

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

PETER BROEKELSCHEN, M.D., *

Petitioner, *

v. *

SECRETARY OF HEALTH *

AND HUMAN SERVICES, *

Respondent. *

No. 07-137V
Special Master Christian J. Moran

Filed: February 4, 2009

Entitlement, flu vaccine, transverse
myelitis, anterior spinal artery
syndrome

*Lisa A. Roquemore, Broker & Associates, P.C., Irvine CA, for petitioner,
Melonie J. McCall, U.S. Dep't of Justice, Washington, D.C., for respondent.*

PUBLISHED DECISION DENYING ENTITLEMENT*

Peter Broekelschen, a doctor, filed a petition seeking compensation under the National Vaccine Injury Compensation Program (“the Program”), 42 U.S.C. §§ 300aa-1 et seq. (2006). Dr. Broekelschen alleges that the influenza vaccination caused him to suffer transverse myelitis. Petition, filed Mar. 1, 2007, at 8.

The evidence demonstrates that Dr. Broekelschen does not suffer transverse myelitis. Largely due to this determination, he is not entitled to compensation. The Clerk’s Office is ordered to judgment in favor of respondent unless a motion for review is filed.

* Because this published decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

All decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, a party has 14 days to identify and to move to delete such information before the document’s disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. 42 U.S.C. § 300aa–12(d)(4); Vaccine Rule 18(b).

I. Facts

Dr. Broekelschen was born on June 18, 1942. Exhibit 3 (Declaration of Peter H. Broekelschen, M.D., signed Feb. 26, 2007) ¶ 2. His declaration describes some medical conditions that he experienced before October 2005. Respondent, however, has not asserted that any of these problems contributed to Dr. Broekelschen's health problems after this date. See Resp't Rep't, filed Aug. 13, 2007.

On October 28, 2005, Dr. Broekelschen received a dose of the flu vaccine. Exhibit 3 ¶ 9; exhibit 1 at 74 (letter written by Dr. John Storch dated May 1, 2006); exhibit 1 at 200 (memo by Dr. Storch dated January 2, 2007); transcript ("tr.") 4 (statement by respondent's counsel that respondent is not challenging the receipt of the flu vaccination).

Five days later, on November 2, 2005, blood was drawn from Dr. Broekelschen because he was having cataract surgery about one week later. The results were normal with two exceptions, the red blood cell count was slightly low and the mean corpuscular hemoglobin was slightly high. Exhibit 1 at B-10109. The experts did not attribute any significance to these results.

On December 16, 2005, Dr. Broekelschen developed a severe crushing pain in his chest from the clavicle to his lower ribs. He also was having pain in both his arms, his fingers, his neck, and left scapula. Exhibit 1 at B-10124. An ambulance transported Dr. Broekelschen to the Hoag Memorial Hospital Presbyterian ("Hoag Hospital") Emergency Room. Exhibit 2 ¶ 10.

After being evaluated in the emergency room, Dr. Broekelschen was admitted to the hospital where he remained until December 29, 2005. Exhibit 1 at B-10124. The records from this admission exceed 400 pages. Exhibit 1, passim. Among the records are the results of several tests that provide the foundation for the opinions presented by the two experts in this case.

Dr. Broekelschen had three cervical MRIs while in Hoag Hospital. The first was performed on the day he was admitted, December 16, 2005. This MRI showed "diffuse degenerative changes of the cervical spine, which [were] mild to moderate in severity . . . [and] moderate left neural foraminal narrowing at C2-C3 and moderate to severe left neural foraminal narrowing at C4-C5." Exhibit 1 at B-10036-37.

The second MRI was performed two days later. The radiologist compared the results of this MRI to the earlier MRI. The December 18, 2005 MRI showed "[t]wo new adjacent [nonenhancing] cervical spinal cord lesions at the C2-C3 and C3 levels Differential diagnostic considerations include transverse myelitis (e.g., demyelinating disease or infectious process) as well as the less likely consideration of ischemia." Exhibit 1 at B-10138.

A third MRI was done on December 20, 2005. This test found that the “[i]ntramedullary signal abnormality at the C2 and C3 is less prominent on today’s exam.” The radiologist believed that the findings “may represent transverse myelitis from various causes and possibly ischemia.” Exhibit 1 at B-10015.

In addition to the MRIs, Dr. Broekelschen underwent other tests whose significance is disputed by the experts. On December 19, 2005, Dr. Broekelschen’s cerebrospinal fluid (“CSF”) was tested by a spinal tap. The CSF contained only one white blood cell. It also contained 63 milligrams of protein per deciliter. Testing on the CSF also showed one oligoclonal band and normal amounts of immunoglobulin G (“IgG”). These results indicate that Dr. Broekelschen did not have multiple sclerosis. Dr. Broekelschen’s myelin basic protein was normal. Exhibit 1 at B-10170 through B-10172; id. at B-10193.

Dr. Broekelschen also had studies of his body using computed tomography (“CT”). Exhibit 1 at B-10020-21, B-10030, B-10032-33. These CT scans led the doctors to obtain two angiograms. An angiogram is the visualization of blood vessels after contrast material is introduced. It is useful in diagnosing a stroke syndrome and a myocardial infarction. Dorland’s Illustrated Medical Dictionary (30th ed. 2003) at 83.

An angiogram from December 19, 2005 showed a “[f]ocal segmental occlusion of the anterior spinal artery at the C2-C3 level.” (There was also a nodule in the left thyroid). The radiologist believed that the most likely diagnosis was hypervascular adenoma, but recognized that a parathyroid adenoma was possible. Exhibit 1 at 18. (An adenoma is “a benign epithelial tumor.” Dorland’s at 28. It is not relevant to this case. Tr. 306.). When an infectious disease specialist reviewed the results of this angiogram, he “doubt[ed] [the diagnosis of] transverse myelitis.” Exhibit 1 at B-10178.

Clinically, Dr. Broekelschen worsened and then improved while in the hospital. He had weakness in his left leg. Exhibit 1 at B-10125.

During his hospitalization, Dr. Broekelschen’s doctors differed in their diagnosis of him. Some doctors believed that he had transverse myelitis. Other doctors thought he had anterior spinal artery syndrome. Details about the records of treating doctors are provided in section III.B.2.c. below.

After staying in the hospital for approximately two weeks, Dr. Broekelschen was discharged. Dr. Broekelschen’s experience while recovering from his injury is not particularly relevant to determining the pending question, which is whether the flu vaccine caused his injury. It is sufficient to note that his recovery has been both lengthy and painful. His recovery, also, is incomplete.

II. Procedural History

The procedural history of this case is relatively straightforward. Dr. Broekelschen filed his petition on March 1, 2007. His petition included records from his hospitalization as well as a report from a doctor he retained, Lawrence Steinman. With support from Dr. Steinman, Dr. Broekelschen alleged that the flu vaccine caused him to suffer transverse myelitis. Pet. at 8.

Respondent filed his report, pursuant to Vaccine Rule 4, on August 13, 2007. Respondent denied that the flu vaccine caused Dr. Broekelschen to suffer transverse myelitis. Respondent also presented the report of a doctor he retained, Benjamin Greenberg.

Pursuant to orders, both parties filed supplemental reports from their experts. Both parties filed medical articles on which their experts relied. With the filing of the supplemental reports, the case was ready for a hearing.

A hearing was held in San Diego, California on February 12-13, 2008. Three witnesses, Dr. Broekelschen, Dr. Steinman, and Dr. Greenberg, testified.

Following the hearing, the submission of briefs was delayed to allow the parties an opportunity to resolve the case. When these efforts were not successful, the parties filed post-hearing briefs. In conjunction with this process, Dr. Broekelschen submitted a motion for an award of interim attorneys' fees and costs. An award of attorneys' fees and costs was made. Broekelschen v. Sec'y of Health & Human Servs., No. 07-137V, 2008 WL 5456319 (Fed. Cl. Spec. Mstr. Dec. 17, 2008). Although the December 17, 2008 decision found that Dr. Broekelschen possessed a reasonable basis and acted in good faith in claiming that the flu vaccine caused him to suffer transverse myelitis, the decision did not comment on whether he was entitled to compensation. Whether Dr. Broekelschen is entitled to compensation is now ready for adjudication.

III. Analysis

A. Standards for Adjudication

To receive compensation under the Program, Dr. Broekelschen must prove either: (1) that he suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding to the flu vaccination, or (2) that he suffered an injury that was actually caused by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec'y of Health and Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, Dr. Broekelschen does not claim that he suffered a table injury. Pet'r Post Hearing Br. at 13. Thus, he must prove causation in fact.

A petitioner may not be given an award through the Vaccine Program based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by

the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material contained in the record. 42 U.S.C. § 300aa-13(b)(1). This universe necessarily includes “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation . . . of the petitioner’s illness.” 42 U.S.C. § 300aa-13(b)(1)(A). Here, because the medical records do not uniformly seem to support Dr. Broekelschen’s claim, Dr. Broekelschen has offered the opinion of Dr. Steinman. Respondent counters with an opinion from Dr. Greenberg.

In this case, the evidence includes conflicting opinions from each side’s experts. The persuasiveness of the experts must be evaluated and the testimony of one side’s expert may be rejected when a reasonable basis supports such a rejection. Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993). A decision about the persuasiveness of an expert is virtually not reviewable on appeal. Bradley v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

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. De Bazan v. Sec’y of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2000) (“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).

Here, a primary dispute between the experts is whether Dr. Broekelschen suffered from transverse myelitis or anterior spinal artery syndrome. Cf. Resp’t Post Hearing Br. at 9 (“Diagnostic accuracy was the biggest point of contention between the experts”). A preponderance of the evidence establishes that it is more likely that Dr. Broekelschen suffered anterior spinal artery syndrome. See section II.B, below. As explained in section II.C, Dr. Broekelschen has not met his burden of establishing, by a preponderance of the evidence, that the flu vaccine caused his anterior spinal artery syndrome.

B. Which Disease Afflicts Dr. Broekelschen

Determining which disease afflicts Dr. Broekelschen is a crucial step in deciding whether Dr. Broekelschen is entitled to compensation. As explained below, the two possible conditions differ in their etiology and differ in the part of the body affected. Thus, Dr. Broekelschen's case differs from Kelley v. Sec'y of Health & Human Servs., 68 Fed. Cl. 84 (2005). In Kelley, the parties disputed whether Mr. Kelley suffered from Guillain-Barré syndrome or chronic inflammatory demyelinating polyneuropathy. Some evidence, at least, supported a finding that these two diseases are "variants of the same disorder, as their shared pathologic features might suggest." Id. at 101 (citation and emphasis omitted). In contrast, here, no persuasive evidence indicates that the two proposed conditions – transverse myelitis and anterior spinal artery syndrome – have a similar pathology. Additionally, no evidence suggests that Dr. Broekelschen suffered both transverse myelitis and anterior spinal artery syndrome at the same time. Thus, determining which condition affects Dr. Broekelschen is one step in determining the cause for Dr. Broekelschen's condition.

On the fundamental point of which condition affects Dr. Broekelschen, the evidence is mixed. Some evidence, including the opinion of Dr. Steinman, weighs in favor of a diagnosis of transverse myelitis. Other evidence, including the opinion of Dr. Greenberg, weighs in favor of a diagnosis of anterior spinal cord artery syndrome caused by a vascular event. On a whole, the latter evidence is more persuasive for the reasons explained below.

As a foundation, the two different possible conditions – transverse myelitis and anterior spinal cord artery syndrome – are explained. Although the presentations are similar, the diseases are not identical. After describing the two possible diseases, Dr. Broekelschen's experience is described in some detail. The evidence regarding Dr. Broekelschen is divided into four components: the results of certain diagnostic testing, the symptoms reported by Dr. Broekelschen, the statements of the doctors who treated Dr. Broekelschen, and, finally, the opinions of the experts retained in this litigation, Dr. Steinman and Dr. Greenberg. An analysis of this evidence indicates that it is more likely than not that Dr. Broekelschen suffered anterior spinal artery syndrome, not transverse myelitis.

1. Description of Transverse Myelitis vs. Anterior Spinal Artery Syndrome

The spinal cord contains nerve tissues. Nerves in different regions of the spinal cord have different functions. The tissues in the front of the spinal cord control motor function. Nerves in the side relate to the sensation of pain and temperature. The back portion of the spinal cord controls proprioception. Tr. 76; see exhibit G (Jan Novy et al. Spinal Cord Ischemia, 63 Arch. Neurol. 1113 (2006) (depictions of the spinal column). Proprioception is a person's ability to sense movements in the person's own body. Dorland's at 1520. Much more about proprioception will be discussed in section III.B.2.b(1), below.

The spinal cord also contains blood vessels. If the flow of blood is interrupted, the tissues that receive oxygen from the blood can be damaged.

The two different conditions – transverse myelitis and anterior spinal artery syndrome – primarily affect different portions of the spinal cord. Transverse myelitis is “inflammation in the spinal cord.” Tr. 91. Usually, the inflammation cuts across the entire spinal cord, metaphorically, cutting the spinal cord in half. Tr. 49; see also exhibit 7, tab 3, (<http://www.hopkinsneuro.org/tm/disease.cfm/condition/Transverse-Myelitis>).

Inflammation in the spinal cord will appear as an abnormality on an MRI. A spinal tap, a procedure in which cerebrospinal fluid is drawn, will usually show an elevation in the number of white blood cells, which fight infection. People with transverse myelitis will usually experience pain in the middle of their back, bowel and bladder dysfunction, and an alteration in the senses. Tr. 109; see also exhibit 7, tab 3, (<http://www.hopkinsneuro.org/tm/disease.cfm/condition/Transverse-Myelitis>).

The precise meaning of the term “transverse myelitis” is inflammation in the spinal cord. (The ending “-itis” means inflammation.) However, “transverse myelitis” is sometimes – perhaps usually – used when the more accurate term is “transverse myelopathy.” “Transverse myelopathy” means damage to the spinal cord. Tr. 346. A few diseases in the spinal cord, such as those that a vitamin deficiency causes, are not inflammatory. Tr. 50. Anterior spinal artery syndrome, which will be discussed further below, is a myelopathy. Tr. 346.¹

Both Dr. Steinman and Dr. Greenberg agree that doctors, including neurologists, do not always use the term “transverse myelitis” in its pure sense, meaning inflammation. Tr. 50 (Dr. Steinman), tr. 181 (Dr. Greenberg), tr. 346 (Dr. Greenberg) accord, exhibit 10 (Chitra Krishnan, et al., “Transverse Myelitis: Pathogenesis, Diagnosis and Treatment,” 9 *Frontiers in Bioscience* 1483 (2004)) at 1485. This lack of precision is significant when the records of the treating doctors are discussed.

¹ Dr. Broekelschen’s post-hearing brief states that “Myelitis and myelopathy appear to be used interchangeably throughout the medical records and reports.” Pet’r Post Hearing Br. at 1 n.1. This statement is probably accurate for at least some doctors. Other doctors, however, appear to have distinguished carefully between myelitis and myelopathy. E.g. Exhibit 9 at B-10653; id. at B-10657.

In this same footnote, Dr. Broekelschen also states that “Both [myelitis and myelopathy] can be caused by the influenza vaccine.” As explained in the text, this decision does not resolve whether the influenza vaccine can cause transverse myelitis. But, even if influenza vaccine can cause myelitis, Dr. Broekelschen’s statement would be true in the limited sense that myelitis is a form of myelopathy. Some forms of myelopathy, an obvious example being trauma, are not caused by the influenza vaccine.

Transverse myelitis is a rare condition. Only approximately 1,400 new cases are diagnosed in the United States each year. Tr. 182.

When doctors consider whether a patient is suffering from transverse myelitis, doctors must rule out other potential causes of the patient's problems. One criterion that excludes the diagnosis of transverse myelitis is a "clear arterial distribution clinical deficit consistent with thrombosis of the anterior spinal artery." Exhibit 10 (Chitra Krishnan, *et al.*, "Transverse Myelitis: Pathogenesis, Diagnosis and Treatment," 9 *Frontiers in Bioscience* 1483 (2004)) at 1485 (Table 2).

Some evidence also indicates that Dr. Broekelschen suffers from anterior spinal artery syndrome. The term "anterior spinal artery" places this condition in one of the blood vessels at the rear of the spinal cord. The term "syndrome" means that the patient is suffering from a collection of physical problems that follow when the anterior spinal artery is blocked, reducing blood flow. The most common cause for anterior spinal artery syndrome is a problem with the blood vessels. Tr. 186; see also tr. 327. Thus, when evidence about Dr. Broekelschen refers to him as having a "vascular" problem, this evidence means anterior spinal artery syndrome. See Dorland's at 2009 (defining "vascular").

Problems with the blood vessels are known as "ischemia," meaning the tissue is starved of oxygen. Tr. 184; accord Dorland's at 954. ("Ischemia" can be contrasted with "infarct," meaning that the tissue has died. Tr. 187.) Ischemia, in turn, can have different causes. For example, the blood vessel could break. Another cause of ischemia is a blockage in the blood vessel. The medical term for a blockage in a blood vessel is thrombosis. Tr. 184-85; accord Dorland's at 1907.

2. Review of Evidence Regarding Dr. Broekelschen

As discussed in the previous section, both transverse myelitis and anterior spinal artery syndrome are diseases affecting the spinal cord. Distinguishing between these two conditions is difficult. Tr. 207. Nevertheless, a preponderance of the evidence indicates that Dr. Broekelschen suffered from anterior spinal artery syndrome.

The evidence about Dr. Broekelschen's condition can be categorized into four different types of evidence. First, there are the results of various tests, including imaging studies. Second, there are Dr. Broekelschen's symptoms, which he described to doctors and about which he testified. These two types of evidence form the basis for the third type of evidence, which are the reports of doctors who treated Dr. Broekelschen both inside the hospital and after he was discharged. The final type of evidence is the opinions given by the doctors retained in this litigation. After these different types of evidence are described, they are analyzed for the evidentiary value. The weighing of this evidence produces the finding that Dr. Broekelschen suffered from anterior spinal artery syndrome.

a. Tests

Doctors at Hoag Hospital performed various tests on Dr. Broekelschen. See tr. 198. For purposes of this case, the two most relevant tests are an angiogram and a series of MRIs. These tests are presented chronologically.

(1) December 16, 2005 MRIs

On December 16, 2005, Dr. Broekelschen underwent several MRIs. An MRI of the thoracic spine did not show any lesions. It happened to suggest degenerative disc disease, although degenerative disc disease is not an issue in this case. Exhibit 1 at B-10035.

The December 16, 2005 MRI of the cervical spine also did not show any lesions, which prompted the doctors to seek other explanations for Dr. Broekelschen's injury. Tr. 319.

(2) December 18, 2005 CT Angiogram

Dr. Broekelschen had a CT angiogram on December 18, 2005. After an initial review, the radiologist, Dr. Van Dalsem, recommended that a conventional angiogram be obtained. Exhibit 1 at B-10020.

(3) December 18, 2005 MRI

The MRI of the cervical spine was repeated on December 18, 2005. Dr. Van Dalsem interpreted a December 18, 2005 MRI of the cervical spine with and without contrast as showing “[t]wo new adjacent nonenhancing cervical spinal cord lesions at the C2-C3 and C3 levels Differential diagnostic considerations include transverse myelitis (e.g., demyelinating disease or infectious process) as well as the less likely consideration of ischemia.” Exhibit 1 at B-10022. The notation of ischemia refers to the possibility that Dr. Broekelschen had a vascular event. Tr. 89 (Dr. Steinman); see also exhibit 9 at B-10627.

(4) December 19, 2005 Angiogram

In an angiogram, the doctor injects a dye into the spinal cord and then takes a series of X-rays. The sequence of X-rays, which operate like a real-time movie, show how the blood flows in the large and medium-sized blood vessels that feed the spinal cord. Angiograms do not have the ability to show the blood flow of the small blood vessels. Tr. 200-03; accord Dorland's at 83.

Dr. Brant-Zawadzki performed an angiogram on Dr. Broekelschen. Dr. Brant-Zawadzki stated that there was “a defect in the anterior spinal artery, the segment at C2-C3 interspace showing no flow” and a “[f]ocal segmental occlusion of the anterior spinal artery at the C2-C2 level.” Exhibit 1 at B-10018.

Although an evaluation of the persuasiveness of the expert's opinions is set forth in section III.B.2.d, below, for the present, it is sufficient to note both Dr. Steinman and Dr. Greenberg, the two doctors retained for this litigation, agree that the results of the angiogram are consistent with a conclusion that Dr. Broekelschen suffered a vascular event. Tr. 89-90 (Dr. Steinman), tr. 121 (Dr. Steinman), tr. 200 (Dr. Greenberg), tr. 375 (Dr. Steinman). However, Dr. Steinman and Dr. Greenberg differ in that Dr. Steinman believes that the angiogram does not explain everything about Dr. Broekelschen's presentation. In contrast, Dr. Greenberg believes that the angiogram is the most important piece of information.

(5) December 20, 2005 MRIs

Two more MRIs were performed on December 20, 2005. The cervical spine continued to show a lesion at the C2-C3 level. The radiologist said the result "may represent transverse myelitis from various causes and possibly ischemia." Exhibit 1 at B-10015.

The MRI of the thoracic spine was interpreted as showing a lesion at the T2 level. The radiologist, Mark Chen, noted that this is new since December 16, 2005. Exhibit 1 at B-10016; see also tr. 66-68 (Dr. Steinman's testimony describing this MRI). The doctor said the result "may represent an inflammatory process . . . and other causes of myelitis."

The second lesion, which is in the thoracic spine, is the basis for Dr. Steinman's opinion that Dr. Broekelschen did not suffer a vascular event, such as anterior spinal artery syndrome. Tr. 68-69, 90. Dr. Greenberg recognizes that a second lesion would be a very rare event. Tr. 258-59.

(6) Other Tests

The angiogram and the MRIs were not the only tests performed on Dr. Broekelschen during his hospitalization, although they are the most significant for purposes of determining whether he has established that the flu vaccine caused his injury. Other tests are less important because they provide little assistance in distinguishing transverse myelitis from anterior spinal artery syndrome. For sake of completeness, some of these tests are summarized below.

(a) Cerebrospinal Fluid

Dr. Broekelschen had a lumbar puncture to draw some his cerebrospinal fluid. This test was performed on December 18, 2005, which was the third day of his hospitalization. This test showed that there was only one lymphocyte (white blood cell) in his cerebrospinal fluid. Exhibit 1 at B-10029; id. at B-10170 through B-10172.

The doctors performed only one lumbar puncture. They did not obtain a second one because the anticoagulants Dr. Broekelschen was taking concerned them. Exhibit 1 at B-10128; see also tr. 134-35.

If Dr. Broekelschen were suffering from an inflammatory process, such as transverse myelitis, then a repeated lumbar puncture would likely show more white blood cells. Tr. 69-70, 121-22, 147. But, this second test was not performed. Therefore, the only test of Dr. Broekelschen's spinal fluid cannot be used to rule out transverse myelitis. Tr. 284 (Dr. Greenberg).

(b) D-Dimer Test

Dr. Broekelschen also had a series of different tests done on his blood. One of these tests is called a D-dimer test. A D-dimer test indicates whether a person is producing blood clots. Tr. 223; accord Dorland's at 166, 520.

This test was done on blood drawn from Dr. Broekelschen on December 19, 2005. Exhibit 1 at B-100156. The result was more than twice the normally expected value. Id. at B-100158.

The result from this test shows that Dr. Broekelschen had formed a clot somewhere in his body. It does not necessarily mean that the blood clot was in his spinal cord. Tr. 322. In addition, there is some uncertainty about when the clot – whatever its location – was formed. The test was run on blood drawn after Dr. Broekelschen had been on bed rest for a few days. Bed rest makes a person more likely to develop blood clots. Tr. 322, tr. 353.

(c) Antinuclear Antibodies

Another test run on Dr. Broekelschen's blood was a test to look for antinuclear antibodies ("ANA"). An ANA test is not very specific, meaning that a positive result does not definitively establish one diagnosis. On the other hand, a positive ANA test indicates that a person's immune system has been activated. Tr. 210-13.

Dr. Broekelschen's ANA test was abnormal. Tr. 71-72; see also exhibit 1 at B-10169. However, the experts provided no information about how an abnormal ANA test distinguishes transverse myelitis from anterior spinal artery syndrome. Rather, Dr. Greenberg suggested that if Dr. Broekelschen were determined to have transverse myelitis, then the positive ANA may suggest a cause other than the flu vaccination. Tr. 225, tr. 269. But, given the finding that Dr. Broekelschen does not have transverse myelitis, exploring this issue is not necessary.

b. Dr. Broekelschen's Clinical Symptoms

In addition to the series of medical tests, Dr. Broekelschen was experiencing various symptoms while he was hospitalized. He testified about them. Tr. 16-33. The medical records that were created while Dr. Broekelschen was hospitalized also provide information about what Dr. Broekelschen was experiencing.

(1) Proprioception

One condition that is useful in distinguishing transverse myelitis from anterior spinal artery syndrome is proprioception. Tr. 76-77. Proprioception relates to the body's ability to understand movement and position of the body, itself. Dorland's at 1520; see also tr. 35 (testimony of Dr. Broekelschen).

On December 19, 2005, a neurologist indicated that Dr. Broekelschen suffered from "anterior spinal artery syndrome." Exhibit 9 at B-10629. According to Dr. Greenberg, a neurologist would make this diagnosis only after determining, through a physical examination, that proprioception is intact. Tr. 316.

A more clear notation that Dr. Broekelschen's proprioception was intact was made on December 20, 2005. Here, a neurologist states that Dr. Broekelschen had "sensory level to pin T4" and "touch-position sense, okay." Exhibit 9 at B-10632. .

These notations, in turn, are incorporated into the discharge summary, which was prepared by Dr. Verghese. It states "Touch perception was preserved. Position sense and vibration sense were preserved in both the upper and lower extremities." Exhibit 1 at B-10125. It describes Dr. Broekelschen's course in the hospital as him having "preservation of touch and dorsal column function." Exhibit 1 at B-10126; see also tr. 126-27 (Dr. Steinman discussing this summary), tr. 257 (Dr. Greenberg discussing the same).

Dr. Broekelschen testified that while he was hospitalized, neurologists examined him and told him that his proprioception was abnormal. Tr. 23, 35, 37-38.

After Dr. Broekelschen was discharged, medical records contain other information about proprioception. On March 29, 2006, Dr. Broekelschen saw Dr. Vanden Noort, who is an expert on multiple sclerosis, a disease that, in some ways, resembles transverse myelitis. Exhibit 1 at B-10072; tr. 81-82. Dr. Vanden Noort stated that Dr. Broekelschen's position sense in his left foot was "poor."

A similar notation is made by a physical therapist during rehabilitation. The physical therapist noted: "Proprioception, impaired right great toe and left great toe." Exhibit 1 at B-100419; accord tr. 82-83.

(2) Pain

Another phenomenon that Dr. Broekelschen experienced while in the hospital was intense pain. The sense of pain tends to preponderate in favor of a vascular event, although as a distinguishing feature, pain is relatively weak evidence. Tr. 123, tr. 152 (Dr. Steinman), tr. 206 (Dr. Greenberg).

c. Opinions of Treating Doctors

The most important point about the reports from doctors who treated Dr. Broekelschen while he was hospitalized is that they did not state a diagnosis conclusively. Various treating doctors expressed different possibilities. Anterior spinal artery syndrome was one diagnosis proposed. Transverse myelitis was also considered. In the final report from hospitalization, the diagnosis appears to be intentionally ambiguous.

Doctors who saw Dr. Broekelschen after hospitalization use the term “transverse myelitis.” Whether this terminology was intentional is not clear.

(1) Records Created During Hospitalization

Dr. Verghese wrote the discharge summary. Exhibit 1 at B-100124 through 129. Although Dr. Verghese was not the doctor who admitted Dr. Broekelschen to Hoag Hospital, Dr. Verghese was the consultant. Tr. 404. He was Dr. Broekelschen’s regular neurologist. Exhibit 9 at B-10627. Dr. Verghese appears to be very familiar with Dr. Broekelschen’s experience while in the hospital. Tr. 194. Dr. Verghese’s discharge summary was “one of the more exceptional discharge summaries” that Dr. Greenberg has read. Tr. 192.

The discharge summary stated:

The differential diagnosis included anterior spinal artery occlusion because of the dissociated sensory loss, the acute onset of symptoms with severe pain, flaccidity in both lower extremities and left upper extremity. On MR scanning, there was no evidence of any edema of the cord which would be against it being due to a myelitis. The possibilities included ischemia as well as possibly an intramedullary lesion due to the immune based reaction such as on a post-vaccine basis.

* * *

The diagnosis has not been clearly established. We will get a second opinion upon discharge from one of the universities so that the data can be reviewed.

* * *

FINAL DIAGNOSES:

1. Cervical myelopathy, etiology unknown.

Exhibit 1 at B-10126 through 128.

In making a final diagnosis, Dr. Verghese's discharge summary uses the term "myelopathy," not myelitis.² Exhibit 1 at B-10128. As discussed in the section describing the two different conditions at issue here, in a precise sense, "myelopathy" is a broad term that encompasses both transverse myelitis and anterior spinal artery syndrome. See section III.B.1, above. Dr. Greenberg, at least, believed that Dr. Verghese's use of "myelopathy" was intentional in the sense of not distinguishing between the two conditions. Tr. 197. Dr. Verghese's statement in the discharge summary that the diagnosis "has not been clearly established" supports this interpretation. A neurologist covering for Dr. Verghese on December 24, 2005, also distinguished myelopathy from myelitis. This neurologist's impression was "evolving cervical / upper thoracic myelopathy – poss[ibly] myelitis." Exhibit 9 at B-10653; accord id. at B-10657.

The records from Dr. Broekelschen's hospitalization contain several passing references indicating that some doctors stated that he suffered from transverse myelitis, but other doctors indicated that the condition was vascular in origin. See Exhibit 9 at B-10629 (notes from December 19, 2005); id. at B-10630 (December 19, 2005 statement from infectious disease specialist noting that he or she "doubt[ed] transverse myelitis in view of [the] angiogram."); id. at B-10637 (note from December 20, 2005, indicating that Dr. Broekelschen was being worked up for a thrombotic embolism); id. at B-10639 (note from December 21, 2005, stating on "steroids for myelitis"); id. at 10640; id. at B-106244; id. at 10655. Some of these notes were discussed during the hearing. Tr. 128; tr. 160-61 (discussing notes from December 19, 2005), tr. 130 (discussing note by infectious disease specialist); tr. 161 (discussing thrombotic embolism).

These records have been reviewed, but a verbose description of them is not necessary. Except for the infectious disease specialist, the doctors do not provide any reasoning for their statements. From the face of the medical records, it is not even clear whether these doctors truly came to any independent judgment about the proper diagnosis. The doctors may have been merely repeating statements made earlier by other doctors, something that special masters see happen on occasion. Thus, these passing references are entitled to little weight. Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994).

² Dr. Steinman stated, at one point, that Dr. Verghese's discharge summary used the term "transverse myelitis." Tr. 165. This statement is not correct. The term in the discharge summary is "myelopathy." See tr. 131 (Dr. Steinman's testimony on this point), 169-70 (same).

Dr. Broekelschen makes a similar error. He argues that "Transverse myelitis caused by the influenza vaccine is the best fit in this case. . . . Petitioner's treating neurologist, Dr. Verghese, thinks so." Pet'r Post-Hearing Br. at 39. However, the record does not support Dr. Broekelschen's statement. Dr. Verghese said that Dr. Broekelschen suffered from myelopathy, not myelitis. Regarding causation, Dr. Verghese said that causation was "possible." Exhibit 1 at B-10069.

It appears that Dr. Storch, the doctor who admitted Dr. Broekelschen to the hospital, wrote a note on December 22, 2005. Although the handwriting is not entirely clear, the author noted that he was going out of town for about two weeks and Dr. Broekelschen testified that Dr. Storch went on vacation before Dr. Broekelschen was discharged from the hospital. Tr. 404. Regardless of the identity of the author, the doctor's note stated: "autoimmune myelitis vs. multiple infarcts." Exhibit 9 at B-10641; see also tr. 162.

An infectious disease specialist echoed Dr. Storch's view on December 23, 2005. The infectious disease specialist noted that there were "new thoracic cord lesions." The differential diagnosis "remains vascular vs. immune related demyelination." This progress note also raised the issue as to whether the flu vaccine caused a demyelinating disease, such as myelitis or acute disseminated encephalomyelitis. Exhibit 9 at B-10646; see also tr. 163.

The statement from the doctor on December 22, 2005, and the statement from the infectious disease specialist on December 23, 2005, are consistent with the discharge summary, which was discussed at the beginning of this section. Dr. Vergheze summarized all the records and came to the conclusion that Dr. Broekelschen suffered from a "myelopathy" without distinguishing whether the myelopathy was myelitis.

(2) Records Created After Discharge

Although the collective medical records created while Dr. Broekelschen was at Hoag Hospital reflect an uncertainty between whether Dr. Broekelschen was suffering from transverse myelitis or from anterior spinal artery syndrome, medical records created after discharge do not contain this same uncertainty. Tr. 209, 265-66. These records indicate that Dr. Broekelschen suffered from transverse myelitis.

On March 29, 2006, Dr. Broekelschen saw Dr. Stanley vanden Noort, a neurologist. Dr. vanden Noort reviewed Dr. Broekelschen's history. This history did not mention that Dr. Broekelschen had an angiogram. Tr. 320. (However, Dr. Broekelschen testified that he brought all his records with him to the appointment. Tr. 27.) Dr. vanden Noort's report summarized a physical examination, which revealed that "Vibration sense is reduced but not absent in the feet. Position sense is poor in the left foot, and strength is poor in the left foot, as well." Dr. Vanden Noort concluded: "Our neuroradiologists concur with the report of transverse myelitis. It is not necessary to pursue alternative diagnoses because he is improving slowly." Exhibit 1 at B-10072.

Two other doctors commented upon Dr. Broekelschen's condition in letters written after his discharge from the hospital. Dr. Storch, who is Dr. Broekelschen's general physician and who administered the flu vaccine to Dr. Broekelschen, stated that the work-up at Hoag Hospital ruled out a vascular cause and that he believed that Dr. Broekelschen was suffering from transverse myelitis. Exhibit 1 at B-10074 (letter, dated May 1, 2006).

Dr. Verghese stated: “it is possible that the myelopathy was secondary to the flu injection that he received.” Exhibit 1 at B-10069.

d. Opinion of Testifying Experts

Each party retained an expert who differed as to what disease Dr. Broekelschen suffered. Dr. Steinman, retained by Dr. Broekelschen, believed that the condition was transverse myelitis. Respondent’s expert, Dr. Greenberg, opined that Dr. Broekelschen suffered from anterior spinal artery syndrome.

In terms of qualification, Dr. Greenberg’s background is worth more weight. Dr. Greenberg practices at the world’s only center dedicated to treating patients with transverse myelitis, which is affiliated with Johns Hopkins University. Tr. 173. Doctors from around the country consult with Dr. Greenberg and his colleagues. Patients travel to be seen at this institution. Due to their specialization, doctors at Johns Hopkins Transverse Myelitis Center see many more people who have – or are believed to have – transverse myelitis than the typical neurologist. Dr. Greenberg’s background in working directly with patients with transverse myelitis on a daily basis adds weight to his opinion.

A comparison between the credentials of Dr. Greenberg and the credentials of Dr. Steinman is not intended to minimize the background of Dr. Steinman. Dr. Steinman has a very impressive background, including being awarded four patents for inventions related to vaccines. Dr. Steinman has also practiced neurology since 1977. Exhibit 2, tab 2 (curriculum vitae). However, the primary difference between Dr. Greenberg and Dr. Steinman is that Dr. Steinman primarily researches and this research focuses on multiple sclerosis. In connection with his work on multiple sclerosis, Dr. Steinman sees or consults on people with transverse myelitis. Tr. 47-48. But, Dr. Steinman’s work on transverse myelitis, although not minimal, is less than Dr. Greenberg’s work on this particular disease. In short, although Dr. Steinman may have a broader range of experiences, Dr. Greenberg has a deeper knowledge about the precise question here – whether Dr. Broekelschen suffered from transverse myelitis.

A second difference between Dr. Steinman and Dr. Greenberg relates to their demeanor while testifying. Both experts were prepared, poised, knowledgeable, and confident. To the extent that there is a difference in demeanor, this factor favors Dr. Greenberg as more persuasive.

Dr. Greenberg’s demeanor suggested that he was attempting to provide the basis for his opinion as forthrightly as possible. He appeared to be primarily interested in explaining his thinking and reasoning. He acknowledged when various reports did not fit his view of the case. His spirit of independence is reflected in his agreement that the flu vaccine, in theory, can cause transverse myelitis. Tr. 190, tr. 247-49. His candor and directness may be a (welcome) byproduct of never testifying in court before testifying in the hearing in this case.

3. Evaluation of Evidence

A preponderance of the evidence supports a finding that Dr. Broekelschen suffered from anterior spinal artery syndrome, not transverse myelitis. The evidence that points to anterior spinal artery syndrome is stronger than the evidence that suggests transverse myelitis. A brief explanation is that respondent, through Dr. Greenberg, presented a picture that incorporates all the evidence. Dr. Broekelschen, through Dr. Steinman, did not account for some evidence, including an important piece of evidence, the angiogram. By presenting a story that is cohesive with all the facts, respondent's version is inherently more persuasive.

The strongest evidence that Dr. Broekelschen suffered from anterior spinal artery syndrome is the angiogram, which was performed on December 19, 2005. This test showed “[f]ocal segmental occlusion of the anterior spinal artery at the C2-C2 level.” Exhibit 1 at B-10018. There is no dispute that the result of the angiogram is consistent with anterior spinal artery syndrome. Tr. 89-90 (Dr. Steinman), tr. 121 (Dr. Steinman), tr. 200 (Dr. Greenberg), tr. 375 (Dr. Steinman).

Although Dr. Steinman recognizes the angiogram as consistent with anterior spinal artery syndrome, Dr. Steinman believes that the angiogram does not explain everything known about Dr. Broekelschen's condition. Specifically, the angiogram does not account for the presence of lesions in two locations on the MRI. Tr. 90, tr. 121. However, as discussed below, Dr. Steinman does not reconcile the MRI with the angiogram.

Dr. Greenberg persuasively explained why the angiogram is such powerful evidence in this case. In many cases in which doctors suspect a vascular event has caused anterior spinal artery syndrome, the doctors cannot identify the problem with the blood vessels for one of two reasons. These are either the blood clot dissipates before any imaging study is conducted or the problem is located in a vessel too small to be detected on an angiogram. Tr. 200, tr. 299.

However, for Dr. Broekelschen, the angiogram revealed an interruption in blood flow in a large artery. Exhibit 1 at B-10018; tr. 222, tr. 299.

This result is very strong evidence that the underlying mechanism is vascular. Dr. Greenberg explained “even when I had a patient who I would bet the farm had a vascular event in the spinal cord, it's actually rare for me to see the smoking gun. Seeing an abnormal spinal angiogram that matches with the patient's presentation, the patient's MRI, what the patient is experiencing is, again, a rarity among rarities.” Tr. 201. Dr. Greenberg continued: “That is a true abnormality that has to be taken seriously. And in the context of somebody who has an acute myelopathy, . . . where we did not have evidence of inflammation, then we would have actually stopped there and we would have said that we are most concerned about vascular events. That's how profound the evidence is.” Tr. 202. Later, Dr. Greenberg said “If there was only a lesion at the cervical cord and proprioception was intact and we had that angiogram, we probably

wouldn't be in this room today. I think the angiogram findings are so profound that nobody would have considered myelitis ever again." Tr. 221.

Additional support for finding that Dr. Broekelschen suffered anterior spinal artery syndrome comes from the medical records about proprioception. As explained in section III.B.1 above, proprioception helps to distinguish anterior spinal artery syndrome from transverse myelitis. When only the anterior portion of the spinal cord is impaired, the patient retains his (or her) proprioception. In contrast, when the entire spinal cord is damaged, the patient loses proprioception.

The medical records created while Dr. Broekelschen was hospitalized state – affirmatively – that Dr. Broekelschen retained his proprioception. Exhibit 9 at B-10632 (neurologist's note from December 20, 2005, stating that Dr. Broekelschen had "sensory level to pin T4" and "touch-position sense, okay."). Dr. Verghese's discharge summary is clear. It states "Touch perception was preserved. Position sense and vibration sense were preserved in both the upper and lower extremities." Exhibit 1 at B-10125.

Against these records, Dr. Broekelschen testified that neurologists examined him and told him that his proprioception was abnormal. Tr. 23, 35, 37-38.

A preponderance of the evidence indicates that Dr. Broekelschen's proprioception while hospitalized was normal. Because the neurologist's notes and Dr. Verghese's discharge summary were prepared while the doctors were observing and treating Dr. Broekelschen, their records are presumed to be accurate. Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Significantly, these records contain an affirmative statement that a neurologist determined Dr. Broekelschen's proprioception to be preserved. Thus, this is not a situation in which the records are silent and Dr. Broekelschen is attempting to supplement the factual record. By claiming that his proprioception was impaired while in the hospital, *see* Pet'r Post Hearing Br. at 31-33; Dr. Broekelschen is proposing a contradiction to the medical records. Finding a direct error in the medical records is much less likely than finding an omission. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 779-80 (2006); Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), *aff'd* 968 F.2d 1226 (Fed. Cir. 1992).

Dr. Broekelschen has not offered a persuasive reason for making a finding contrary to the medical records. Although Dr. Broekelschen's general medical training increases his ability to understand what is happening to him as a patient, Dr. Broekelschen still could have made an error like any other witness. Dr. Broekelschen may have confused when a doctor told him that his proprioception was abnormal. After all, on March 29, Dr. Vanden Noort determined that Dr. Broekelschen's position sense was "poor." Exhibit 1 at B-100072. In any event, it is not necessary to determine why Dr. Broekelschen testified that a doctor told him that his proprioception was abnormal. It is sufficient to find that Dr. Broekelschen's testimony is not more persuasive than the medical records created contemporaneously with Dr. Broekelschen's treatment. Under these circumstances, a preponderance of the evidence shows that Dr.

Broekelschen retained his sense of proprioception while hospitalized. See Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (stating whether contemporaneous medical records or later-given oral testimony is more persuasive is a determination that “is uniquely within the purview of the special master.”).

Therefore, two strong pieces of evidence support the finding that Dr. Broekelschen suffered anterior spinal artery syndrome. The angiogram shows, unmistakably, that the blood flow in one of Dr. Broekelschen’s arteries in his spinal cord was blocked. Exhibit 1 at B-10018. As discussed below, Dr. Broekelschen’s case includes very little about the angiogram. This omission is a shortcoming. In addition to the angiogram, the other strong piece of evidence supporting a finding of anterior spinal artery syndrome is the finding regarding proprioception. The medical records, which were created while Dr. Broekelschen was hospitalized, indicate that Dr. Broekelschen retained his sense of proprioception. Exhibit 1 at B-10125 through B-10126; exhibit 9 at 10632. This clinical finding matches what is expected with anterior spinal artery syndrome. Thus, these two pieces of evidence favoring a finding of anterior spinal artery syndrome are quite persuasive.

There are also other pieces of evidence that support this finding, although these are secondary. The less significant evidence includes the opinions of treating doctors and the opinions of testifying experts.

With regard to evaluating the opinions of treating doctors, two general points must be made at the onset. First, the diagnosis made by any treating doctor is not binding on a special master. 42 U.S.C. § 300aa–13(b). Second, in this case, the treating doctors are not consistent in their diagnoses. In a practical sense, these two points relate to each other because the opinion of one treating doctor is contradicted by the opinion of a different treating doctor. In this situation, no one opinion can be conclusive. See Tiufekchiev v. Sec’y of Health & Human Servs., No. 05-437V, 2008 WL 3522297 *12 (Fed. Cl. Spec. Mstr. July 24, 2008) (addressing difficulties in relying on statements of treating doctors when their reports are contradictory).

Of the various statements offered by treating doctors, the one that is entitled to the most weight is the discharge summary written by Dr. Verghese. Dr. Verghese’s discharge summary benefits from the insights about Dr. Broekelschen that Dr. Verghese has because Dr. Verghese was Dr. Broekelschen’s neurologist for many years. The discharge summary is detailed, evidencing a comprehensive understanding of Dr. Broekelschen’s course in the hospital. The bottom line of the discharge summary is that Dr. Verghese believed that Dr. Broekelschen had “[c]ervical myelopathy, etiology unknown.” Exhibit 1 at B-10128.

Dr. Verghese’s ambivalence between an anterior spinal artery syndrome or a transverse myelitis is consistent with the records of various doctors who cared for Dr. Broekelschen while in the hospital. As summarized in section III.B.2.c. above, these doctors presented a range of opinions. None of these are particularly helpful in determining which condition Dr. Broekelschen suffered.

The doctors' treatment of Dr. Broekelschen is consistent with their notes in the sense that the doctors seemed to provide treatment as if a vascular event caused him to suffer an anterior spinal artery syndrome and as if inflammation was causing transverse myelitis. To prevent additional vascular events, the doctors placed Dr. Broekelschen on medication to prevent blood clots. This decision, in turn, led to the doctors' decision not to obtain a second spinal tap. The doctors were concerned that if they wanted to perform a second spinal tap, then they would have to discontinue the anti-coagulating medication and this discontinuance could lead to another vascular event. Exhibit 1 at B-10128 (discharge summary), tr. 134-35, (Dr. Steinman), tr. 197-98 (Dr. Greenberg).

On the other hand, the doctors also gave Dr. Broekelschen steroids. Exhibit 9 at B-10639; exhibit 1 at B-10127 (Solu-Medrol). The steroids minimize the response of the immune system. The delivery of steroids is consistent with a belief that Dr. Broekelschen was suffering from transverse myelitis. Tr. 300.

As a whole, the collection of statements and the actions of the doctors who treated Dr. Broekelschen in the hospital provides little basis for finding transverse myelitis as opposed to anterior spinal artery syndrome. For virtually every point in favor of one diagnosis, there is a point in favor of the other diagnosis.

After Dr. Broekelschen was discharged from the hospital, two doctors (Dr. vanden Noort and Dr. Storch) stated that he suffered from transverse myelitis. Dr. Broekelschen, fairly, points to their statements as evidence that this is the condition from which he suffered. Pet'r Post Hearing Br. at 5, 6-7, 34. Yet, for reasons explained below, Dr. vanden Noort's letter and Dr. Storch's letter are not determinative. One reason for not giving these letters much weight is that Dr. Verghese continued to state that Dr. Broekelschen suffered from a myelopathy, not myelitis.

Dr. vanden Noort's March 29, 2006 report indicates that he agreed with the diagnosis of transverse myelitis. Exhibit 1 at B-10072.

This report is entitled to some weight, but it is not dispositive. "Any such diagnosis . . . [contained in the record] . . . shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, . . . the special master or court shall consider the entire record and the course of the injury." 42 U.S.C. § 300aa-13(b). One factor to consider in evaluating medical reports, including Dr. vanden Noort's report, is "contrary medical evidence." Vanienken-Ryals v. Office of Pers. Mgmt., 508 F.3d 1034, 1042 (Fed. Cir. 2007).

Here, various factors make Dr. vanden Noort's statement less persuasive. Dr. vanden Noort did not report that he reviewed the results of Dr. Broekelschen's angiogram, which is evidence contrary to the diagnosis of transverse myelitis. In addition, Dr. vanden Noort stated that he "agreed with" the diagnosis of transverse myelitis. The term "agreed with" indicates that someone informed Dr. vanden Noort that the diagnosis was transverse myelitis. However, the record, especially Dr. Verghese's discharge summary, shows that the diagnosis was much more

in flux. Further, Dr. vanden Noort explicitly disclaimed any need “to pursue alternative diagnoses because [Dr. Broekelschen] is improving slowly.” This statement suggests that Dr. vanden Noort did not consider, and then reject, the possibility that Dr. Broekelschen suffered from anterior spinal artery syndrome. Instead, Dr. vanden Noort appears to have determined that the diagnosis of transverse myelitis fit the information he knew about Dr. Broekelschen and that further exploration about the origins of Dr. Broekelschen’s condition was unlikely to improve his outcome. Exhibit 1 at B-10072. Furthermore, Dr. Broekelschen’s development of difficulties with proprioception after his discharge from the hospital is consistent with a blood clot throwing off additional clots. Tr. 301 (Dr. Greenberg); but see tr. 389 (testimony of Dr. Steinman agreeing that this scenario is possible but unlikely).

Dr. Verghese stated that Dr. Broekelschen “developed a myelopathy. . . . It is possible that the myelopathy was secondary to the flu injection that he received.” Exhibit 1 at B-10069 (letter, dated April 21, 2006). Dr. Verghese’s use of the term “myelopathy” does not differentiate between transverse myelitis and anterior spinal artery syndrome. This letter is important because Dr. Verghese was Dr. Broekelschen’s treating neurologist.

Dr. Storch, Dr. Broekelschen’s general physician, wrote a letter “To Whom It May Concern” on May 1, 2006. Dr. Storch stated “a vascular etiology for the pain was ruled out.” The “current working diagnosis is transverse myelitis with lesions in the high cervical and high thoracic spine area.” Exhibit 1 at B-10074. This letter is entitled to some weight, but is not persuasive. Dr. Storch does not identify who ruled out a vascular pathology. The discharge summary is quite clear that Dr. Verghese, Dr. Broekelschen’s treating neurologist, believed that the diagnosis was uncertain and suggested that it could be anterior spinal artery syndrome. Exhibit 1 at B-10124 through 128. Beyond identifying the person who “ruled out” the vascular source, the more potentially persuasive fact is the reason the vascular event was ruled out. Without understanding the basis for Dr. Storch’s statement, it is difficult to give Dr. Storch’s letter much weight. Perreira, 33 F.3d at 1377 n.6; Davis v. Sec’y of Health & Human Servs., 20 Cl. Ct. 168, 173 (1990). In light of the angiogram, which indicates that there was no blood flow in a large artery, the reason to discount the angiogram is important.

In sum, the reports of all doctors who treated Dr. Broekelschen both inside and outside of the hospital provide relatively little valuable information in determining which condition affected Dr. Broekelschen. Under these circumstances, the testimony of the experts retained for litigation has increased relevance.

The relative weight of the testifying experts also favors a finding that Dr. Broekelschen suffered from anterior spinal artery syndrome. For the reasons given in section III.B.2.d. above, Dr. Greenberg was a more persuasive witness than Dr. Steinman. Dr. Greenberg’s background makes him especially well-suited to answer the question about whether Dr. Broekelschen suffered transverse myelitis because Dr. Greenberg practices neurology at the only center in the United States devoted to the treatment of transverse myelitis. This specialization means that Dr. Greenberg reviews many more cases of transverse myelitis or suspected transverse myelitis than

a typical neurologist. Therefore, Dr. Greenberg's opinion is entitled to more weight than the contrary opinion of Dr. Steinman.

Dr. Steinman's opinion that Dr. Broekelschen did not have anterior spinal artery syndrome is based upon the two MRIs that were interpreted to show lesions at two different levels of Dr. Broekelschen's spinal cord. Exhibit 1 at B-10015 (cervical spine); exhibit 1 at B-10016 (thoracic spine); see also tr. 66-68 (Dr. Steinman's testimony describing this MRI). Lesions in two different places in the spinal cord are more commonly found with transverse myelitis.

However, lesions can be found in more than one location in conditions other than transverse myelitis. The two MRIs are consistent with a rare type of vascular event, one in which subsidiary clots travel to different locations.

A blood clot may spin off other blood clots that travel and locate downstream from the primary blood clot. In such a case, the MRI will show inflammation in two different places. Tr. 223-24. Dr. Steinman and Dr. Greenberg agreed that it is possible for clots to appear in two places. Tr. 68-69 (Dr. Steinman stating "if it's really vascular, it would be odd to find two different areas involved unless somebody is throwing off chunks of clot"), tr. 259-60 (Dr. Greenberg). Both agreed that blood clots in two locations are very rare. In Dr. Greenberg's colorful phrase, it is like getting a hole-in-one on a par 5 hole. Tr. 223.

By itself, the rarity of the event is not a reason to find that it did not happen. The Federal Circuit indicates that rare events can happen. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 550 (Fed. Cir. 1994). Indeed, the Vaccine Program is based upon a premise that adverse reactions to a vaccine happen rarely, but, when they do happen, the injured party is entitled to compensation. Thus, Dr. Broekelschen's argument against the probability that he had more than one blood clot because such an event is very rare is not very persuasive.

When the stronger evidence indicates that Dr. Broekelschen suffered an anterior spinal artery syndrome and the weaker evidence indicates that Dr. Broekelschen suffered transverse myelitis, a preponderance of the evidence supports a finding that Dr. Broekelschen suffered an anterior spinal artery syndrome. This factual determination harmonizes the entire record.

The hypothesis presented by Dr. Broekelschen – that the presence of two lesions on the MRIs must mean transverse myelitis – was considered but cannot be accepted. The question becomes how does the angiogram fit with transverse myelitis? Dr. Broekelschen presented no persuasive answer to this question.

The closest that Dr. Steinman came to explaining a link between the angiogram and transverse myelitis was very indirect and not persuasive. Dr. Steinman stated that any inflammation in the spinal cord would cause extravasation (movement) of white blood cells from the blood vessels into the spinal cord. The purpose of these white blood cells is to respond to the

inflammation. Tr. 72-74. Dr. Steinman summarized his point as saying a patient does not have “myelitis, any myelitis, without an aggressive involvement of the blood vessels anyway.” Tr. 74-75. Other than this passage, Dr. Steinman did not discuss the results of the angiogram, except to comment that a vascular event is inconsistent with two lesions as shown on the MRI.

Dr. Greenberg supplied more information about extravasation during his testimony. He explained that extravasation happens at the capillary level, which are tiny blood vessels. But, the problem revealed in Dr. Broekelschen’s angiogram is a problem in a large blood vessel from which blood cells do not extravasate into the spinal cord. Tr. 222, tr. 235. Further, extravasation is “a normal physiologic process and the blood vessel wall is never damaged.” Tr. 293.

During his rebuttal testimony, Dr. Steinman agreed with part of Dr. Greenberg’s explanation. Dr. Steinman agreed that extravasation occurs in the tiny blood vessels. Tr. 364-65. However, Dr. Steinman was silent about whether extravasation would damage small blood vessels’ walls, let alone large arteries. Dr. Steinman also did not discuss whether the extravasation that he described would appear as shown on Dr. Broekelschen’s angiogram. See tr. 364-67.

It is not clear whether Dr. Steinman intended to suggest that extravasation associated with transverse myelitis would appear on an angiogram. If he did, the weight of the evidence supports rejecting such a contention. Tr. 293 (Dr. Greenberg’s testifying “We don’t see signs of thrombosis or hemorrhage in normal transverse myelitis or even extreme cases of transverse myelitis.”). In any event, the result is the same – Dr. Steinman has not proposed a way to reconcile the angiogram with an inflammatory event. See tr. 369.

Dr. Steinman’s theory would have been more persuasive if he explained how an angiogram, showing an interruption in blood flow in a large artery, fits with transverse myelitis. See Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (stating “[t]he special master concluded that the expert based his opinion on facts not substantiated by the record. As a result, the special master properly rejected the testimony of petitioner’s medical expert.”).

There is no reasonable likelihood that the angiogram presents incorrect information. (Unlike MRIs, see tr. 220, tr. 307-08; angiograms are not subject to a wide range of interpretation.) Neither Dr. Steinman nor Dr. Greenberg offered any possibility that the angiogram results are wrong. Dr. Greenberg actually praised angiograms for their reliability. Tr. 307. The angiogram strongly indicates that Dr. Broekelschen’s problem has a vascular origin.

As mentioned, Dr. Steinman did not discuss the angiogram in his testimony very much, except to say that it was not consistent with the MRI. See tr. 121, tr. 369. Similarly, Dr. Broekelschen’s brief commented on the angiogram very little. Dr. Broekelschen argued that no treating doctor ever commented that the angiogram was as “profound” as Dr. Greenberg claims it to be. Pet’r Post Hearing Br. at 36-37; Pet’r Reply at 9. This argument missed the mark. In fact,

a specialist in infectious disease doubted transverse myelitis due to the angiogram. Exhibit 1 at B-10178. Moreover, asking Dr. Steinman to comment upon the conclusiveness of the angiogram could have constituted some evidence and may have prompted Dr. Steinman to explain how the angiogram fits with his theory of transverse myelitis. As the record stands, Dr. Broekelschen is free to argue against the weight of the angiogram, but this argument appears to be without much factual support. An argument is not a substitute for evidence. Gilda Industries, Inc. v. United States, 446 F.3d 1271, 1281 (Fed. Cir. 2006).

Whether intentional or not, Dr. Broekelschen’s overlooking of the angiogram leaves a considerable gap in his proof. “Spinal angiography is the diagnostic study of choice to define the presence of a vascular malformation.” Exhibit 10 (Chitra Krishnan, et al., “Transverse Myelitis: Pathogenesis, Diagnosis and Treatment,” 9 *Frontiers in Bioscience* 1483 (2004)) at 1488.

As noted previously, special masters are required to evaluate the record as a whole. 42 U.S.C. § 300aa–13. Here, the weight of the entire record – including (but not limited to) the angiogram, the MRIs, the finding regarding proprioception, the statements of treating doctors, and the testimony of Dr. Broekelschen, Dr. Steinman and Dr. Greenberg – indicates that Dr. Broekelschen suffered anterior spinal artery syndrome. The version proposed by Dr. Greenberg, that Dr. Broekelschen suffered a vascular event leading to anterior spinal artery syndrome, incorporates all the evidence, albeit with a suggestion that the primary blood clot spun off secondary blood clots. In contrast, the version offered by Dr. Steinman largely, if not entirely, ignored one of the most valuable pieces of evidence, the angiogram. Under these circumstances, the preponderance of evidence supports the finding that Dr. Broekelschen suffered a vascular event leading to anterior spinal artery syndrome.³

C. Whether Dr. Broekelschen Has Established That He Is Entitled To Compensation for Anterior Spinal Artery Syndrome

The finding that Dr. Broekelschen suffers from anterior spinal artery syndrome is just one step for determining whether he is entitled to compensation for this condition. Through Dr.

³ Although some evidence supports a finding that Dr. Broekelschen suffered transverse myelitis, a preponderance of evidence supports a finding that he suffered anterior spinal artery syndrome. Because a preponderance of evidence favors one side, this decision is not a “close call.” Therefore, the phrase in Althen that “close calls regarding causation are resolved in favor of injured claimants,” Althen, 418 F.3d at 1280; does not require a finding in favor of Dr. Broekelschen.

Moreover, it is not entirely clear that this phrase from Althen is binding or is dicta. The statute requires the petitioner to demonstrate certain matters “by a preponderance of the evidence.” 42 U.S.C. § 300aa–13(a)(1). Earlier decisions of the Federal Circuit have assigned the burden of proof to petitioners. Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Hines v. Sec’y of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Bunting, 931 F.3d at 873.

Steinman, Dr. Broekelschen presented some evidence that the flu vaccine caused his anterior spinal artery syndrome. However, this evidence falls well short of the standard required to be awarded compensation.

The quality and amount of the evidence supporting the theory that the flu vaccine caused Dr. Broekelschen to suffer anterior spinal artery syndrome were weak and relatively sparse. After respondent filed Dr. Greenberg's report in which he indicated that Dr. Broekelschen suffered anterior spinal artery syndrome, Dr. Broekelschen filed a supplemental report from Dr. Steinman. Dr. Steinman wrote that even if Dr. Broekelschen suffered a vascular injury, the influenza "vaccination could have been the basis for the vascular injury, including the anterior spinal artery syndrome." Exhibit 5 at 1.⁴ To support his statement, Dr. Steinman cited an article by Dominic Foo and Alain B. Rossier, which was included as part of exhibit 5.

Dr. Greenberg, in turn, also presented a supplemental report, which respondent filed as exhibit C. Dr. Greenberg reviewed the Foo and Rossier article. Dr. Greenberg also obtained two relevant articles that Foo and Rossier cited – one was by A. Theodore Steegman, written in 1952, and the other was written in 1953 by Richard S. Paine and Randolph K. Byers. Respondent filed these two articles as tab 1 and tab 2, respectively, of exhibit C. Dr. Greenberg challenged Dr. Steinman's proposition that the flu vaccine can cause a vascular event. Exhibit C.

Perhaps in accord with this theory's secondary status, the parties elicited relatively little testimony from Dr. Steinman and Dr. Greenberg about whether the flu vaccine can cause – and, did, in fact, cause – Dr. Broekelschen's anterior spinal artery syndrome. Their post-trial briefs, too, say relatively little about this issue. Pet'r Br. at 12, quoting exhibit 5 (Dr. Steinman's supplemental report), at 38; Resp't Post Hearing Br. at 13, 26, 32-33. Consequently, the following analysis of whether Dr. Broekelschen has established the required elements is relatively brief as well.

To prove causation in fact, a petitioner must establish at least 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.

⁴ In passing, Dr. Steinman also contends that a vascular event could have caused a transverse myelitis. Tr. 116. Addressing this contention is not necessary because of the finding that Dr. Broekelschen did not suffer transverse myelitis.

Althen v. Sec’y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec’y of Health and Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

“Theory” means a proposed explanation for how the vaccine caused the injury. Although Althen requires a “medical theory,” the petitioner is not required to provide “proof of specific biological mechanisms.” Knudsen, 35 F.3d at 549.

An example of a “medical theory” is molecular mimicry. This theory posits that similarities between the molecular structure of the vaccine and parts of the body cause the body to attack itself while responding to the vaccine. Molecular mimicry is the theory offered by Dr. Steinman to explain how the flu vaccine could cause transverse myelitis. Tr. 94; exhibit 2, tab 1 at 3.

Here, it is not entirely clear that Dr. Steinman has proposed “a medical theory causally connecting the vaccination and the injury” when “injury” means anterior spinal artery syndrome. Dr. Steinman’s supplemental report indicates that he believes the flu vaccine is the most probable cause of Dr. Broekelschen’s anterior spinal artery syndrome. Exhibit 5 at 2. However, Dr. Steinman does not provide a theory, connecting the flu vaccine to anterior spinal artery syndrome. Exhibit 5. Similarly, Dr. Steinman’s direct testimony does not provide a theoretical link explaining how the flu vaccine can cause anterior spinal artery syndrome. See tr. 113-19. At the prompting of the undersigned, Dr. Steinman may have offered molecular mimicry as a theory to explain the causal connection between the flu vaccine and a vascular event. Tr. 148-50 (Dr. Steinman).

Dr. Steinman in his report and testimony referred to the Foo and Rossier article. This article reviewed the literature about anterior spinal artery syndrome and identified 60 cases. Of this group of 60, a single case had a probable cause of “post-vaccination.” An additional eight cases were listed as having the probable cause of “post-infection.” Exhibit 5 (Dominic Foo and Alain B. Rossier, Anterior Spinal Artery Syndrome And Its Natural History, 21 *Paraplegia* 1 (1983)) at 2-5.⁵ Foo and Rossier did not offer a medical theory. Although a table included a row titled “probable cause,” Foo and Rossier did not actually say that either a vaccination or an infection caused the anterior spinal artery syndrome in the particular cases. Instead, they stated “In children, [anterior spinal artery syndrome] is often associated with post-infectious or post-vaccination myelopathy.” Id. at 7.

The group of eight post-infection and one post-vaccination cases of anterior spinal artery syndrome identified by Foo and Rossier come from two other articles. The first is A. Theodore Steegmann, Syndrome of the Anterior Spinal Artery, 2 *Neurology* 15-35 (1952). The second is Richard S. Paine and Randolph K. Byers, Transverse Myelopathy in Childhood, 85 *A.M.A. J of*

⁵ The page numbers refer to the pagination in the original article, not the pagination within exhibit 5.

Diseases in Children 151-63 (1953). In their (lack of) analysis as pertinent to Dr. Broekelschen's case, these two articles resemble the Foo and Rossier article. The Steegman article and the article by Paine and Byers do not state that a vaccine or an infection caused a myelopathy. In particular, they do not propose a medical theory of how causation would happen. Exhibit C, Tab 1 & Tab 2.

Besides the literature, it is arguable that Dr. Steinman intended to rely upon molecular mimicry as a theory underlying his alternative argument that the flu vaccine can cause anterior spinal artery syndrome. Tr. 148-50. But, Dr. Steinman did not show that molecular mimicry is a reliable theory to connect the flu vaccine and anterior spinal artery syndrome. A foundation for the theory of molecular mimicry is that the protein sequence of an antigen (here, the flu vaccine) resembles the protein sequence of a portion of the body (here, the cells of the vascular system in the spinal cord). Dr. Steinman has not shown that this similarity, which is sometimes known as homology, is present.⁶ Dr. Steinman recognized that his theory could be tested, but it has not been. Tr. 149.

In determining whether molecular mimicry is a reliable theory to explain how the flu vaccine can cause anterior spinal artery syndrome, the testability of this hypothesis should be considered. "Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested." Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593 (1993); Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (affirming special master's use of Daubert in vaccine program cases). Here, no persuasive evidence demonstrates that Dr. Steinman's theory – at least as it attempts to connect the flu vaccine to anterior spinal artery syndrome – is reliable.

The need to produce a reliable medical theory explaining how the flu vaccine can cause anterior spinal artery syndrome is particularly acute in this case. The nine case reports that Foo and Rossier identified as occurring after infection (eight cases) or after vaccination (one case) happened between 1929 and 1952. Exhibit C, tab 1 at 17-26 and exhibit C, tab 2 at 152. Arguably, the most analogous case, the one involving vaccination was from 1934. Exhibit C, tab 2 at 152 (case 7). Given the advances in creating vaccines in the last 75 years, it is difficult to draw any meaningful conclusions from the notations about this five-year-old girl and apply them to Dr. Broekelschen's case. Such reasoning could have been useful, but the comparability of the cases would seem to require an identification of the general medical theory. Because no theory was provided in Dr. Steinman's supplemental expert report, the proposed comparison is not persuasive.

⁶ In contrast, Dr. Steinman produced some evidence showing homology between the flu vaccine and part of the nerve cells to support molecular mimicry as a theory to explain how the flu vaccine can cause transverse myelitis. Exhibit 2, tab 1 at 3.

To the extent that Dr. Broekelschen is offering molecular mimicry as a theory, he has not demonstrated the reliability of this theory in this context. The theory connecting the vaccine to the injury “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). Dr. Broekelschen has not met his burden on this issue.

For these reasons, Dr. Broekelschen has failed to establish one of the three elements required by Althen. Because he has not presented a reliable medical theory connecting the flu vaccine to his anterior spinal artery syndrome, he is not entitled to compensation. Furthermore, because of the lack of proof on this element, discussing the remaining two prongs from Althen is not necessary. But, it should be noted that Dr. Broekelschen’s evidence on the other two prongs was also relatively thin.

IV. Conclusion

A preponderance of the evidence establishes that Dr. Broekelschen suffers from anterior spinal artery syndrome, not transverse myelitis. Almost no evidence establishes that the flu vaccine caused this condition in Dr. Broekelschen. Therefore, Dr. Broekelschen is not entitled to compensation. The Clerk’s Office is directed to enter judgment in favor of respondent unless a motion for review is filed.

IT IS SO ORDERED.

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