

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

KAREN TIUFEKCHIEV, *

Petitioner, *

v. *

SECRETARY OF HEALTH *

AND HUMAN SERVICES, *

Respondent. *

No. 05-437V
Special Master Christian J. Moran

Filed: July 24, 2008

entitlement, hepatitis B,
treating doctors

Clifford J. Shoemaker, Esq., Shoemaker & Associates, Vienna, Virginia, for Petitioner;
Michael P. Milmo, Esq., United States Dep't of Justice, Washington, D.C., for Respondent.

PUBLISHED DECISION DENYING ENTITLEMENT*

Karen Tiufekchiev brings a claim pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq. (2006). Ms. Tiufekchiev claims that the hepatitis B vaccination caused her to develop myalgia-fibromyalgia. Petition at 1. A preponderance of the evidence establishes that Ms. Tiufekchiev is not entitled to compensation. Thus, the Clerk's Office is ORDERED to enter a decision in favor of respondent.

* 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. Factual History

Ms. Tiufekchiev was born on May 9, 1965. Exhibit 11 at 1. She received her first hepatitis B vaccination on June 20, 2003. Exhibit 11 at 6; transcript (“tr.”) 12. Ms. Tiufekchiev was attending nursing school and school administrators required that all students receive the hepatitis B vaccine. Tr. 10-11. At that time, her primary physician was Dr. Joseph Lee at Potomac Family Practice. Exhibit 11.

Approximately two weeks after the vaccination, Ms. Tiufekchiev began experiencing itching on her arms and pain in her knees that occurred when she was seated for over an hour. Since no rash accompanied the itching and the pain in her knees subsided after she moved around, she did not report these symptoms to her doctor. Exhibit 19 at 1 (Affidavit of Karen Tiufekchiev, dated July 18, 2005); tr. 13.

Ms. Tiufekchiev received a second vaccination on July 28, 2003. Exhibit 11 at 6; tr. 14. Again, approximately two weeks after that vaccination, she noticed itching on her arms and “an odd tingling sensation in both [her] pinkies, mostly in the left.” Exhibit 19 at 1; tr. 14. After consulting with Dr. Lee, Ms. Tiufekchiev went to see Dr. Randall Peyton, an orthopedist, on August 27, 2003. Id.; exhibit 11 at 2; exhibit 4 at 1.

Dr. Peyton diagnosed Ms. Tiufekchiev with “left shoulder pain, cervical radiculopathy, left ulnar neuropathy, and cervical degenerative disk disease.” Exhibit 4 at 1. He prescribed a course of Medrol Dosepak and cervical traction. Id. at 2. Dr. Peyton also stated that an MRI should be considered if the discomfort was not alleviated by these treatments. Id.; tr. 19-21.

Ms. Tiufekchiev went to see Dr. Lisa Kurtz, a neurologist, on September 3, 2003. Exhibit 8 at 25; tr. 22. Dr. Kurtz’s impression was that Ms. Tiufekchiev had “a history of neck

pain with upper extremity tingling and pain, possibly secondary to cervical radiculopathy.” Id. at 26. Dr. Kurtz recommended that Ms. Tiufekchiev have an MRI of her cervical spine and possible physical therapy, subject to the results of that MRI. Id.

Ms. Tiufekchiev followed up with Dr. Kurtz on September 8, 2003, complaining of numbness in her first, right toe. Id. at 27. Dr. Kurtz recommended an MRI of the lower back as well as the cervical spine. Id.

On September 12, 2003, Ms. Tiufekchiev went to Dr. John Rees, a radiologist, for an MRI of her cervical spine. Id. at 11. Dr. Rees noted that Ms. Tiufekchiev’s cervical vertebral column was “diffusely straightened and there is a slight reversal of the lordosis.” Id.

In a September 15, 2003 visit with Dr. Kurtz, Ms. Tiufekchiev expressed concern that the symptoms might be multiple sclerosis (“MS”) because she “heard from an orthopedic doctor that the hepatitis B vaccine has been linked possibly to neurologic problems such as MS.” Id. at 5. She reported that she had received the hepatitis B vaccination two weeks before her symptoms began. Dr. Kurtz informed Ms. Tiufekchiev that she was unaware of the association between the hepatitis B vaccine and MS. Dr. Kurtz ordered an MRI on Ms. Tiufekchiev’s lower back. Id.

On September 23, 2003, Ms. Tiufekchiev had an MRI of the lumbar spine. Dr. Louis Kirschner, a neurologist, found “no evidence of disc herniation, spinal canal stenosis. Degenerative disc disease at L5-S1, L4-L5 with mild bulging disc seen at L4-L5.” Id. at 8.

An MRI of Ms. Tiufekchiev’s brain on September 25, 2003 was found to be normal. Exhibit 8 at 9.

During another visit with Dr. Kurtz on September 26, 2003, Ms. Tiufekchiev again reported that she was concerned about multiple sclerosis and a possible connection with the

hepatitis B vaccination. Id. at 67. Dr. Kurtz again stated that she did not believe that Ms. Tiufekchiev had MS and did not know of any relationship between the hepatitis B vaccine and MS. Id. Dr. Kurtz prescribed Celexa, Celebrex, and Flexeril for Ms. Tiufekchiev's continued neck and lower back pain. She also recommended physical therapy. Id. at 68.

Ms. Tiufekchiev went to physical therapy from October 1, 2003 through June 9, 2004. Exhibit 10 at 1-15. Her therapist described her experience as "highly variable responses to treatment, but overall improvement and pain has been reduced in intensity and frequency." Exhibit 7 at 1. Ms. Tiufekchiev reported that her pain died down a little, but she was still unable to resume a normal life. Exhibit 19 at 2.

During the time she was attending physical therapy, Ms. Tiufekchiev saw Dr. Lenz at Johns Hopkins University. Her chief complaint was pain in both arms, especially below her elbows into her pinky fingers. Ms. Tiufekchiev told Dr. Lenz that her problems began approximately 10 days after receiving the hepatitis B vaccination. Dr. Lenz believed that the source of Ms. Tiufekchiev's pain could be a neuropathy at the thoracic outlets. Exhibit 32 at 10-11; see also tr. 24-25. Dr. Lenz believed that the foraminal stenosis at C5-C6 was the source of Ms. Tiufekchiev's pain. He recommended that Ms. Tiufekchiev continue physical therapy and obtain a nerve conduction study. Id.

On March 26, 2004, Ms. Tiufekchiev saw Dr. Steven Marshak. Exhibit 20 at 9. Dr. Marshak wrote in his progress report that Ms. Tiufekchiev has had muscle pain since having an adverse reaction to the hepatitis B vaccination. Id. An undated summary of care listed, under significant medical problems, "myalgia secondary to Hep B injection." Id. at 3. All lab tests,

including an ANA, sed. rate, Lyme disease, serum chemistries, and CBC, came back with normal results. Id. at 16-19.

On April 19, 2004, Ms. Tiufekchiev saw Dr. Ruben Cintron, another neurologist. Exhibit 5 at 1. Dr. Cintron found that she had

multiple fibromyalgia type symptoms with bony arthritis fluctuating in intensity and location since two weeks after second booster for hepatitis vaccine eight months ago. I reviewed her entire workup and records and [do] not feel that any other findings can explain her symptoms. I do believe that she probably had a postvaccination reaction and discussed that at length with her. She is hesitant to trying neuromodulating medications. Recently has been having more knee pain than anything else. I have recommended to see a rheumatologist and follow with me in three months.

Id.

Ms. Tiufekchiev saw Dr. Annette Hudler on July 12, 2004. Dr. Hudler noted that Ms. Tiufekchiev reported myofascial pain syndrome secondary to an adverse vaccine reaction. Exhibit 20 at 8, 11.

In a letter dated July 20, 2004, Dr. Tamie Dixon, a chiropractor, stated that she examined Ms. Tiufekchiev in August of 2003 and noted an “acute onset symptoms that were consistent with cervical radiculopathy of the left arm and hand.” Exhibit 6 at 1. Dr. Dixon further noted that it was apparent to her and to the neurologist that “the onset and severity of the symptoms was consistent with post vaccination syndrome. [Ms. Tiufekchiev’s] prognosis is guarded as the full reaction [of] the vaccine and its sequela may take another 12 months.” Id.

On August 18, 2004, Dr. Cintron wrote Ms. Tiufekchiev a note stating that she was unable to return to school because of problems secondary to a vaccine reaction. Exhibit 9 at 1.

Ms. Tiufekchiev presented to Dr. Chakurkar, a pulmonary doctor, with respiratory problems. Exhibit 13 at 4. Dr. Chakurkar noted that her back and body pain developed after the hepatitis B vaccine and inquired if she had been told that she had any vaccine-induced polyneuritis or neuropathy. Ms. Tiufekchiev replied that she had not been told of any. Id. Dr. Chakurkar sent her for a chest x-ray but did not make any specific diagnoses during that visit. Id. at 5.

On April 18, 2005, Ms. Tiufekchiev had a follow-up visit with Dr. Cintron. Exhibit 18 at 2. He stated that her symptoms were “fibromyalgia-like” and “almost sound like decompensating cognitive issues.” Id. Dr. Cintron prescribed her Xanax for her anxiety and recommended that she speak to an infectious disease doctor to determine if she had some immunodeficiency-type state. Id.

II. Procedural History

Ms. Tiufekchiev filed her petition seeking compensation on April 1, 2005. The petition contained one medical record. On April 22, 2005, Ms. Tiufekchiev filed an additional 11 exhibits. Ms. Tiufekchiev periodically filed additional exhibits until she appeared to have produced all relevant records.

In his report, pursuant to Vaccine Rule 4, respondent stated that Ms. Tiufekchiev had not established that she was entitled to compensation. Respondent’s report raised three issues, which issues remain to be resolved. First, respondent noted that Ms. Tiufekchiev had not “offer[ed] a reputable medical or scientific theory causally connecting the vaccine to any alleged injury.” Resp’t Rep’t, filed July 10, 2006, at 13-14. Second, respondent acknowledged that “certain medical records suggest the possibility of a relationship between the claimant’s condition and

vaccination.” Id. at 14. Respondent argued that the opinion contained in these records was speculative because no medical or scientific theory persuasively established that the hepatitis B vaccine “can cause the injury alleged” by Ms. Tiufekchiev. Id. (emphasis in original). In this regard, respondent requested an opportunity to explore the basis of the treating doctor’s statements, “[i]n the event that the Court intends to rely” on them. Id. Finally, respondent asserted that the medical records show that “most or all of [Ms. Tiufekchiev’s] symptoms may be related to degenerative disc disease.” Id. at 15.

Approximately nine months later, Ms. Tiufekchiev filed a report from Dr. Joseph Bellanti. Exhibit 22. Dr. Bellanti is a board-certified immunologist. He opined that “that the most logical explanation for Mrs. Tiufekchiev’s symptoms is an adverse reaction to her hepatitis B vaccines.” Id. at 6. In finding that the hepatitis B vaccine was the cause of Ms. Tiufekchiev’s symptoms, Dr. Bellanti stated that the degenerative disc disease was not the cause of “most” of her symptoms. Id. Dr. Bellanti did not diagnose Ms. Tiufekchiev with a particular disease, illness or syndrome. He said that the hepatitis B vaccine was the cause of her “symptoms.” Exhibit 22 at 6. Shortly after Ms. Tiufekchiev filed Dr. Bellanti’s report, she filed literature supporting Dr. Bellanti’s opinion.

Respondent filed a report from Dr. Lawrence Kagan on June 5, 2007. Dr. Kagan is a rheumatologist. In his report, Dr. Kagan stated that “[t]here is insufficient evidence in this case to link this disorder to [the] hepatitis B vaccination. There are several more probable causes indicated in the record for petitioner’s ailments.” Exhibit A at 10. Dr. Kagan identified disc disease in Ms. Tiufekchiev’s cervical spine, disc disease in Ms. Tiufekchiev’s lumbar spine, and severe anxiety as other more likely causes.

This case was scheduled a hearing for October 30, 2007. The associated pre-trial conference was held on October 20, 2007. Order, dated August 21, 2007.

During the pre-trial status conference, the issue about respondent's request to explore the basis of the treating doctor's opinions was discussed. Due to the closeness in time to the hearing date, the matter was deferred until after the hearing.

The hearing was held on October 30, 2007. Ms. Tiufekchiev testified. Dr. Bellanti and Dr. Kagan also testified.

Following the hearing, respondent filed a written motion seeking the right to interview one treating doctor, Dr. Cintron. Ms. Tiufekchiev filed an opposition to this motion. An oral argument, which was digitally recorded, was held on February 1, 2008. (Citations to this argument are "Oral Argument at xx:xx," providing the time of the statement.) Following this argument, the parties were given the opportunity to file post hearing briefs. Order, dated February 5, 2008.

The parties have filed post hearing briefs. Thus, this case, including respondent's motion to interview a treating doctor, is ripe for resolution.

III. Analysis

Ms. Tiufekchiev is entitled to compensation if she establishes, among other elements, that she "sustained, or had significantly aggravated, any illness, disability, injury or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine [listed in the vaccine injury table]." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Here, Ms. Tiufekchiev does not argue that the vaccine "significantly aggravated" any illness. Pet'r Post Hearing Br. Thus, the question is

whether Ms. Tiufekchiev established that she “sustained . . . any illness, disability, injury or condition . . . which was caused by” the hepatitis B vaccine.

When a petitioner claims compensation for an injury not listed on the Vaccine Injury table, 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.

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).

An analysis of the evidence for these factors leads to the conclusion that Ms. Tiufekchiev has not met her burden. Consequently, she is not entitled to compensation. Ms. Tiufekchiev’s failure of proof is most apparent with regard to the third prong in Althen – “a proximate temporal relationship between vaccination and injury.” Thus, this prong is discussed first.

A. A Showing of a Proximate Temporal Relationship Between Vaccination and Injury

Ms. Tiufekchiev fails to meet her burden of proof on this issue because she presented no evidence about the appropriate temporal relationship between the hepatitis B vaccine and her injury. This omission prevents an award of compensation in her favor.

Dr. Bellanti’s report does not define the appropriate temporal relationship. The word “time” does not appear in it. The word “temporal” only appears in a sentence stating: “Case reports in the literature have identified . . . [several] autoimmune conditions temporally

associated with [hepatitis B vaccine].” Exhibit 22 at 6. Yet, Dr. Bellanti’s report does not say what would be considered the appropriate temporal period for Ms. Tiufekchiev’s condition.

Similarly, a review of Dr. Bellanti’s testimony indicates that Dr. Bellanti did not define the temporal relationship that he would find to be appropriate. See tr. 59-107. The closest Dr. Bellanti comes to discussing the appropriate temporal relationship is during cross-examination, where he discussed articles that associated the hepatitis B vaccine with some adverse consequences. Tr. 98-99. However, even this tangential reference is not sufficient because the subjects of the articles cited by Dr. Bellanti suffered from conditions different from Ms. Tiufekchiev – a fact that Dr. Bellanti conceded in his testimony. Id.

Ms. Tiufekchiev has not presented an argument that the literature she filed establishes the appropriate temporal relationship. The omission from the post trial brief is consistent with the scope of the testimony in the hearing. During the hearing, Dr. Bellanti did not discuss any article extensively. The parties were advised to discuss literature during the hearing, as stated in the pre-hearing order. Order, filed October 23, 2007, ¶ 4. The parties were also reminded of this suggestion during the hearing. Tr. 58. Without expert testimony explaining the concepts and theories presented in the medical literature filed, understanding the complex literature can be difficult. Presumably, if a party filed medical literature that advances a theory presented by a party’s expert, this information would be discussed by the expert during the hearing.

Ms. Tiufekchiev may not have pursued an argument based upon the medical articles as an implicit concession that they are not helpful. Most of the articles submitted by Dr. Bellanti associate hepatitis B vaccine with conditions that are not the same as conditions from which Ms. Tiufekchiev suffered. For example, Dr. Bellanti describes one article as discussing arthritides

(inflammation in the joints), but Dr. Bellanti recognizes that Ms. Tiufekchiev did not suffer from that problem. Tr. 99. In another example, Dr. Bellanti discussed an article about hepatitis B being associated with demyelinating conditions. However, Ms. Tiufekchiev's tests for demyelination were normal. Tr. 99-100. Special masters may find literature that discusses conditions different from the condition from which the petitioner suffers to be unpersuasive. Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1359 (Fed. Cir. 2006), cert. denied, ___ U.S. ___, 127 S.Ct. 2909 (2007).

The article that appears to be most closely related to a condition possibly suffered by Ms. Tiufekchiev is an article discussing neuropathy authored by Dr. Geier. Tr. 99; see exhibit 27 at 3 (Mark R. Geier et al., A Review of Hepatitis B Vaccination, 2(2) Expert Opin. Drug Safety, 113 (2003)). The probative value of this article is minimal. The basis for Dr. Geier's article is his examination of the database maintained as part of the Vaccine Adverse Event Reporting Systems (VAERS). Exhibit 27 at internal page 116. However, it is well established that information extracted from the VAERS database may not be reliable because information entered into the VAERS database may not be accurate. Thus, the United States Court of Federal Claims "uniformly has upheld the . . . concerns about the reliability of VAERS data." Analla v. Sec'y of Health & Human Servs., 70 Fed. Cl. 552, 558 (2006) (citing cases). Thus, even this article – assuming that Ms. Tiufekchiev is advancing it as part of her case – is not helpful in establishing the appropriate temporal relationship.

Dr. Bellanti's opinion that the hepatitis B vaccine caused Ms. Tiufekchiev some injury does not substitute for an express statement about the appropriate temporal relationship. Evidence that the temporal relationship is appropriate is not implied from a general statement

about causation as demonstrated in Pafford. In Pafford, the petitioners introduced evidence that a vaccine caused Still's disease through two experts, Dr. Levin and Dr. Geier. Id. at 1356. Dr. Geier's testimony was rejected as unpersuasive. Id. at 1359. Eliminating Dr. Geier left Dr. Levin's testimony. Presumably, Dr. Levin believed that the temporal sequence was appropriate — otherwise, he could not have expressed an opinion about causation. However, he did not express an opinion about the appropriate temporal relationship. Id. at 1358. Consequently, in that case, the special master found that the petitioners did not satisfy their burden of proof “due, in part, to the absence of ‘evidence indicating an appropriate time frame in which Still's disease will manifest subsequent to a triggering event.’” Id. (quoting special master's decision). The Federal Circuit held that the special master's reasoning complied with the test established in Althen. Id. at 1358-59.

The present case is comparable to Pafford in that here Dr. Bellanti expressed an opinion about causation without testifying about the appropriate temporal relationship. This omission is the same as Dr. Levin's testimony and opinion in Pafford.

The gap in Ms. Tiufekchiev's evidence about an appropriate temporal relationship parallels a gap in her post hearing brief. Ms. Tiufekchiev cites the standard language from Althen, which is quoted above. Pet'r Post Hearing Br. at 8. The post hearing brief, however, does not assert, let alone cite, any evidence for the proposition that Ms. Tiufekchiev has established, by a preponderance of the evidence, the “proximate temporal relationship between vaccination and injury,” as required by Althen.

The failure to establish the temporal relationship means that Ms. Tiufekchiev is not entitled to compensation. Pafford, 451 F.3d at 1358-59. Although a finding that Ms.

Tiufekchiev failed to establish, by a preponderance of the evidence, this element resolves the case, the remaining Althen elements are also discussed for the sake of completeness.

B. A Medical Theory Causally Connecting the Vaccination and the Injury

The evidence presented regarding a medical theory was relatively short and conclusory. On this point, the total of Dr. Bellanti's report states that "It is certainly biologically plausible that the hepatitis B vaccines could cause these immune mediated injuries. The medical theories of causation for this type of adverse reaction include molecular mimicry, polyclonal activation, bystander effect, and other principles of autoimmunity described in my textbook." Exhibit 22 at 6.

By process of elimination, Ms. Tiufekchiev effectively advanced two different theories: polyclonal activation and bystander effect. This is because no portion of Dr. Bellanti's textbook was submitted into evidence. In addition, on cross-examination, Dr. Bellanti backed away from using molecular mimicry as a viable theory in this case. He stated that "[t]he theory of molecular mimicry is probably not as tenable because there really hasn't been any component of the vaccine that has been shown to have a cross-reacting antigen." Tr. 79.

For the remaining two theories, Ms. Tiufekchiev brought forth very little evidence. On direct examination, Dr. Bellanti defined – in very general terms – the two theories. He stated:

The second theory is something called [polyclonal] activation where a vaccine could give a nonspecific activation of the B cell system or the T cell system and cause injury.

Another is called the bystander effect where a reaction to the hepatitis B by virtue of the cytokines that are produced damage tissue secondarily, so there are several theories that have been put forth to explain why a vaccine can give rise to immunologically mediated disease.

Tr. 71-72. Other than this passage, the terms “polyclonal” and “bystander” appear in the transcript only in the context of Dr. Bellanti stating that these theories are preferred more than molecular mimicry. Tr. 79.

Ms. Tiufekchiev did not bring forth any evidence to buttress Dr. Bellanti’s statement that polyclonal activation and bystander effects are reliable theories to explain how the hepatitis B vaccine caused her injury. On the other hand, respondent did not challenge the reliability of those theories.

As the proponent of Dr. Bellanti’s testimony, Ms. Tiufekchiev bears the burden of establishing the reliability of his opinion. Doe/03 v. Sec’y of Health & Human Servs., Fed. Cl. redacted, 2007 WL 2350645 (Spec. Mstr. July 31, 2007) (citing Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589 (1993)); see also Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994); Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998) (en banc) (discussing Daubert); Parker Hannifin Corp. v. United States, 71 Fed. Cl. 231, 235 (2006) (United States bears the burden of proving when a document was signed when the United States is using the document to support a motion to dismiss).

Here, Ms. Tiufekchiev did not offer any persuasive evidence about the reliability of Dr. Bellanti’s theory that the hepatitis B vaccination induces an adverse reaction through either polyclonal activation or bystander effect. Corroborating evidence does not have to be peer-reviewed medical articles. Althen, 418 F.3d at 1281. On the other hand, reliability is not established merely because an expert says his own testimony is reliable. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 157 (1999) (quoting General Elec. Co. v. Joiner, 522 U.S. 136, 137 (1997)). Instead, special masters may use the broad standards set forth in Daubert to evaluate the

reliability of the expert's testimony. 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). After Terran, decisions from judges of the Court of Federal Claims have consistently cited to Daubert when reviewing decisions of special masters. E.g., De Bazan v. Sec'y of Dept. 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."), appeal docketed, No. 08-2013 (Fed. Cir. Dec. 1, 2007); Campbell v. Sec'y of Dept. of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006); Piscopo v. Sec'y of Health & Human Servs., 66 Fed. Cl. 49, 54 (2005).

Ms. Tiufekchiev offers little evidence (and no persuasive evidence) that the hepatitis B vaccine can induce either polyclonal activation or bystander effect. In her post trial brief, Ms. Tiufekchiev describes Dr. Bellanti's credentials. Pet'r Post Hearing Br. at 10-11; see also exhibit 22 (Dr. Bellanti's curriculum vitae). "But possessing requisite credentials alone is not enough to render expert testimony admissible." Fuesting v. Zimmer, Inc, 421 F.3d 528, 535 (2005), opinion vacated in part on rehearing, 448 F.3d 936 (7th Cir. 2006), cert. denied, ___ U.S. ___, 127 S.Ct. 1151 (2007); accord Banks v. United States, 75 Fed. Cl. 294, 300-02 (2007) (analyzing proposed expert's credentials and factors listed in Daubert). "[W]ithout more than credentials and a subjective opinion, an expert's testimony that 'it is so' is not admissible." Hathaway v. Bazany, 507 F.3d 312, 318 (5th Cir. 2007) (citation and quotation marks omitted) (affirming district court's decision to exclude testimony of proposed expert).

Beyond Dr. Bellanti's credentials, Ms. Tiufekchiev could potentially argue that the literature submitted by Dr. Bellanti supports a theory that the hepatitis B vaccine can cause, via

either polyclonal activation or bystander effect, Ms. Tiufekchiev's injury. (This is merely a "potential argument" because other than two passing references at page 10 in her post hearing brief, Ms. Tiufekchiev does not present any argument based upon the literature.)

The literature submitted does not support a finding that Dr. Bellanti's opinion regarding polyclonal activation or bystander effect is reliable. There are three problems with the articles.

First, as discussed in section III.,A., above, Ms. Tiufekchiev solicited almost no testimony about the articles. The omission is notable because both before the trial and during the trial, itself, the parties were advised to have the experts discuss the pertinent materials. This lack of development of testimony, combined with a failure to raise the articles in a post trial brief, is tantamount to a waiver of any argument based upon the articles.

Second, even if the articles were the subject of extensive testimony, an examination of them suggests that the articles have little persuasive value. The articles are a collection of case reports. Case reports have little reliability in establishing causation, as Dr. Bellanti, himself, recognized:

Q: Do you agree or disagree with the statement that a case report is in and of itself not evidence of causation; it just shows a temporal association between one event and another event?

A: That is true. That's one piece, one link in the chain.

Tr. 98. This point is recognized in legal cases. See, e.g., McClain v. Metabolife Intern., Inc., 401 F.3d 1233, 1253 (11th Cir. 2005); Meister v. Medical Engineering Corp., 267 F.3d 1123, 1129 (D.C. Cir. 2001); Glastetter v. Novartis Pharmaceuticals Corp., 252 F.3d 986, 989-90 (8th Cir. 2001).

Third, only one article even mentions “polyclonal activation” and that reference is in passing. Exhibit 27 at 7 (Mark R. Geier et al., A Review of Hepatitis B Vaccination, 2(2) Expert Opin. Drug Safety. 119 (2003)). Ms. Tiufekchiev has not cited any more pertinent passages and a review of the articles has not revealed anything more substantial. No discussion of bystander activation was found. To the extent that the articles proposed any theory by which the hepatitis B vaccine can cause various conditions, the articles primarily discuss the development of “immune complexes” which is not a theory advanced by Dr. Bellanti. Ms. Tiufekchiev’s cursory treatment of the medical theories Dr. Bellanti advanced, polyclonal activation and bystander effect, failed to establish their reliability under the facts presented here.

In sum, Ms. Tiufekchiev’s presentation of a medical theory was not persuasive. Ms. Tiufekchiev elicited minimal testimony about the two theories her expert advanced. She supplied almost no evidence to indicate that Dr. Bellanti’s theories were reliable. She has not met her burden of proof on this element.

C. A Logical Sequence of Cause and Effect Showing That the Vaccination Was the Reason for the Injury

The remaining element from Althen is “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Althen, 418 at 1278. Ms. Tiufekchiev’s proof falters here as well. The finding that Ms. Tiufekchiev did not meet her burden of proof is based on an analysis of the argument advanced by her (challenge-rechallenge) and, separately, an analysis of an argument that could have been, but was not, advanced by her (statements of treating doctors).

1. Challenge-Rechallenge

Ms. Tiufekchiev's argument is that her case qualifies as an example of challenge-rechallenge. Pet'r Post Hearing Br. at 13.¹ Dr. Bellanti defined the challenge-rechallenge model as: "if you are sensitized with one immunization a subsequent immunization will not only give you another response, but an expanded response, which we call the anamnestic . . . or booster or secondary response, which she apparently had as evidenced by more symptoms." Tr. 68-69; accord tr. 136-37 (testimony of Dr. Kagan). This theory has previously contributed to petitioners prevailing in this program. See, e.g., Hall v. Sec'y of Health & Human Servs., Fed. Cl. 02-1052V, 2007 WL 3120284 (Spec. Mstr. Sept. 12, 2007).

Setting aside Ms. Tiufekchiev's failure to establish an appropriate temporal relationship and her failure to establish a reliable medical theory, Ms. Tiufekchiev's case does fit the challenge-rechallenge model in a limited sense. Approximately two weeks after receiving the first dose of the hepatitis B vaccine, Ms. Tiufekchiev experienced itching in her left arm. Tr. 13. After she received the second dose of the hepatitis B vaccine, Ms. Tiufekchiev again experienced some itchiness and also some tingling in her left arm. Exhibit 19 at 1; tr. 14. This sequence could show challenge-rechallenge, which, in turn, is some evidence of a logical sequence of cause and effect showing that the hepatitis B vaccine was the reason for Ms. Tiufekchiev's itchiness and tingling.

¹ Besides challenge-rechallenge, Ms. Tiufekchiev could have presented other evidence to establish the logical sequence of cause and effect. See Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2005) (holding that special master erred in requiring petitioner to establish at least one of several factors, including challenge-rechallenge). This decision focuses on challenge-rechallenge because it is the argument that Ms. Tiufekchiev advances. See Pet'r Post Hearing Br. at 11.

However, there are two problems with relying upon the challenge-rechallenge paradigm too heavily. First, as the previous paragraph mentions, Ms. Tiufekchiev still has not fulfilled her burden of proving the other two elements of Althen. She has not established a reliable theoretical link between the hepatitis B vaccine and her injury. Relatedly, she has not established the appropriate temporal relationship. The lack of information from Dr. Bellanti about the appropriate temporal relationship is significant because evaluating causation in the absence of evidence about time is difficult. For example, hypothetically, if a reliable medical theory posited that the hepatitis B vaccine could cause Ms. Tiufekchiev's injuries within 3-7 days, the fact that Ms. Tiufekchiev developed an injury 14 days after vaccination would not show an adverse reaction.

The second problem with the challenge-rechallenge paradigm in Ms. Tiufekchiev's case is that it isolates a small number of events from Ms. Tiufekchiev's complex medical picture. After the first hepatitis B vaccination, Ms. Tiufekchiev experienced itching. After the second dose, she had itching and tingling. Then, she developed more significant problems such as pain in her fingers which would travel up her left arm and shoulder to her posterior neck causing sharp pain. Exhibit 2 at 1; Exhibit 4 at 1; tr. 16. Ms. Tiufekchiev also described swelling and pain in her knuckles. Exhibit 4 at 1; tr. 21. Treating doctors diagnosed Ms. Tiufekchiev as having degenerative disc disease from a review of an MRI. Exhibit 4 at 8. Dr. Bellanti does not dispute that Ms. Tiufekchiev suffers from degenerative disc disease. He thinks it was not the cause of all of her problems. Exhibit 22 at 6. In contrast, Dr. Kagan, respondent's expert, believes that structural problems, such as degenerative disc disease, explains why Ms. Tiufekchiev's condition worsened over time. Tr. 137.

Consequently, although the challenge-rechallenge model can be persuasive in some cases, it is not always dispositive and it is not persuasive in this case. Dr. Bellanti's use of challenge-rechallenge does not fulfill Ms. Tiufekchiev's burden of establishing, by a preponderance of the evidence, a logical sequence of cause and effect.

2. Treating Doctors

Although not addressed in Ms. Tiufekchiev's brief, she could have argued that the reports of Dr. Cintron, Dr. Marshak, Dr. Hudler and Dr. Dixon support a finding of logical sequence of cause and effect. Because special masters are obligated to consider "the record as a whole," 42 U.S.C. § 300aa-13(a); these physicians' reports will be considered. However, it is emphasized that Ms. Tiufekchiev has not argued in her post trial brief that these reports fulfill her burden of producing evidence showing a logical sequence of cause and effect. See Vaccine Rule 8(f) (stating "Any . . . argument not raised specifically in the record before the special master shall be considered waived.")

The record contains some statements that could have been advanced in support of an argument that a doctor associated Ms. Tiufekchiev's condition with the hepatitis B vaccination. For example, Dr. Cintron stated that "I reviewed her entire workup and records and [do] not feel that any other findings [other than the hepatitis B vaccine] can explain her symptoms. I do believe that she probably had a postvaccination reaction and discussed that at length with her." Exhibit 5 at 1 (report dated April 19, 2004). Dr. Marshak stated in his report that Ms. Tiufekchiev "has had . . . muscle pain since having adverse reaction to hepatitis vaccine." Exhibit 20 at 9. Dr. Hudler noted that Ms. Tiufekchiev reported myofascial pain syndrome secondary to an adverse vaccine reaction. Exhibit 20 at 8, 11. Finally, Dr. Dixon stated that she

examined Ms. Tiufekchiev in August 2003 and noted an “acute onset of symptoms that were consistent with cervical radiculopathy of the left arm and hand” and that “the onset and severity of the symptoms was consistent with post-vaccination syndrome.” Exhibit 6 at 1.

However, the existing record does not permit much weight to be given to these physicians’ statements. There is an absence of explanation as to how these physicians came to their conclusion and there is the presence of conflicting information from other treating doctors.

Dr. Marshak stated that Ms. Tiufekchiev’s symptoms appeared since she had the vaccination. Nowhere does Dr. Marshak state that the vaccination actually caused Ms. Tiufekchiev’s symptoms.

Dr. Hudler stated in his notes that Ms. Tiufekchiev reported myofascial pain syndrome secondary to an adverse vaccine reaction. There is no explanation as to whether this information was taken verbatim from Ms. Tiufekchiev or if this was, in fact, Dr. Hudler’s own diagnosis.

Dr. Dixon, a chiropractor, appears to diagnosis Ms. Tiufekchiev’s symptoms as post-vaccination syndrome. However, of all Ms. Tiufekchiev’s physicians, Dr. Dixon’s report, as a chiropractor, is afforded the least evidentiary weight of the treating doctors. Anderson v. Sec’y of Dept. of Health and Human Servs., Fed.Cl. 06-168V, 2006 WL 5626962, at *3 (Spec. Mstr. October 13, 2006); see also Diaz v. Shalala, 59 F.3d 307, 314 (2d Cir. 1995) (interpreting regulations issued pursuant to the Social Security Act).

It appears that Dr. Cintron may have based his opinion upon the elimination of other possible causal factors and the temporal sequence of events reported by Ms. Tiufekchiev. This process does not support a finding that a vaccine caused an injury. Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

Ms. Tiufekchiev also cannot buttress Dr. Cintron's opinion by claiming that the process of differential diagnosis validates his opinion. The process of eliminating other possible causes does not necessarily mean that a remaining factor (here the hepatitis B vaccine) caused the condition. Instead, the doctor must also establish (or rule in) that the potential antecedent event can actually cause the condition. See Ruggerio v. Warner Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005) (affirming trial court's exclusion of expert opinion as unreliable). In light of the absence of reliable evidence connecting the hepatitis B vaccine to Ms. Tiufekchiev's condition as discussed in section III. B., above, Dr. Cintron's opinion is not persuasive.

Respondent requested an opportunity to attempt to gather additional information from Dr. Cintron. Resp't Mot. to Interview Treating Physician, filed Nov. 15, 2007. Ms. Tiufekchiev, however, resisted this effort. Pet'r Resp. to Resp't Mot. to Interview Treating Physician, filed Jan. 8, 2008. Ms. Tiufekchiev, apparently, determined that obtaining more information from Dr. Cintron was not likely to help her case.² Ms. Tiufekchiev expected that more information from

² In her response to respondent's motion, Ms. Tiufekchiev makes several assertions about various problems that would occur if additional information were sought from Dr. Cintron. Pet'r Resp. at 3. It is not necessary to address these concerns because no additional information is being sought from Dr. Cintron.

However, it should be noted that Ms. Tiufekchiev fails to explain the basis for her concerns. For example, Ms. Tiufekchiev argues that "[i]njecting lawyers and litigation into the middle of a doctor-patient relationship has tremendous potential to poison that relationship." There are at least four flaws with this argument. First, Ms. Tiufekchiev started this process by using Dr. Cintron's statement to buttress Dr. Bellanti's opinion. Oral Argument at 1:46:05 - 1:46:17. By relying on Dr. Cintron's statement, Ms. Tiufekchiev should have been aware that Dr. Cintron would be exposed to the discovery process. Second, no evidence indicates that Ms. Tiufekchiev and Dr. Cintron have an on-going relationship that would be "poisoned." Third, as Ms. Tiufekchiev notes, at worst, interactions with an attorney only have the "potential" to harm the relationship. No evidence indicates how Dr. Cintron would have reacted negatively to a request for more information. Fourth, even if Dr. Cintron would have reacted negatively, doctors testify about their diagnoses and treatment of their patients in judicial and administrative (such as workers' compensation) proceedings frequently. If the medical profession and the legal

Dr. Cintron would not have assisted her in proving her case by making his statement more persuasive and more reliable.

Another obstacle with relying upon Dr. Cintron's April 19, 2004 statement is that Ms. Tiufekchiev's original doctor, Dr. Kurtz, rejected Ms. Tiufekchiev's suggestion that the hepatitis B vaccine caused her to suffer an injury, which Ms. Tiufekchiev suspected might have been multiple sclerosis. Exhibit 8 at 23 (report dated September 15, 2003). In addition, Dr. Lenz from John Hopkins University stated that he believed the source of Ms. Tiufekchiev's pain was foraminal stenosis at C5-C6. Exhibit 32 at 12-13. Thus, treating doctors came to conclusions that point in opposite directions.

The Federal Circuit stated that "Althen III explained that medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280). Implementing this statement in the context of this case is difficult because the statements and records of treating physicians are not consistent. Ms. Tiufekchiev's case, therefore, differs from the record in Capizzano in which "the treating physicians consistently considered the vaccine in their differential diagnoses as a potential cause of petitioner's [condition]." Capizzano v. Sec'y of Health & Human Servs., Fed. Cl. 00-759, 2006 WL 3419789 *13 (Spec. Mstr. Nov. 8, 2006.) ("Capizzano IV"). Although Dr. Cintron treated Ms.

profession can accommodate each other in these other settings, similar cooperation can be expected to occur in proceedings pursuant to the Vaccine Act.

Tiufekchiev and rendered an opinion that the vaccine caused her injuries, his statement does not necessarily trump the contrary opinion reached by Dr. Kurtz or by Dr. Lenz.³

³ Citing Althen, Capizzano attaches greater weight to the opinions of treating doctors than Althen actually provides. Althen states that 42 U.S.C. § 300aa–13(a)(1) allows “medical opinion as proof” of causation. Althen, 418 F.3d at 1280.

Althen does not state that “medical records and medical opinion testimony are avored in vaccine cases.” Nor does Althen state that “treating physicians are likely to be in the best position” to determine causation in vaccine cases. Giving a statement from a treating doctor more weight merely because the doctor is a treating doctor appears problematic for at least four reasons.

First, establishing a presumption that statements from treating doctors are entitled to more weight may create an inconsistency with the statute. Section 13(b)(1) requires the special master to consider “any . . . medical judgment . . . which is contained in the record regarding the . . . causation . . . of the petitioner’s illness.” This direction is qualified, however, by another portion of the same section. “Any such . . . judgment . . . shall not be binding on the special master or court. In evaluating the weight to be afforded to any such . . . judgment, . . . the special master or court shall consider the entire record.” Practically, any statement that is “avored” is likely to also be “binding.”

Second, Capizzano did not explain why treating doctors should be favored in all cases. The Federal Circuit has acknowledged that the Office of Personnel Management and the Merit Systems Protection Board may evaluate opinions of treating doctors by considering “doubts about professional competence, contrary medical evidence, failure of the professional to consider relevant factors, lack of particularity in relating diagnosis to nature and extent of disability.” Vanieken-Ryals v. Office of Personnel Management, 508 F.3d 1034, 1042 (Fed. Cir. 2007). These concerns about how doctors evaluate claims for disability retirement are valid concerns about how doctors determine causation in the Vaccine Program.

Third, in determining whether a vaccine caused a particular injury, treating doctors do not necessarily have an inherent advantage over non-treating doctors. The opinion of treating doctors is probably most valuable when the course of treatment depends upon differentiating the underlying cause of the patient’s signs and symptoms. But this rarely happens in the Vaccine Program because causation determinations rarely rest upon traits that treating doctors can typically observe.

For most cases in the Vaccine Program, treating doctors may actually be at a relative disadvantage because their practices typically are general. In contrast, non-treating doctors, who are the experts retained by the parties in the litigation, may specialize in researching the possible adverse effects of vaccines.

The treating doctors, at least in the vast majority of cases, are not through their records providing the causation evidence normally adduced through an expert, but are providing the medical “snapshot” through their contemporaneous notes, tests, and reports that allows medical experts and ultimately the decision-maker to tie the medical theory to the clinical

Therefore, even if Ms. Tiufekchiev had advanced Dr. Cintron's report as part of her proof of a logical sequence of cause and effect (and her brief does not), Dr. Cintron's report is not evidence of such persuasiveness that it constitutes a preponderance of the evidence on this subject. Consequently, Ms. Tiufekchiev has not proven this element.

D. Alternative Cause

Through Dr. Kagan, respondent proffered an alternative cause for Ms. Tiufekchiev's injuries, degenerative disc disease. See Resp't Post Hearing Br. at 15. Because Ms. Tiufekchiev has not met her burden of establishing the three factors listed in Althen, an evaluation of

course and determine whether the course of medical events is "logical." Capizzano IV, 2006 WL 3419789 at *14.

Ms. Tiufekchiev even acknowledged during oral argument that, in general, most treating doctors "have no clue how vaccines cause injuries." Ms. Tiufekchiev went on to argue that the treating physicians often do not understand the biological mechanisms associated with vaccines or the medical theories of causation and that 90% of treating physicians "are not qualified." Oral Argument at 2:20:05-2:20:45.

In this sense, the value of treating doctors in the Vaccine Program may be less than the value of opinions presented by treating doctors in the Social Security system. Cf. Guerrieri v. Brown, 4 Vet. App. 467, 472 (1993) (rejecting treating physician rule for veterans' cases). Claimants seeking benefits pursuant to the Social Security Act on the ground that they are disabled are not required to prove what caused their disability. 42 U.S.C. § 423(d)(1)(A), 2(a); 20 C.F.R. § 404.1520; Dixon v. Barnhart, 353 F.3d 602, 605 (8th Cir. 2003) (listing five-step sequential analysis). Instead, the predominant inquiry is doctors may have great familiarity with those traits of the applicant because treating doctors observe the applicant (their patient) directly. Thus, the Social Security Administration favors reports for treating doctors. 56 Fed. Reg. 36932, 36934-35 (Aug. 1, 1991); see also 65 Fed. Reg. 11866 (Mar. 7, 2000) (clarifying meaning of "treating source").

Lastly, deference to treating doctors – merely because they have seen the petitioner – could distort the truth-seeking aspect of litigation in the Vaccine Program in either direction. Some treating doctors seem reluctant to state that a vaccine caused an adverse effect. Their statements could support an erroneous denial of compensation. Similarly, some treating doctors seem quick to state that a vaccine caused an adverse effect. These statements could support an undeserved award of compensation.

Nevertheless, these concerns have not prevented an evaluation of Dr. Cintron's report. For the reasons discussed in the test, Dr. Cintron's report is not persuasive.

respondent's theory is not required. See Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1151-52 (Fed. Cir. 2007).

IV. Conclusion

Ms. Tiufekchiev has failed to establish, by a preponderance of the evidence, any of the three elements listed in Althen. Therefore, she is not entitled to compensation. Absent a motion for review, the Clerk's Office is instructed to enter judgment in favor of respondent.

IT IS SO ORDERED.

S/ Christian J. Moran

Christian J. Moran
Special Master