IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

ESTHER HALL,	*	
	*	
Petitioner,	*	No. 02-1052V
	*	Special Master Christian J. Moran
v.	*	
	*	Filed: September 12, 2007
SECRETARY OF HEALTH	*	Published: October 4, 2007
AND HUMAN SERVICES,	*	
	*	Entitlement; hepatitis B; shoulder
Respondent.	*	injury.

Richard Gage, Esq., Richard Gage, P.C., Cheyenne, Wyoming, for Petitioner;
Melonie McCall, Esq., United States Department of Justice, Washington, DC, for Respondent.

RULING FINDING ENTITLEMENT[*]

Esther Hall claims that the hepatitis B vaccination caused an injury to her shoulder, diagnosed by some doctors as brachial plexus neuropathy. Pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq. (2000), Ms. Hall filed a petition seeking compensation for her shoulder injury. A preponderance of the evidence establishes that Ms. Hall is entitled to compensation.

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[*] 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).

Vaccine Rule 18(b) states that 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, petitioner 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.

I. Factual History

The parties do not contest the accuracy of the contemporaneously created medical records. See post-trial briefs. The following summary sets forth the information relevant to deciding this case.

Ms. Hall was born on May 27, 1947. Though the majority of her medical history until receiving the hepatitis B vaccination is irrelevant to this case, one part of her medical history will be discussed because respondent suggests that her shoulder pain may have derived from a condition she had before the vaccination. See Resp't Rep't, filed Dec. 9, 2002, at 6-7.

In January 1996, Ms. Hall experienced some pain in her shoulder. She saw Dr. Schuler, an orthopedist, three times in that month. Dr. Schuler diagnosed Ms. Hall as having tendinitis in the long head of her left biceps. Exhibit 17 at 2. After January 25, 1996, Ms. Hall did not require additional medical treatment because the pain resolved. Tr. 9, 24.

Three years later, in 1999, Ms. Hall was working as a nurse in Denver, Colorado. Tr. 7; exhibit 13 at 2. As part of her employment, she received the first dose of the hepatitis B vaccine on July 27, 1999. Exhibit 14; tr. 10. Afterwards, she felt discomfort in her shoulder for about three weeks. This pain and discomfort restricted her range of motion for about two weeks. Exhibit 4 at 31; tr. 10-11. Ms. Hall did not seek medical attention for these problems. They resolved before she received the second dose of the vaccine. Tr. 11.

On August 30, 1999, Ms. Hall received her second dose of the hepatitis B vaccine. Exhibit 14; tr. 11; see also tr. 6 (statement by respondent's counsel agreeing to date of second vaccination).

On the following day, Ms. Hall's left arm was swollen, red, and hot. She felt an ache in her deltoid and the ache radiated to her axilla, which is the medical term for armpit, and spread down to the inside of her forearm. Exhibit 4 at 31; tr. 12.[1]

Approximately four days later (September 3, 1999), Ms. Hall felt numbness in the second, third and fourth fingers of her left hand. Abducting (drawing her arm away from her body) was difficult. She had difficulty driving and dressing. She was experiencing a great deal of pain in her shoulder. Exhibit 4 at 31; tr. 12-13.

She saw Dr. Tracy Johnson on September 13, 1999. Dr. Johnson is board certified in physical medicine and rehabilitation. She also describes herself as a specialist in electrodiagnosis. Dr. Johnson obtained a history consistent with the information provided above. Dr. Johnson also noted that Ms. Hall brought literature about drug reactions to the hepatitis B vaccine to the appointment. Exhibit 4 at 31-33.

Dr. Johnson conducted a physical examination. She reported "tenderness over the extensor musculature of her left upper extremity." Ms. Hall's strength in both upper arms was "5/5 with only giveaway weakness due to pain on the left with elbow fixation." A rating of

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[1] Ms. Hall's testimony about the precise number of days between the second dose and the start of her problems is inconsistent with what she told Dr. Johnson on September 13, 1999. In an appointment on that day, she said that the pain started the "next day." Exhibit 4 at 31.

In contrast, her testimony on November 19, 2003, indicated the pain did not start for two days. Her memory about the details of these events is not accurate. For example, she said that she received the shot on August 30, 1999, and that date was a Thursday. Tr. 11-12. However, the calendar indicates that that date was a Monday. Therefore, because Ms. Hall spoke to Dr. Johnson within two weeks of being vaccinated, Dr. Johnson's record is more likely to be accurate than Ms. Hall's testimony. Cucuras v. Sec'y of Health & Human Servs., 993 F.3d 1525, 1528 (Fed. Cir. 1993).

"5/5 " means she had no weakness. Ms. Hall also displayed decreased reflexes and sensation in her left upper arm. Id. at 32.

Dr. Johnson believed that "Ms. Hall has likely developed a brachial plexitis from the hepatitis B vaccination." Dr. Johnson prescribed prednisone. She also recommended an electrodiagnostic examination if Ms. Hall had not improved in a week. Id. at 33.

A week later, Ms. Hall had a follow up consultation. Ms. Hall reported that the pain in her left axilla had gotten better. She also had less, but still some, tingling and numbness in the second and third fingers of her left hand. Dr. Johnson recommended an electrodiagnostic exam. Id. at 28.

Ms. Hall was able to have an electromyography ("EMG") performed on October 1, 1999. Dr. Johnson interpreted the results as indicating "a lower trunk or medial cord brachial neuropathy." Id. at 18-19; see also tr. 27 (Ms. Hall's testimony about the EMG). About six weeks later, Ms. Hall told an occupational therapist that Dr. Johnson had told her that the nerves in the plexus area were not damaged. Exhibit 6 at 6; tr. 28. During the hearing, Dr. Round explained that the EMG "could be" consistent with a brachial plexopathy. Tr. 45.

Ms. Hall had two more appointments with Dr. Johnson, one on October 19, 1999, and a second on November 2, 1999. Exhibit 1 at 14-17. In the earlier appointment, Ms. Hall was concerned because she was feeling more pain. Dr. Johnson's physical examination indicated that her "[s]trength in bilateral upper extremities was 5/5." Id. at 16. Dr. Johnson referred Ms. Hall to Dr. Round for a second opinion. Id. at 17, 20; tr. 16.

Ms. Hall saw Dr. Round on November 15, 1999. He is a board-certified neurologist. Exhibit 18; tr. 36. Dr. Round conducted a physical examination and found that her strength was

5/5. Exhibit 5 at 1; tr. 26. Her reflexes were normal. Her sensation to pinpricks in her second, third and fourth digits of her left hand was diminished. Tr. 40. Dr. Round believed that she had a form of brachial plexus neuropathy. Tr. 43. However, identifying the impaired nerves was "very difficult." Tr. 44. Dr. Round also recognized during his testimony that Ms. Hall's presentation was not a typical presentation of brachial neuritis. Tr. 51, 55.

In May 2000, Ms. Hall returned to see Dr. Johnson. Ms. Hall reported that the shoulder pain, hand pain, and associated numbness had just about resolved. Exhibit 4 at 5; tr. 29. However, the pain in her elbow returned. Tr. 32.

Over the next three years, Ms. Hall saw three doctors whose reports are relevant to this case. In September 2000, Dr. Roberta Anderson-Oeser, a doctor who practiced in the same office as Dr. Johnson, evaluated Ms. Hall. One reason for this evaluation was to provide information relevant to a claim for workers' compensation benefits that Ms. Hall had filed. Dr. Anderson-Oeser determined that Ms. Hall had reached her maximum medical improvement and assigned her a rating of her disability. Exhibit 4 at 1-2. In Colorado, the state where Ms. Hall claimed workers' compensation benefits, "maximum medical improvement" means additional medical treatment will not improve the condition. Allee v. Contractors, Inc., 783 P.2d 273, 279 (Colo. 1989).

In May 2001, Ms. Hall was evaluated by two other doctors. The first, Dr. Sander Orent, was apparently retained by Ms. Hall's employer in defending the workers' compensation claim. Dr. Orent questioned whether the hepatitis B vaccination can cause brachial plexopathy and questioned whether brachial plexopathy was the correct diagnosis. Exhibit 7.

In addition, Dr. Caroline Gellrick also examined Ms. Hall in the context of the claim for workers' compensation. Dr. Gellrick appears to work for the state of Colorado, as opposed to a litigant. Dr. Gellrick accepted that the hepatitis B vaccination can cause neurologic problems based upon information in the "brochure" for the hepatitis B recombinant vaccine. (Dr. Gellrick is probably referring to material prepared by drug manufactures that lists adverse events associated with the drug. See 21 C.F.R. § 201.57(g).) Exhibit 8.

As of November 19, 2003, the date Ms. Hall testified, she had not been seen by an orthopedist. Tr. 31. She was receiving acupuncture from Dr. Castro. Tr. 31. By 2007, Ms. Hall reported that acupuncture was too expensive for her to afford. Ms. Hall continues to have problems with weakness in her arm and pain and numbness in three fingers of her left hand. Exhibit 24 (Ms. Hall's affidavit, dated June 5, 2007).

II. Procedural History

Ms. Hall filed her petition along with eight exhibits on August 23, 2002. She filed additional exhibits containing more medical records in October, November, and December 2002.

Respondent filed its report, pursuant to Vaccine Rule 4, and also presented the report of Dr. Kenneth Gorson, on December 9, 2002. Dr. Gorson is a board-certified neurologist. Exhibit B; tr. 62. Respondent opposed Ms. Hall's claim for compensation.

Ms. Hall filed, as exhibit 16, the report of Dr. Ralph Round. Dr. Round treated Ms. Hall's shoulder problem and believes that the hepatitis B vaccinations caused her brachial plexus neuropathy. Ms. Hall also filed additional medical records. To address these new materials, respondent obtained a supplemental report from Dr. Gorson, which was filed as exhibit C.

With the submission of expert reports from both sides, the case was then scheduled for a hearing. As part of her submissions before the hearing, Ms. Hall filed medical articles as exhibits 20 thru 23. A few days before the hearing, respondent presented medical literature, which was subsequently filed as exhibits D thru G. See tr. 34-35. Although Ms. Hall was granted an opportunity to respond to these articles, order, dated November 24, 2003; Ms. Hall did not file additional materials.

The special master to whom this case was assigned conducted a hearing on November 19, 2003. Three witnesses testified at the hearing: Ms. Hall, Dr. Round, and Dr. Gorson.

Because the record, consisting of medical reports, medical articles, and testimony from the November 19, 2003 hearing appeared complete, a briefing schedule was established. The rounds of filing briefs concluded in June 2004.

About one year later, a status conference was held. Discussions were summarized in a three paragraph order filed on June 6, 2005. During the status conference and in the order, the special master presented her views of the case, suggesting that Ms. Hall may be entitled to compensation. The special master's opinion was that

> while petitioner had not proven a diagnosis of brachial plexus neuropathy, petitioner was in fact injured by her August 30, 1999 hepatitis B vaccination. The special master explained that it appeared that this case might be a case of positive rechallenge. The issue of positive rechallenge was not addressed at hearing. In light of these beliefs, the special master requested that counsel pursue a litigative risk settlement. If the parties are unable to settle this case, the special master will reopen the proceedings to take more evidence regarding petitioner's injury.

Order, filed June 6, 2005. For reasons not entirely clear from the record, the parties' opportunity to resolve the case extended nearly one year.

In April 2006, the case was reassigned and a status conference was held. Ms. Hall indicated that she wanted to obtain another report from an expert. Consequently, a deadline for filing an expert report was set as June 19, 2006. Order, filed April 18, 2006.

Ms. Hall did not file an expert report on June 19, 2006. Instead, she explained that she required additional time and more time was extended. This pattern repeated. On January 17, 2007, Ms. Hall stated that she "expects to file an expert report within the next sixty days." Pet'r Status Rep't, filed January 17, 2007. Thus, a new deadline was set for March 23, 2007.

Without having filed any new evidence, Ms. Hall filed a "memorandum." Ms. Hall requested guidance from the special master on how to proceed. Pet'r Mem., filed March 28, 2007.

Over the next few months, the case progressed. A digitally recorded status conference was held on April 24, 2007, during which the parties and the special master discussed the options available to both Ms. Hall and respondent, including the possibility of presenting evidence about challenge-rechallenge. Ms. Hall was ordered to file a status report, expressing how she wanted to proceed. Order, dated April 25, 2007. After missing one deadline, Ms. Hall filed this status report on June 29, 2007. Ms. Hall indicated that she did not wish to present any additional evidence. Pet'r Status Rep't, filed June 29, 2007. During a July 5, 2007 status conference, respondent stated that it did not intend to present any additional evidence. Both parties also stated that the case could be decided without additional legal briefs. Thus, the case is ready for decision.

III. Analysis

Three issues warrant discussion. First, whether Ms. Hall suffers from a condition known as "brachial plexus neuropathy." This question is not resolved because assigning a label to Ms. Hall's condition is not relevant to determining whether she is entitled to compensation. Second, whether Ms. Hall has established, by a preponderance of the evidence, that the hepatitis B vaccines caused her shoulder injury. She has. Third, whether any alternative factor was shown to have caused Ms. Hall's shoulder injury. A preponderance evidence establishes that no other factor caused Ms. Hall's shoulder injury. Consequently, for the reasons explained in the following paragraphs, Ms. Hall is entitled to compensation.

A. Whether Ms. Hall Suffers From "Brachial Plexus Neuropathy"

Respondent opens its legal arguments by stating that "[a]n initial question in this case is whether petitioner suffers from brachial plexus neuropathy." Resp't Br., filed April 15, 2004, at 5. Respondent argues, with some persuasiveness, that Ms. Hall does not suffer from brachial plexus neuropathy because the symptoms of that condition include arm weakness and Ms. Hall has normal strength in her arms. Id. at 6-9; see also tr. 38, 65 (Dr. Round and Dr. Gorson defining brachial plexus neuropathy).

Respondent's point, even if correct, is simply not relevant to determining whether Ms. Hall is entitled to compensation. The Vaccine Act authorizes compensation to any person who, among other requirements, "sustained . . . any illness, disability, injury or condition." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) (emphasis added); accord Kelley v. Sec'y of Health & Human Servs., 68 Fed. Cl. 84, 100 (2005) (reversing special master for analyzing whether Mr. Kelley suffered

from chronic inflammatory demyelinating polyneuropathy or Guillain-Barré syndrome).[2] The phrase "illness, disability, injury, or condition" is sufficiently broad, especially when preceded by the word "any" that assigning a label to Ms. Hall's condition does not advance the analysis.

Ms. Hall's claim fits within the bounds of the Vaccine Act. In her petition, she seeks compensation for "left brachial plexus neuropathy and a decreased range of motion of the left shoulder." Petition at ¶ 3. She further stated that she "continued to suffer from pain, numbness, a diminished range of motion, and other associated problems." Id. at ¶ 4. While the petition specifically identifies brachial plexus neuropathy as her injury, both the petition and the medical records indicate that she seeks compensation because her shoulder does not function normally after being vaccinated. Her claim requires adjudication of the question whether the hepatitis B vaccination caused her shoulder injury, regardless of the label assigned to that injury.

B. Whether The Hepatitis B Vaccine Caused Ms. Hall's Injury

The Federal Circuit stated the elements a petitioner must establish to be entitled to compensation. 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).

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[2] Kelley was decided after briefing was completed in this case.

Here, a preponderance of evidence establishes that Ms. Hall has met each of the three factors. For ease of explanation, the second factor is discussed last because it is the most controverted in this case.

The first factor is that Ms. Hall present a theory linking her vaccination to her shoulder injury. Ms. Hall's expert, Dr. Round, opined that a vaccination can cause a person's immune systems to attack the person's own body. Tr. 47-49.

An auto-immune reaction as a theoretical basis for an injury being caused by a vaccine is not controversial. Respondent's expert, Dr. Gorson, explained that an auto-immune reaction is biologically plausible. Tr. 78-79. Dr. Gorson recognizes that some vaccines — although not the hepatitis B vaccine — are believed to cause problems to shoulders. Id.; see also 42 C.F.R. § 100.3 (category II) (Vaccine Injury Table associating brachial neuritis with vaccines containing tetanus toxoid); exhibit G (Peripheral Neuropathy (Peter James Dyck et al., eds., 1993)) at 933 (stating that vaccines against typhoid, smallpox, tetanus, pertussis, diphtheria, and influenza have caused neuralgic amyotrophy, which is another term for the condition known as brachial plexus neuropathy). Thus, respondent appears to concede that the first factor of Althen is met. See Resp't Br., filed April 15, 2004, at 10. Even if respondent did not make this concession, a preponderance of the evidence establishes the theoretical basis for her claim.

Respondent also concedes that Ms. Hall satisfies the third Althen factor — an appropriate temporal sequence. See Resp't Br., filed April 15, 2004, at 10. For the first dose, Ms. Hall's pain started approximately ten days later. For the second dose, the problems started one day later.

Dr. Gorson acknowledged that a reaction within three days is within the time doctors expect. Tr. 84-86; see also exhibit E (S.H. Subramony, AAEE Case Report #14: Neuralgic Amyotrophy (Acute Brachial Neuropathy), 11 Muscle & Nerve 39 (1988)) at 41 (stating "a few days to 2 weeks or more pass" between the inciting event, such as an immunization, and the onset of shoulder pain). Thus, a preponderance of the evidence establishes Ms. Hall has met her burden of proving the third Althen prong.

After resolving the first and third factors, the remaining question is whether Ms. Hall met the second Althen factor — "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Here, respondent mounts its most serious challenge. Respondent argues that a theoretical basis plus an appropriate temporal relationship even when combined with an absence of other causes does not entitle a petitioner to compensation. Resp't Br., filed April 15, 2004, at 12-14 citing Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 n.4 (Fed. Cir. 1993); Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1147 (Fed. Cir. 1992); Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991); Hasler v. United States, 718 F.2d 202, 204-05 (6th Cir. 1983). Respondent contends that evidence demonstrating specific causation for Ms. Hall is required.

The validity of respondent's legal position might be questioned due to more recently decided cases. Respondent's post-trial briefs, which were filed in 2004, cite three Federal Circuit cases, decided between 1991 and 1993. Since 2004, the Federal Circuit decided Althen, Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317 (Fed. Cir. 2006); Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006), cert. denied, ___ U.S. ___, 127 S.Ct. 2909 (2007); and Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146 (Fed. Cir. 2007).

Whether these four cases have reshaped (and lessened) petitioner's burden might be debated reasonably. However, resolving any dispute about how Althen, Capizzano, Pafford and Walther affect this Program is unnecessary in Ms. Hall's case, because even under the legal test based upon the older cases proposed by respondent, Ms. Hall prevails.

A preponderance of the evidence shows that Ms. Hall has established a logical sequence of cause and effect by presenting evidence about her specifically. The persuasive evidence is that Ms. Hall's history fits the challenge-rechallenge paradigm. In addition, Ms. Hall's claim is supported by the opinion of her treating doctors.

The Federal Circuit recognizes the concept known as "challenge-rechallenge." "A rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine." Capizzano, 440 F.3d at 1322.

Ms. Hall received two doses of the hepatitis B vaccine and after each dose, she experienced problems in her shoulder within two weeks of the vaccination. First, she received her first dose of the hepatitis B vaccine on July 27, 1999. Exhibit 14; tr. 10. She felt pain and discomfort for about three weeks and had restricted motion in her arm for about two weeks. Exhibit 4 at 31; tr. 10-11. Although no evidence directly states when these problems began, an estimated onset date can be inferred. Ms. Hall stopped having these problems before the second dose of the hepatitis B vaccine, which she received on August 30, 1999. Assuming that these problems stopped a few days short of August 30, 1999, Ms. Hall's pain and discomfort started approximately August 6, 1999, or ten days after her vaccination.

The circumstances surrounding Ms. Hall's receipt of the second dose of the hepatitis B vaccine were developed more extensively. The date of the second dose was August 30, 1999.

Exhibit 14; tr. 11. The next day, Ms. Hall's arm was swollen, red and hot. Exhibit 4 at 31; tr. 12. Her problems worsened over the next few days.

Thus, Ms. Hall illustrates the challenge-rechallenge paradigm. The amount of time between the first vaccination and the start of problems (approximately 10 days) was more than the amount of time between the second vaccination and the start of problems (approximately one day). The reaction to the second vaccination was also more severe. A quicker, more intense reaction is typical in challenge-rechallenge cases. See De Bazan v. Sec'y of Health & Human Servs., 70 Fed. Cl. 687, 698 (Fed. Cir. 2006).

An example of challenge-rechallenge fulfills the second factor of Althen. Respondent conceded as much when it argued to the Federal Circuit in Capizzano. "The government argues that epidemiologic studies, rechallenge, pathological markers, and general acceptance are merely four ways to satisfy the second prong of Althen III." Capizzano, 440 F.3d at 1325 (emphasis added). Rechallenge is compelling evidence because it happens to a particular person. The specificity fulfills respondent's demand, based upon Hodges, Grant, Bunting, and Hasler, that a petitioner bring forth evidence to show that he or she suffered an injury due to the vaccination.

Without mentioning rechallenge, Ms. Hall's treating doctors also determined that the hepatitis B vaccinations caused her shoulder problem. For example, Ms. Hall told her treating physician, Dr. Johnson, that she had experienced shoulder problems after both of her vaccinations. Exhibit 4 at 31. While Dr. Johnson does not spell out her reasoning in her reports (and neither party attempted to obtain more information from Dr. Johnson about her rationale), Dr. Johnson stated that "Ms. Hall has likely developed a brachial plexitis from the Hepatitis B vaccination she received." Exhibit 4 at 33. Dr. Johnson's conclusion, therefore, supports a

finding that the hepatitis B vaccination caused Ms. Hall's shoulder problems. See Capizzano, 440 F.3d at 1326 (instructing special masters to consider opinions of treating physicians). Another doctor in Dr. Johnson's group, Dr. Anderson-Oeser, also stated in a report for workers' compensation that Ms. Hall "has residuals from a left brachial plexopathy secondary to the hepatitis B vaccination." Exhibit 4 at 2. In addition, Dr. Round, before he was retained as an expert witness in the litigation, shared this assessment. Exhibit 5 at 3; tr. 58.

In opposing Ms. Hall's claim for compensation, respondent and Dr. Gorson set the evidentiary bar too high. For example, respondent argues that "[w]ithout compelling evidence in the form of peer-reviewed medical journal articles, epidemiological studies, or other dependable evidence that [] has been tested and has gained support in the general medical community, Dr. Round's opinion and theory of causation is unreliable and inadequate as a matter of law to establish causation." Resp't Br., filed April 15, 2004, at 11. The Federal Circuit's decision in Althen, which was decided after respondent filed its briefs, stated that neither articles published in peer-reviewed medical journals nor epidemiological studies are required. Althen, 418 F.3d at 1279-80. Respondent's legal argument about the type of evidence required is no longer tenable.

Similarly misplaced is Dr. Gorson's criticism about the theory espoused by Dr. Round that the hepatitis B vaccinations caused Ms. Hall's shoulder problem. To Dr. Gorson, this theory is not supported because proving that theory requires "supporting scientific data that epidemiologically proves the causation." Tr. 74; accord exhibit C (report of Dr. Gorson suggesting that Dr. Round "provide the citations in the medical literature that indicate a compelling epidemiological link between Hepatitis B vaccination and brachial neuritis.") As just noted, epidemiological evidence is not required in the Vaccine Program.

Although much of the hearing consisted of the testimony of Dr. Round and Dr. Gorson, their opinions about causation are not dispositive. Instead, the dispositive fact is that Ms. Hall experienced a challenge and rechallenge. It is unfortunate that this issue was not identified before the November 19, 2003 hearing. However, the June 6, 2005 order alerted the parties to this issue after the hearing, and the case was put on hold to allow the parties to consider this issue. Order, filed June 6, 2005. Furthermore, between April 24, 2007 and July 5, 2007, both parties were granted an opportunity to submit evidence addressing challenge and rechallenge. Neither party elected to do so. See order, filed July 5, 2007; Pet'r Status Rep't, filed June 29, 2007. Thus, there is no procedural impediment to resolving the case based upon a challenge and rechallenge.

In sum, a preponderance of the evidence demonstrates that Ms. Hall has fulfilled the three prongs established by Althen.

C. Whether Something Other Than The Vaccines Caused Ms. Hall's Injury

One question remains – whether something other than the hepatitis B vaccination caused Ms. Hall's shoulder injury. This issue merits discussion because some material suggests that respondent was attempting to raise a cause, other than the vaccine, for Ms. Hall's injury. See Resp't Br., filed April 15, 2004, at 9 ("there are several other equally likely causes of petitioner's symptoms."). Respondent, however, did not develop this argument extensively. Nevertheless, for sake of completeness, this issue is resolved. For the reasons explained below, it is resolved in favor of Ms. Hall.

Respondent's contention that factors unrelated to the vaccine caused Ms. Hall's injuries is based upon the opinion of Dr. Gorson. In Dr. Gorson's report, he noted that Ms. Hall received

treatment for a shoulder problem three years before her vaccination. Exhibit A at 2. Dr. Gorson also opined that Ms. Hall "has carpal tunnel syndrome . . . and perhaps an orthopedic disorder." Id. at 3. A preponderance of the evidence fails to establish that any of the three identified factors caused Ms. Hall's injury.

First, Dr. Gorson commented that Ms. Hall was treated for tendinitis in her left shoulder in 1996. Exhibit A at 2. Dr. Schuler saw Ms. Hall three times in January 1996. The records do not show any treatment after January 25, 1996. Exhibit 17. Ms. Hall testified that she did not follow up because the pain resolved. Tr. 9, 24. Because more than three years passed without Ms. Hall having any shoulder trouble, the possibility that the shoulder problem in 1999 was actually a recurrence of the tendinitis is remote. Even Dr. Gorson, to his credit, refused to link Ms. Hall's current shoulder problem to the earlier tendinitis. Tr. 75-76. Dr. Round agrees. Exhibit 16 at 4. Thus, Ms. Hall's earlier problem with her shoulder does not prevent her from receiving compensation.

Second, Dr. Gorson stated that Ms. Hall's medical records suggest that she has carpal tunnel syndrome. Exhibit A at 3. To prevail on this argument, at a minimum, respondent would need to establish that Ms. Hall has carpal tunnel syndrome. No evidence about how carpal tunnel syndrome develops was introduced. See tr. A preponderance of the evidence fails to establish that Ms. Hall has carpal tunnel syndrome.

The strongest evidence that Ms. Hall had carpal tunnel syndrome was Dr. Gorson's report that states that the October 1, 1999 electrophysiologic study (exhibit 4 at 18) shows a median neuropathy localized in Ms. Hall's wrist, a showing that is consistent with carpal tunnel syndrome. Exhibit A at 3. Although this point could have constituted a factor unrelated to the

vaccine that caused Ms. Hall's shoulder problem, respondent did not elicit testimony from Dr. Gorson about carpal tunnel syndrome during the hearing. See tr.

Besides the mention of carpal tunnel syndrome in Dr. Gorson's report, another piece of evidence relating to carpal tunnel syndrome was a portion of Dr. Round's testimony. He acknowledged that based upon the EMG, carpal tunnel syndrome was a possible diagnosis in the fall 1999. Tr. 45. However, Dr. Round thinks that Ms. Hall does not have carpal tunnel syndrome. Exhibit 16 at 4. His recognition that carpal tunnel syndrome was "possible" fails to present a probative opinion. Van Epps v. Sec'y of Health and Human Servs., 26 Cl. Ct. 650, 654 (1992); Doe v. Sec'y of Health and Human Servs, 19 Cl. Ct. 439, 450 (1990).

More persuasive evidence supports the proposition that Ms. Hall does not have carpal tunnel syndrome. Respondent has not identified any treating physicians who considered that diagnosis and a review of the record reveals none. Ms. Hall's treating doctors have not diagnosed carpal tunnel syndrome. Tr. 16-17. Nor have any of the doctors who saw Ms. Hall for the workers' compensation case diagnosed her with carpal tunnel syndrome. Exhibit 7 at 3; exhibit 8. The lack of a diagnosis of carpal tunnel syndrome makes sense because her symptoms do not match the problems typically associated with carpal tunnel syndrome. Tr. 82-84. In short, Dr. Gorson's theory that Ms. Hall has carpal tunnel syndrome must be rejected as unsubstantiated.

Third, Dr. Gorson's report suggests an "orthopedic disorder." Exhibit A at 3. In his testimony, Dr. Gorson mentioned that the problem could be a "minor rotor cuff injury that could have been missed on the ultrasound." Tr. 81; see also id. at 87-88. The ultrasound to which Dr. Gorson refers was performed by Dr. Wakeshima in October 2001. After reviewing the results,

Dr. Wakeshima considered and rejected the possibility of a rotator cuff injury. Exhibit 10 at 15-20. The diagnosis of a treating doctor is entitled to deference. See Capizzano, 440 F.3d at 1326. Furthermore, Dr. Gorson was not confident in his suggestion because he had not examined Ms. Hall. Tr. at 81-82. Thus, the preponderance of the evidence shows that Ms. Hall does not have an orthopedic disorder.

Whether a petitioner bears the burden of ruling out alternative causes or whether the respondent bears the burden of establishing an alternative cause is a point on which panels of the Federal Circuit may have addressed inconsistently. Compare Walther, 485 F.3d at 1150 (stating "[a] plain reading of the statutory text more naturally places the burden on the government to establish that there is an alternative cause by a preponderance of the evidence.") with Pafford, 451 F.3d at 1360 (Dyk, J., dissenting) (stating "[t]he majority today holds that petitioners . . . must establish, as essential elements of a prima facie showing of causation in off-Table cases, . . . an absence of 'alternative causes' of the injury.").

Deciding which party bears the burden of proof is not necessary. Identifying the party bearing the burden of proof is decisive only when the evidence is truly in equipoise. Andrew Corp. v. Gabriel Electronics, Inc., 847 F.2d 819, 824 (Fed. Cir. 1988); Cook v. United States, 46 Fed. Cl. 110, 113 n.5 (2000); see also Director, OWCP v. Greenwich Collieries, 512 U.S. 267, 272-76 (1994) (discussing difference between burden of persuasion and burden of producing evidence).

Here, the evidence regarding alternative causes is not in equipoise. It preponderates in favor of a finding that an alternative factor did not cause Ms. Hall's shoulder disability. If Ms. Hall bears the burden of proof, she has met her burden by establishing, by a preponderance of the

evidence, that neither her earlier shoulder tendinitis nor carpal tunnel syndrome nor an undefined orthopedic injury caused her current shoulder disability. Alternatively, assuming that respondent bears the burden of proof, respondent has not met its burden of showing, by a preponderance of the evidence, that any factor other than the hepatitis B vaccination caused Ms. Hall's current shoulder disability.

IV. Conclusion

Ms. Hall has established that the hepatitis B vaccine caused her shoulder injury. She is entitled to compensation. The parties are ORDERED to contact the undersigned's law clerk to schedule a status conference to discuss the damages phase of this case.

IT IS SO ORDERED.

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Christian J. Moran
Special Master