a. Circumstantial Evidence in the Medical Records and Statements of Treating Doctors**

If a treating doctor stated that a vaccine is likely to have caused an injury, then special masters should consider this evidence carefully. E.g., Moberly, 592 F.3d at 1323; Capizzano, 440 F.3d at 1326. Expressions of causation by treating doctors are relevant to determining whether there is a causal theory connecting the vaccine and the injury because, as a matter of logic, a statement that a vaccine did cause an injury presupposes that a vaccine can cause an injury.

The gap in Ms. Caves’s evidence is that the treating doctors did not state that the flu vaccine caused her transverse myelitis. Instead, the treating doctors generally presented a sequence of events in which the flu vaccination preceded the onset of Ms. Caves’s transverse myelitis. As discussed in more detail in section IV.B.1 below, the treating doctors did not take the next step of concluding that this sequence means a causal connection. Ms. Caves, however, does interpret the statements of treating doctors as implying causation. E.g. Pet’r Br. at 24 (“Joan’s treating physicians also believed it ‘logical’ that the flu vaccine caused her TM.”). This argument is not persuasive because an “inoculation is not the cause of every event” that follows it. Grant 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983)).

**b. Alternative Causes**

Ms. Caves appears to argue that eliminating other potential causes of Ms. Caves’s transverse myelitis supports a finding that the flu vaccine caused the transverse myelitis. This reasoning is flawed because medical science does not know the cause of all cases of transverse myelitis. Tr. 51 (Dr. Smith); see also tr. 102 (Dr. Safran).

Further, using a differential diagnosis as evidence supporting an assertion that the flu vaccine is a cause of transverse myelitis is not persuasive. Differential diagnosis may be useful in selecting a probable cause among several established causes but differential diagnosis cannot supply the foundational step of determining what is a cause. Tamraz v. Lincoln Elec. Co., 620 F.3d 665, 674 (6th Cir. Sept. 8, 2010); Hendrix ex rel. G.P. v. Evenflo Co., Inc., 609 F.3d 1183, 1197-98 (11th Cir. 2010) (affirming district court’s exclusion of expert’s opinion because the doctor “fail[ed] to show how, by ‘scientifically valid methodology’ traumatic brain injury could ever be a possible cause of autism in anyone.”) (citation omitted); Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005) (affirming trial court’s exclusion of an expert’s opinion on the ground that the opinion was not reliable according to the Daubert standard).

**c. Case Reports**

Ms. Caves includes “case reports” as another item that is useful in considering whether petitioners have met their burden of proof with regard to Althen prong 1. Pet’r Br. at 19. The basic gap in Ms. Caves’s argument with regard to case reports is Ms. Caves’s briefs do not cite any case reports linking flu vaccine to transverse myelitis.<sup>5</sup>

An independent review of the record reveals that respondent filed an article from 1982 that cites to an article from 1971, reporting two cases of acute transverse myelitis following an influenza vaccination. Dr. Fenichel stated that “data concerning a cause-and-effect relationship between immunization and [acute transverse myelitis] is circumstantial and based upon the temporal relationship.” Exhibit F (Gerald M. Fenichel, Neurological complications of immunization, 12 *Annals of Neurology* 119-28 (1982)) at 122. Dr. Safran appeared to agree with Dr. Fenichel, saying that these reports do not establish a causal relationship. Tr. 195-98. (Dr. Smith was not asked to comment on the Fenichel paper.) The limited value of case reports has been recognized in non-binding cases that have offered guidance in how trial fora should evaluate an expert’s testimony. *E.g. McClain v. Metabolife Intern., Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005); *Meister v. Medical Engineering Corp.*, 267 F.3d 1123, 1125 (D.C. Cir. 2001); *Glastetter v. Novartis Pharmaceuticals Corp.*, 252 F.3d 986, 989-90 (8th Cir. 2001). Consequently, Ms. Caves’s reference to case reports does not help her meet her burden of demonstrating a persuasive and reliable theory causally connecting the flu vaccine to transverse myelitis.

**d. Animal Models**

The analysis for animal models is similar to the analysis for case reports in that although Ms. Caves argues that animal models may be useful in meeting petitioners’ burden for prong 1, Ms. Caves has not presented studies involving animal models. According to Dr. Smith’s testimony, animal models have shown that autoimmunity, a process in which an immune system attacks its host, exists. Tr. 20-21. Dr. Safran agreed. Tr. 183. So, there is reliable evidence to accept that the proposition that a body’s immune system may turn against itself.

This finding does not advance Ms. Caves’s case because her burden is to establish a medical theory causally connecting the vaccine to her injury. Ms. Caves did not present any animal models involving the flu vaccine and she did not present any animal models involving something like transverse myelitis. Her briefs do not cite any animal models. Therefore, on the critical question of whether the flu vaccine can cause transverse myelitis, Ms. Caves’s citation to “animal models” does not help her case.

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<sup>5</sup> The record in Ms. Caves’s case differs from the record in Doe 93 in which the petitioner and her expert advanced case reports in support of the claim that the flu vaccine can cause transverse myelitis. For the reasons explained in that decision, the case reports were not persuasive. Doe 93, 2010 WL 4205677, at \*11-14.

e. **Supporting Statements in the Scientific Literature**

As another factor to consider in determining whether Ms. Caves has met her burden of presenting a persuasive medical theory causally connecting the flu vaccine and transverse myelitis, Ms. Caves has also identified supporting statements in the scientific literature. Within this category, Ms. Caves has discussed two articles that, she contends, backs up her theory. See Pet'r Br. at 13 and Pet'r Reply at 17.

The first article is by Kai Wucherpfennig and was submitted as exhibit 29, tab A (Kai W. Wucherpfennig & Jack L. Strominger, Molecular mimicry in T cell-mediated autoimmunity: viral peptides activate human T cell clones specific for myelin basic protein, 80 Cell 695-705 (1995)). Dr. Wucherpfennig showed that some substances, such as the herpes simplex virus and the Epstein-Barr virus, induce the creation of T-cells, which are part of the immune system, and that these T-cells also react with myelin basic protein, a part of the nervous system. The Wucherpfennig article, therefore, lends support to the notion that an autoimmune process is likely to happen under some circumstances. See tr. 24-26 (Dr. Smith's testimony).

Whether the introduction of the flu vaccine causes a proliferation of self-attacking T-cells is not known. Dr. Wucherpfennig did not test the influenza vaccine, although he tested some portions of the influenza A virus. Exhibit 29 (Wucherpfennig) at 698-99. The Wucherpfennig experiment could have been repeated to test the influenza vaccine. Tr. 209-12. Dr. Smith did not know whether the influenza vaccine has been tested subsequently. Tr. 76-77. Dr. Safran also did not know this. Tr. 180-83. This evidence about testing is a pertinent criterion because in accord with Supreme Court precedent, the Federal Circuit has stated that one factor a special master in the Vaccine Program may consider in evaluating an expert's opinion is whether the offered theory "can be (and has been) tested." Terran, 195 F.3d at 1316 n.2 (quoting Daubert, 509 U.S. at 593).

The second article cited in Ms. Caves's briefs is an article authored by Dr. Smith, which was filed as exhibit 29, tab B (Derek R. Smith, M.D. & Howard L. Weiner, M.D., Immunologic aspects of neurologic and neuromuscular diseases, 278 J. Am. Med. Ass'n 1956-61 (1997)). Ms. Caves contends that this article "explains his theory in this case," Pet'r Reply at 17, although Ms. Caves elicited no testimony from Dr. Smith about this article.

Dr. Smith's article is credited as presenting statements that were generally accepted in the medical community when the article was published in a peer-reviewed journal in 1997. This article suggests that transverse myelitis is a disease mediated through the immune system. On this point, there seems to be little contrary evidence.

The more specific question for Ms. Caves's case is whether the flu vaccine starts the sequence of events leading the immune system to cause transverse myelitis. Dr. Smith's article is silent on this point. It does not mention "immunizations" or "vaccinations." Therefore, although this publication enhances Dr. Smith's standing in the field, the article does not inform anyone about whether the flu vaccine causes transverse myelitis.

**f. Views of the Expert Witnesses**

Ms. Caves also relies upon the opinions expressed by her expert (Dr. Smith) and respondent's expert (Dr. Safran). Ms. Caves emphasizes that Dr. Safran agreed that molecular mimicry is "well within the bounds of medical probability." Pet'r Br. at 13, quoting exhibit C (Dr. Safran's report) at 2; accord id. at 23 ("both experts agree that . . . molecular mimicry is biologically plausible"); Pet'r Reply at 5 (again quoting exhibit C); id. at 15 (stating petitioner "has offered a mechanism of injury accepted by Dr. Safran").

The interpretation given by Ms. Caves to Dr. Safran's testimony takes his testimony out of context. Dr. Safran's "concession" that molecular mimicry is a biologically plausible theory in the abstract does not significantly assist Ms. Caves in establishing a persuasive case that flu vaccine causes transverse myelitis. Dr. Safran distinguished between molecular mimicry as theoretical construct and what has been demonstrated for flu vaccine and transverse myelitis. Tr. 127 (Dr. Safran stating "I agree that molecular mimicry is a valid and reasonable theory. I don't agree that it applies in this case."); see also tr. 121-22 (Dr. Safran stating that he "could understand how, in theory, it [molecular mimicry] might be something to think about. . . . Therefore, it's an interesting theory and it may be reliable for other things."). On the specific question about a causal connection between flu vaccine and transverse myelitis, Dr. Safran presented an opinion that was contrary to Ms. Caves's case. Dr. Safran opined that the flu vaccine does not cause transverse myelitis. Tr. 90. Dr. Safran stated that almost all neurologists would not agree with the statement that the molecular structure of the flu vaccine resembles the molecular structure of a portion of the spinal cord. Tr. 177-78. Cf. Moberly, 592 F.3d at 1325 (discussing the testimony of respondent's expert that "people in the field don't think [the theory offered by petitioner is] biologically plausible").<sup>6</sup>

The lack of support from respondent's expert means that the views of petitioner's expert must be examined with great care. Dr. Smith is qualified to opine on whether the flu vaccine can cause transverse myelitis because he, among other credentials, directs a center caring for patients with multiple sclerosis, which is a disease with some similarities to transverse myelitis. He also is conducting clinical trials and has published articles. Tr. 11-14. Based in part on this

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<sup>6</sup> Ms. Caves argues that "a 'general acceptance' requirement for medical theories in the Vaccine Program has been explicitly rejected by the Federal Circuit in Althen and Andreu." Pet'r Reply at 12 n.10.

Ms. Caves is correct that petitioners are not required to demonstrate that a medical theory is generally accepted. However, before Althen and Andreu, the Federal Circuit held that special masters may consider whether a theory is generally accepted in weighing the expert's testimony. Terran, 195 F.3d at 1316. Here, the lack of general acceptance is just one factor – and a relatively trivial factor at that – for finding that Ms. Caves has failed to meet her burden of proof for prong one of Althen.

training and experience, Dr. Smith concluded that the flu vaccine caused Ms. Caves's transverse myelitis. Tr. 33-34.<sup>7</sup>

When asked on direct examination to explain the basis for his opinion, Dr. Smith provided essentially three reasons: (1) that the flu vaccine stimulated a response in Ms. Caves's immune system, (2) the timing between the vaccination and the onset of Ms. Caves's transverse myelitis was appropriate, and (3) that in the absence of another cause, the vaccine is "most likely" the cause of the transverse myelitis. Tr. 33-34. Dr. Smith's opinion was explored further on cross-examination. In response to questioning by respondent, Dr. Smith stated that in the VAERS database, "there may be some appearance, based on statistical analysis that is not scientifically sound, that . . . there is an increased risk of transverse myelitis after flu vaccination." Tr. 52. Dr. Smith also acknowledged that "compared to the amount of exposure to say influenza vaccine, we [the medical community] don't have a lot of well controlled studies." Tr. 57.

The reasoning employed by Dr. Smith is not persuasive for it has been rejected by the Federal Circuit. In Moberly, the petitioners presented evidence that "amounts at most to a showing of temporal association between a vaccination and [an injury], together with the absence of any other identified cause for the ultimate neurological injury." 592 F.3d at 1323. The Federal Circuit affirmed the special master's rejection of this evidence by stating "'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.'" Id., (quoting Althen, 418 F.3d at 1278).

Dr. Smith's opinion appears not to be any stronger than the opinion that was rejected in Moberly. Ms. Caves argues that "clearly her theory is supported by substantially more evidence than the ipse dixit (i.e. unsupported assertion) of her expert." Pet'r Reply at 14 n.12. The evidence that Ms. Caves presented has been discussed in the preceding paragraphs. A careful analysis of this evidence shows that there is a fairly wide gap between Ms. Caves's allegation and the evidence to support it.

The Supreme Court has recognized that "experts commonly extrapolate from existing data." General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997). Nonetheless, district courts, which control the admissibility of expert testimony, "may conclude that there is simply too great an analytical gap between the data and the opinion proffered" and may exclude the opinion as unreliable. Id. In the Vaccine Program, in which special masters also weigh the persuasiveness of expert testimony, a special master may find the expert's extrapolation to be too great to be persuasive. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1339 (Fed. Cir. 2010) (quoting Joiner). Similarly, in the Vaccine Program, "'an expert opinion is no better than the

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<sup>7</sup> The cited portion of Dr. Smith's testimony occurs toward the conclusion of his direct testimony. Earlier in his direct testimony, Dr. Smith discussed autoimmune diseases, such as transverse myelitis. In this context, Dr. Smith did not discuss whether the flu vaccine causes transverse myelitis. See tr. 17-26.

soundness of the reasons supporting it.” Id. at 1339 n.3 (quoting Perreira v. Sec’y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994)). In accord with these decisions and for the reasons explained above, Ms. Caves has failed to meet her burden of establishing a medical theory supporting causation in accordance with Althen prong 1.

**g. Additional Arguments Made by Petitioner**

The previous sections have analyzed the evidence presented by Ms. Caves. Ms. Caves makes additional arguments that she should be compensated because, according to her, other similarly situated petitioners have been compensated in other cases. These other cases, strictly speaking, are not “evidence” in Ms. Caves’s case. Nevertheless, the arguments will be considered.

Ms. Caves argues that because other petitioners have been compensated when they alleged that a vaccine, including the flu vaccine, caused them to suffer transverse myelitis, she should be compensated, too. Pet’r Br. at 11; Pet’r Reply at 22-23. To the extent that Ms. Caves is presenting an argument based in law, this argument is legally untenable. A settlement by the government is not an admission that can be used to establish entitlement in future cases. In addition, a decision by a special master is not binding precedent.

Furthermore, to the extent that Ms. Caves’s argument depends upon the similarity in evidence, Ms. Caves has not established this foundation. Ms. Caves asserts that the evidence in Schmidt v. Sec’y of Health & Human Servs., No. 07-20V, 2009 WL 5196169 (Fed. Cl. Spec. Mstr. Dec. 17, 2009), included some of the same medical literature filed in this case. Pet’r Br. at 11 n.6. In Schmidt, petitioners filed eight articles. It appears that only one of these articles, the article by Dr. Fenichel, was also filed in this case. The decision in Schmidt appears not to have been based primarily on Fenichel but rather on an article by Dr. Kerr, which is not included in Ms. Caves’s case.<sup>8</sup> Consequently, the record in Schmidt appears to be much different from the present record and these differences justify a different outcome. See Lampe, 219 F.3d at 1368 (noting that many cases in the Vaccine Program “turn[] on [their] facts.”); Whitcotton v. Sec’y of Health & Human Servs., 81 F.3d 1099, 1108 (Fed. Cir. 1996) (stating “Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence.”); Sharpnack v. Sec’y of Health & Human Servs., 27 Fed. Cl. 457, 461 (1993) (stating “variations in the analysis of the special masters are within Program standards.”).

**h. Additional Evidence Filed by Respondent**

Through this point, the decision has addressed the evidence submitted by Ms. Caves and arguments made by Ms. Caves. For the reasons set forth above, Ms. Caves has not met her burden of establishing, by a preponderance of the evidence, a medical theory causally

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<sup>8</sup> The Kerr article, which Ms. Caves has not requested an opportunity to file, was considered in Doe 93. Doe 93, 2010 WL 4205677, at \*11-14.

connecting the flu vaccine to transverse myelitis. This finding has been reached without considering any of the evidence that respondent introduced to undermine the persuasiveness of Ms. Caves's evidence. Thus, examining the evidence introduced by respondent is superfluous in the sense that respondent's evidence does not support petitioner's case. Nevertheless, special masters are directed to consider the "record as a whole," 42 U.S.C. § 300aa-13(a), and this record may include evidence that respondent offers "to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief." Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008).

The evidence introduced by respondent includes the opinions of Dr. Safran and articles concerning the incidence of demyelinating diseases. Dr. Safran, like Dr. Smith, is qualified to opine about whether the flu vaccine causes transverse myelitis. Dr. Safran, also like Dr. Smith, is a director at a multiple sclerosis clinic. Over Dr. Safran's 40-year career as a neurologist, he has treated approximately two cases of transverse myelitis per year. Dr. Safran also has treated numerous patients with multiple sclerosis, many of whom have problems in their spinal cord resembling transverse myelitis. Tr. 85-88.

Some of Dr. Safran's opinions have been discussed in the context of Ms. Caves's reliance on certain portions of his testimony. It is correct that Dr. Safran finds reliable the theory that molecular mimicry may explain how some substances lead to some autoimmune diseases. But, Dr. Safran stated that the flu vaccine is not a substance that causes transverse myelitis. Dr. Safran reached this opinion because of certain epidemiological studies.

The epidemiological studies gave Dr. Safran a method of examining whether the incidence of transverse myelitis among people receiving flu vaccination was greater than the incidence of transverse myelitis among people who had not received a flu vaccination. Based primarily on a study by the Mayo Clinic and secondarily on studies from Israel and the United States military, Dr. Safran stated that the background rate of transverse myelitis is approximately 8 cases per million person-years. Tr. 90-94; tr. 156-57; exhibit L (Ettore Beghi et al., Incidence of Acute Transverse Myelitis in Rochester, Minnesota, 1970-1980, and Implications with Respect to Influenza Vaccine, 1 *Neuroepidemiology* 176-88 (1982)). (Dr. Smith was asked about the incidence of transverse myelitis, but he did not have any opinion. Tr. 213.) Dr. Safran also stated that studies that have examined whether the flu vaccination has increased the number of cases of transverse myelitis have not detected an increased incidence. Tr. 90-94; tr. 164-66.<sup>9</sup>

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<sup>9</sup> To some extent, Dr. Safran also found confirmation in a study of the database of Vaccine Adverse Events Reporting System (VAERS), conducted by Ms. Penina Haber from the Centers for Disease Control. Dr. Safran stated that the VAERS data, if accurate, shows that flu immunization tends to prevent transverse myelitis. According to Ms. Haber's presentation, only 43 cases of transverse myelitis were reported to have followed 70 million doses of flu vaccination. These figures mean that the incidence is approximately 0.5 cases per million people, which is lower than the background rate of approximately 8 cases per million person-years. Tr. 95-100; tr. 165.

The epidemiology tends to show that the flu vaccine does not cause transverse myelitis, but does not absolutely prove a lack of causation. Conclusive evidence from epidemiology is not possible because if the antecedent caused an additional case of disease extremely rarely, such as one additional case per ten million exposures, then the epidemiology study would need to be extremely large to detect the increased incidence. See tr. 157-60 (Dr. Safran discussing study of the incidence of Guillain-Barré syndrome after 1976 swine flu vaccination); tr. 199-202 (Dr. Smith).

Although epidemiological studies cannot disprove a causal connection between a substance and a disease to a level of scientific certainty, when epidemiological studies are part of the record, “a special master may consider [them] in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury.” Andreu, 569 F.3d at 1379. This consideration is permitted although a special master may not require petitioners to introduce epidemiological studies to meet their burden of proof. Althen, 418 F.3d at 1280.

Here, no epidemiological study supports Ms. Caves’s theory as Dr. Smith acknowledged. Exhibit 29 at 2. There is some epidemiological support for Dr. Safran’s opinion that the flu vaccine does not cause transverse myelitis. So, the epidemiological evidence weighs in respondent’s favor.

It is important to place this assessment about epidemiological evidence in context. As discussed above, when only Ms. Caves’s evidence is analyzed, it falls short of constituting a preponderance of the evidence. Ms. Caves’s case is not a case in which her evidence would have been persuasive but for the introduction of rebutting evidence from respondent. If respondent had not introduced epidemiological evidence or it were not considered, Ms. Caves’s case still would have been found to be unpersuasive.

## **B. Althen Prong Two**

The second prong of Althen is “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Althen, 418 F.3d at 1278. This phrasing is sometimes simplified to asking did the vaccine cause the injury. See Pafford, 451 F.3d at 1359-60 (affirming of special master’s “can cause” and “did cause” test as consistent with the Althen test). Evidence pertinent to the second prong can be divided into three categories: (1) the

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The analysis of VAERS data performed by Ms. Haber as presented by Dr. Safran is not entitled to much weight. First, the foundation for this analysis is the VAERS database, which may overreport or underreport instances of diseases following vaccination. See tr. 152; Analla v. Sec’y of Health & Human Servs., 70 Fed. Cl. 552, 558 (2006). Second, the basis for the assertion that 70 million flu vaccinations were given — which is a critical piece of datum — was not provided. Tr. 97-99. Third, Ms. Haber appears to have presented her conclusions at a conference and no evidence suggests that her analysis was subject to the peer-review found in scientific journals. Fourth, Dr. Safran, who presented the results of this study, is not an epidemiologist. Tr. 176.

statements of treating doctors, (2) the opinion of Dr. Smith, and (3) potential alternative causes for Ms. Caves's transverse myelitis.

### **1. Statements of Treating Doctors**

In determining whether petitioners have introduced preponderant evidence on the second element of the Althen test, special masters have been instructed to consider the views of treating physicians. Capizzano, 440 F.3d at 1326. Consequently, these statements are considered in this context even though there was some discussion of them in connection with the first prong of Althen.

Ms. Caves maintains that she has submitted supporting evidence from her treating doctors. Ms. Caves cites to reports from Dr. Ali (exhibit 5 at 32), Dr. Young (exhibit 9 at 3), Dr. Chang (exhibit 5 at 35), and Dr. Khan (exhibit 5 at 20). Pet'r Br. at 24-26. Ms. Caves contends that "her treating physicians repeatedly associated her TM with the flu vaccine." Id. at 26.

This argument and these reports were addressed in the Nov. 25, 2008 Order, 2008 WL 5970976, at \*7-8. It is sufficient to say that there is a difference between a statement "associating" a vaccine with a disease and a statement that a vaccine caused a disease. Developments both in the law and in the evidence confirm the conclusion reached in the November 25, 2008 order.

At the hearing, Dr. Smith and Dr. Safran provided their interpretations of these medical records. Dr. Smith testified that when a treating doctor writes "TM status post flu shot," the statement "implies the possibility" of causation. Tr. 74. Dr. Safran testified that treating doctors were recording Ms. Caves's history and making a simple temporal association, not a causal association. Tr. 111. This testimony, thus, confirms that the analysis in the November 25, 2008 order that there is a distinction between association and causation.

The difference between a temporal association and a causal relationship was discussed in one of the cases testing the theory that vaccines cause autism. In that case, the special master rejected the petitioners' argument because the treating doctor was recognizing a temporal relationship. Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 331968, at \*128 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Upon a motion for review, the Court of Federal Claims found that "the Special Master properly evaluated these records." Cedillo v. Sec'y of Health & Human Servs., 89 Fed. Cl. 158, 176 (2009). The Federal Circuit affirmed this analysis. Cedillo, 617 F.3d at 1347. The reasoning in Cedillo supports the conclusion of the November 25, 2008 order, finding that the treating doctors did not state that the flu vaccine caused Ms. Caves's transverse myelitis.

## 2. Dr. Smith's Opinion

Ms. Caves also relies on the testimony of her expert, Dr. Smith. Dr. Smith opined that flu vaccine caused Ms. Caves's transverse myelitis because the flu vaccine stimulated Ms. Caves's immune system, that the timing was appropriate, and that there was no other "more appealing cause." Tr. 33-34. Ms. Caves makes a similar argument in her brief:

Joan has also satisfied Althen prong 2. In this regard, she has demonstrated that the only "logical" conclusion is that the vaccine caused her TM. It is "logical," Joan submits, because she has shown that the flu vaccine can cause TM; that she suffered TM; that the symptoms of her TM occurred within a medically appropriate period of time after the vaccine; and that no other likely cause of her TM was identified. In other words, the only "logical" conclusion is that the flu vaccine was the likely cause of her injury.

Pet'r Br. at 24.

This "'logical' conclusion" is not persuasive because the same logic has already been rejected by the Federal Circuit. As discussed previously, the petitioners-appellants in Moberly advanced essentially the same argument to the Federal Circuit. Moberly rejected this argument. 592 F.3d at 1323. Ms. Caves provides no basis for distinguishing Moberly. This omission is telling particularly because the order filed after the trial encouraged the parties to discuss Moberly. Order, filed Jan. 27, 2010, at 3. Consequently, the reasoning in Moberly will be followed here and this means that Ms. Caves has not established the second element of Althen.

## 3. Possible Alternative Causes

Respondent has identified three conditions, other than the flu vaccine, that could have caused Ms. Caves's transverse myelitis: the herpes zoster virus, cytomegalovirus, and a sinus cold virus. Resp't Br. at 20-23; see also tr. 101-02; tr. 128-29; tr. 148-50 (testimony of Dr. Safran). Ms. Caves contends that these factors did not cause her transverse myelitis. Pet'r Br. at 28-30; Pet'r Reply at 18-22. Determining the effect, if any, of these three viruses is not necessary in determining whether Ms. Caves has satisfied prong two of Althen.

Ms. Caves's "'logical' conclusion" and Dr. Smith's opinion rest, in part, upon an assertion that other likely causes of Ms. Caves's transverse myelitis have been ruled out. This assertion is, in fact, disputed because respondent maintains that these viruses could have been causative. But, even if respondent's position were rejected, the "simplistic elimination of other potential causes of the injury [does not] suffice[], without more, to meet the burden of showing

actual causation.” Moberly, 592 F.3d at 1323. Consequently, a detailed analysis of the three viruses is omitted.<sup>10</sup>

### C. Althen Prong Three

Although Ms. Caves has failed to establish the first and second prongs of Althen, the remaining prong will also be discussed. To be entitled to compensation, Ms. Caves must establish “a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278. She has met her burden of proof on this element.

Ms. Caves received the flu vaccine on November 18, 2005. Exhibit 10 at 5. On December 11, 2005, Ms. Caves visited an emergency room because she was having pain and weakness in her legs and back.

Both experts stated that if it were assumed that the flu vaccine can cause transverse myelitis, then the timing of events in Ms. Caves’s case was consistent with a finding that the flu vaccination caused her transverse myelitis. Dr. Smith stated that the peak number of events for autoimmune process is two to three weeks, although there may be outliers. Tr. 26. Dr. Safran agreed that the timing in Ms. Caves’s case was appropriate. Tr. 173. Therefore, Ms. Caves has established the “proximate temporal relationship.”

A finding of a proximate temporal relationship does not, by itself, establish that Ms. Caves is entitled to compensation. The Federal Circuit has consistently stated that timing, by itself, does not demonstrate causation-in-fact. Moberly, 592 F.3d at 1323 (quoting Althen, 418 F.3d at 1278); Grant, 956 F.2d at 1148. In addition to an appropriate temporal relationship, successful petitioners also establish “(1) a medical theory causally connecting the vaccination and the injury; [and] (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Althen, 418 F.3d at 1278. For the reasons explained above, Ms. Caves’s case was not persuasive on these other two elements.

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<sup>10</sup> On the other hand, if Ms. Caves had established the first prong of Althen and if she had also otherwise established the second prong of Althen, then this detailed analysis of possible other causes would be required before finding that Ms. Caves is entitled to compensation.

**V. Conclusion**

Ms. Caves has not established the elements required for compensation. Thus, the Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

IT IS SO ORDERED.

S/ Christian J. Moran  
Christian J. Moran  
Special Master