In the United States Court of Federal Claims

No. 99-500V
(Filed Under Seal: July 21, 2008)
(Reissued for Publication: August 6, 2008)[1]

JAY NUSSMAN,	*	
	*	
Petitioner,	*	Vaccine Act; Motion for Review; Hepatitis B Vaccine; Seizure Disorder; Causation; Althen; Pafford; Challenge-Rechallenge; Temporal Relationship; Vaccine Rule 8(f); Waiver; Capizzano; Sequelae
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Clifford J. Shoemaker, Vienna, VA, for petitioner.

Voris E. Johnson, United States Department of Justice, Washington, DC, for respondent.

OPINION

SWEENEY, Judge

Petitioner seeks compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34 (2000 & Supp. IV 2005), for injuries that he alleges resulted from two hepatitis B vaccinations. In a January 31, 2008 decision, the special master denied petitioner entitlement to Vaccine Act compensation. Presently before the court is petitioner's motion for review of the special master's decision. For the reasons set forth below, the court sustains the special master's decision.

I. BACKGROUND

A. Factual History

[1] Vaccine Rule 18, found in Appendix B of the Rules of the United States Court of Federal Claims, affords each party fourteen days in which to object to the disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy." Neither party objected to the public disclosure of any information contained in this opinion.

Petitioner Jay Nussman was born on August 17, 1978.[2] Ex. 22 at ¶ 1. Aside from the normal childhood illnesses and injuries, petitioner suffered from hand tremors beginning no later than age ten, Ex. 3 at 1, and underwent psychotherapy between October 1991 and June 1992, Ex. 1 at 2. Petitioner's mother had a history of poliomyelitis, depression, and thyroid cancer, while petitioner's father had a history of "major motor or grand mal seizures." Id. Further, both of petitioner's grandmothers had a history of psychiatric disorders. Id.

Academically, in grades four through six, petitioner was a good student, receiving mostly As and Bs in his classes. Ex. 25 at 3-7. During this time, he participated in his school's Academically Talented Program. Ex. 21 at ¶ 3. Standardized testing placed petitioner between the ninetieth to ninety-ninth percentile nationally in most subject areas in the fourth grade, while in the fifth and sixth grades petitioner scored between the seventy-second to ninety-ninth percentiles in most areas. Ex. 25 at 8-10. According to an educational evaluation performed in March 1993, petitioner began to have difficulty with his school work in the sixth grade, with organization highlighted as a problem. Ex. 23 at 2. However, in the seventh grade, which spanned from 1991 to 1992, petitioner again received mostly As and Bs in his classes. Ex. 25 at 13.

Petitioner received a hepatitis B vaccination on December 10, 1992.[3] Ex. 1 at 2; Ex. 21 at ¶ 5. Forty-one days later, on January 20, 1993, while returning to New Jersey from a trip to Washington, DC, petitioner experienced an episode of confusion. Ex. 9 at 12; Ex. 21 at ¶ 5.

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[2] The facts are derived from petitioner's exhibits ("Ex.") and the transcript of the July 19, 2007 hearing ("July Tr.").

[3] As the special master noted in his decision, petitioner did not provide a contemporaneous record of his hepatitis B vaccination. Nussman v. Sec'y of HHS, No. 99-500V, 2008 WL 449656, at *2 (Fed. Cl. Spec. Mstr. Jan. 31, 2008). Petitioners are required to submit with their petition, among other items, "supporting documentation" that the injured person "received a vaccine set forth in the Vaccine Injury Table," or a statement indicating that such documentation is "unavailable to the petitioner and the reasons for their unavailability." 42 U.S.C. § 300aa-11(c). Although petitioner's counsel averred in the July 26, 1999 petition that "counsel hereby affirms that he is in the process of obtaining the medical records to be filed," Pet. ¶ 4, a copy of the vaccination record–a key record in Vaccine Act cases–was not requested from petitioner's pediatrician until 2004, about five years after he filed the petition and more than two years after petitioner's pediatrician was required to have kept a copy of the record pursuant to New Jersey law, Nussman, 2008 WL 449656, at *2. However, the special master found, and the court agrees, that there is a preponderance of evidence that petitioner received a hepatitis B vaccination on December 10, 1992. See id. Further, respondent does not contest this finding. See Resp't Posthr'g Br. 24 ("[W]hile it would be preferable to have an actual vaccination record to establish the dates of immunization, respondent is satisfied in this case that the vaccination history submitted by petitioner is sufficient to prove, at least by a preponderance of the evidence, that petitioner's first Hep B vaccine occurred on December 10, 1992 . . . .").

Petitioner's memories from this trip remain "fuzzy." Ex. 22 at ¶ 4. According to his mother, petitioner "entered the car confused." Ex. 21 at ¶ 5. He then "shut his eyes for twenty minutes" and when he woke up, "he asked . . . where he was" and "appeared to have lost his memory of the entire trip to Washington DC." Id. Petitioner then became upset and his nose began to bleed. Id. ¶ 6.

Petitioner's parents immediately took him to the emergency room at Laurel Regional Hospital in Laurel, Maryland. Id.; Ex. 9 at 11-14; Ex. 22 at ¶ 4. The emergency room physician diagnosed petitioner with "confusion of unknown etiology" and discharged him with instructions to follow up with his pediatrician the next day. Ex. 9 at 12, 14. Petitioner's pediatrician recommended that petitioner see a pediatric neurologist, and specifically recommended Arnold P. Gold, M.D. Ex. 21 at ¶ 7. Dr. Gold's first available appointment was not until the middle of February, so, in the meantime, petitioner's parents took petitioner to see another pediatric neurologist–Joseph Schneider, M.D.[4] Id. According to petitioner's mother, Dr. Schneider's impression was "seizure-manifestation." Id.

Petitioner was seen by Dr. Gold on February 17, 1993. Ex. 2 at 1-4. Upon completing his physical examination, Dr. Gold concluded that petitioner "showed no evidence of a neurologic deficit . . . ." Id. at 3. Dr. Gold indicated that petitioner's January 20, 1993 episode "could describe a partial seizure or might be of psychogenic etiology." Id. Dr. Gold then noted that two days prior to the appointment, petitioner underwent an electroencephalogram ("EEG"), the results of which were mildly abnormal and could have been consistent with a partial seizure disorder. Id. at 4, 16, 19. Thus, given petitioner's January 20, 1993 episode and the EEG results, Dr. Gold recommended that petitioner have a magnetic resonance imaging ("MRI") scan of his brain. Id. at 4. In addition, Dr. Gold recommended that petitioner "be followed without any maintenance anticonvulsant," which should "only be considered in the event of subsequent spells." Id. Petitioner underwent the MRI scan on February 19, 1993, the results of which were "completely normal." Id. at 19. Dr. Gold apparently related the MRI results to petitioner's mother, who indicated to Dr. Gold that she "planned to obtain a formal psychoeducational evaluation [of] her son." Id.

Based on his parents' concerns about his "general memory lapses in and out of school, as well as in academic tasks involving memory" and "declining grades," petitioner underwent an educational evaluation in March 1993. Ex. 23 at 2-7; see also Ex. 21 at ¶ 8 (describing petitioner's increasing difficulty with his Algebra and Spanish classes). The evaluator concluded: "Current educational testing shows [petitioner] to be performing within the average range of academic functioning with definite weaknesses in the areas of written language and his ability to work quickly while processing all the information needed." Ex. 23 at 7. Also in March

[4] Dr. Gold offered a different description of the referral process in his contemporaneous record. Dr. Gold indicated that petitioner's pediatrician referred petitioner to Dr. Schneider, and that further consultation with Harvey White, M.D., resulted in the referral to Dr. Gold. Ex. 2 at 1.

1993, petitioner took the New Jersey Grade 8 Early Warning Test. Ex. 25 at 57. He scored within the highest proficiency level in reading and mathematics, and one point outside the highest proficiency level in writing. Id. Petitioner ultimately received three As, four Bs, and five Cs in his eighth grade classes, with two of the Cs being in "Math 8" and "Spanish 8." Id. at 13.

Petitioner received another hepatitis B vaccination on April 1, 1993.[5] Ex. 1 at 2; see also Ex. 29 at ¶ 1 (indicating, in a supplemental affidavit prepared by petitioner's mother on May 9, 2007, that the vaccination must have occurred on Thursday, April 1, 1993, because the appointment was at the end of the week and petitioner's pediatrician did not see patients on Fridays). But see Ex. 14 at 3 (indicating, in a report prepared by Peter M. Crain, M.D. on November 13, 2004, that petitioner received his second hepatitis B vaccination on Sunday, April 4, 1993). Subsequently, not more than three days after the vaccination, petitioner had a second episode that petitioner's mother labeled a "seizure."[6] Ex. 21 at ¶ 9. Petitioner's mother learned

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[5] As with the December 10, 1992 hepatitis B vaccination, petitioner did not submit a contemporaneous record of the April 1, 1993 hepatitis B vaccination. However, the special master found, and the court agrees, that there is a preponderance of evidence that petitioner received a hepatitis B vaccination on April 1, 1993. See Nussman, 2008 WL 449656, at *4. Further, respondent does not contest this finding. See Resp't Posthr'g Br. 24 ("[W]hile it would be preferable to have an actual vaccination record to establish the dates of immunization, respondent is satisfied in this case that the vaccination history submitted by petitioner is sufficient to prove, at least by a preponderance of the evidence, that petitioner's . . . second Hep B vaccine occurred on April 1, 1993.").

[6] The date of this second episode is not clear from the records. In her first affidavit, signed on December 18, 2006, petitioner's mother indicated that the episode occurred three days after the vaccination (i.e., April 4, 1993), Ex. 21 at ¶ 9, but in her second affidavit, signed on May 9, 2007, she indicated that the episode occurred during the weekend following the vaccination (i.e., April 3 or April 4, 1993), Ex. 29 at ¶ 1. Further, in a report prepared on March 14, 1997, neurologist Poorvi Patel, M.D. wrote that petitioner's mother asserted that the second episode occurred the day after the second vaccination. Ex. 3 at 1-2. Because petitioner's mother telephoned Dr. Gold on April 4, 1993, to report the seizure, July Tr. 239, and because Dr. Gold did not prescribe an anticonvulsant until April 5, 1993, Ex. 28 at 5; Ex. 30 at 1, the only probable dates for the second episode are April 2, April 3, or April 4, 1993. The special master concluded that the episode occurred on April 4, 1993. Nussman, 2008 WL 449656, at *4-5. Although respondent argued in its posthearing brief that petitioner had not proven by a preponderance of evidence the precise date of the second episode, Resp't Posthr'g Br. 24-25, respondent did not contest the special master's finding in its response to petitioner's motion for review, Resp't Mem. Resp. Pet'r Mot. Review ("Resp.") 3 ("Three days later, on April 4, 1993, petitioner experienced an event at a friend's house . . . .), 14-17 (discussing the three-day temporal relationship between the second hepatitis B vaccination and the second episode). For the purposes of this decision, it is immaterial whether this second episode occurred on April 2, April 3, or April 4, 1993.

from a friend of petitioner, Andy, that while petitioner was at Andy's house, he blacked out and vomited.[7] Id. Petitioner has no independent recollection of either event. Id.; Ex. 22 at ¶ 7; July Tr. 189-91, 202. Petitioner's mother telephoned Dr. Gold on April 4, 1993, to report the episode.[8] July Tr. 239.

As a result of petitioner's second episode, Dr. Gold prescribed the anticonvulsant Tegretol on April 5, 1993. Ex. 28 at 5; Ex. 30 at 1. On April 22, 1993, petitioner underwent another MRI scan of his brain, which revealed normal findings for an adolescent male. Ex. 2 at 7, 14. Then, either on May 5 or May 7, 1993, petitioner returned to see Dr. Gold. See id. at 7 (May 7, 1993); Ex. 28 at 15 (May 5, 1993). Dr. Gold noted petitioner's recent academic difficulties, about which a Child Study Team had been convened, and recommended a program of psychotherapy. Ex. 2 at 7; Ex. 28 at 15. In addition, Dr. Gold adjusted petitioner's Tegretol dosage, described his plan to maintain petitioner on Tegretol until age sixteen, and indicated his intent to repeat an MRI scan in six to nine months and an EEG in one year. Ex. 2 at 7; Ex. 28 at 15.

On May 21, 1993, the Child Study Team classified petitioner as "perceptually impaired" and adopted an Individualized Education Program to begin the next school year. Ex. 21 at ¶ 10; Ex. 23 at 13; Ex. 25 at 47-51. Then, as recommended by Dr. Gold, petitioner underwent a third MRI scan on December 27, 1993, which revealed a "[s]light asymmetry of the temporal horns and the lateral ventricle." Ex. 2 at 14; accord Ex. 28 at 47. In a January 21, 1994 letter to

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[7] Andy did not provide an affidavit or testify at hearing. Nussman, 2008 WL 449656, at *10. However, special masters are not constrained by the Federal Rules of Evidence, 42 U.S.C. § 300aa-12(d)(2)(B); Vaccine Rule 8(c), such as the hearsay rule enunciated in Federal Rule 802. The special master in this case found the testimony of petitioner's mother to be credible, Nussman, 2008 WL 449656, at *11, and the court will not overturn the special master's credibility determination. See Pafford v. Sec'y of HHS, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (noting that the United States Court of Appeals for the Federal Circuit ("Federal Circuit") "accords great deference to a Special Master's determination on the probative value of evidence and the credibility of witnesses"); Lampe v. Sec'y of HHS, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (reaffirming that "'the probative value of the evidence'" and "'the credibility of the witnesses'" are "'matters within the purview of the fact finder'" (quoting Munn v. Sec'y of HHS, 970 F.2d 863, 871 (Fed. Cir. 1992))).

[8] Dr. Gold indicated in a March 15, 2007 typewritten letter that one of petitioner's parents telephoned him on April 3, 1993, to report a "second seizure." Ex. 28 at 53. As noted by the special master, "[t]his letter holds relatively little persuasive value." Nussman, 2008 WL 449656, at *5 n.4. First, the letter was written in 2007, approximately fourteen years after the events at issue. Id.; Ex. 28 at 53. In addition, the letter is not supported by Dr. Gold's handwritten notes, and there is no other indication how Dr. Gold refreshed his recollection. Nussman, 2008 WL 449656, at *5 n.4; Ex. 28 at 53.

petitioner's pediatrician, Dr. Gold indicated that petitioner should next "be evaluated electrically and clinically in May 1994." Ex. 28 at 47.

Petitioner returned to see Dr. Gold on April 1 or April 2, 1994, for his "previously described seizure disorder." See Ex. 2 at 5-6 (April 2, 1994); Ex. 28 at 14 (April 1, 1994). Dr. Gold reported that petitioner remained free of seizures and that he planned to maintain petitioner on Tegretol and order supplementary studies. Ex. 2 at 5-6. Dr. Gold contemplated "decreasing and discontinuing the Tegretol . . . after the summer vacation period." Id. at 6. In addition, Dr. Gold wrote: "Relative to seizures[, petitioner]'s father believes that they are related to the hepatitis B vaccination in that the initial seizure occurred three weeks after the first immunization and the second seizure four days after the second vaccination. This time sequence would be highly atypical for a vaccinal encephalopathy." Id. Notably, Dr. Gold's record of (1) petitioner's father's suggestion of a causal relationship between the hepatitis B vaccinations and petitioner's episodes and (2) his own opinion regarding the suggestion constitute the first mention of such a possibility in the medical records.

Dr. Gold also commented on petitioner's academic progress in his April 1994 report. Id. at 5. Dr. Gold noted that petitioner received collaborative instruction in English and social studies and that petitioner was in an advanced biology class. Id.; see also Ex. 22 at 8 (noting, in petitioner's affidavit, that petitioner was "classified as being a Special Education Student in high school," which meant he could participate in collaborative classes). Petitioner was on the honor roll in "the first marking period" but had "difficulties in the second marking period." Ex. 2 at 5; cf. Ex. 31 at 7 (indicating petitioner's final grades for each year in high school as mostly As and Bs, with one C in his sophomore year and three Cs in his senior year). Dr. Gold also indicated that petitioner was undergoing successful psychotherapy in weekly sessions. Ex. 2 at 5; see also Ex. 22 at 8 (noting, in petitioner's affidavit, that petitioner was seeing "a psychologist weekly to work through [his] anxiety and anger").

Petitioner had another EEG on April 28, 1994. Ex. 28 at 44-45. In a May 6, 1994 letter to petitioner's pediatrician, Dr. Gold wrote that while there was "intermittent generalized rhythmical slowing . . . , there were no definitive epileptiform discharges observed." Id. at 44. Dr. Gold concluded that "there was no evidence of a seizure disorder with only mild nonspecific abnormalities of questionable significance." Id. Dr. Gold relayed this information, presumably to petitioner's parents, during a May 31, 1994 telephone call. Id. at 13. During the same telephone call, Dr. Gold reiterated his plan to decrease and ultimately discontinue petitioner's use of Tegretol after the summer vacation. Id. Although not contemporaneously noted in the medical records, Dr. Gold did begin to taper petitioner's Tegretol dosage. See id. at 39; Ex. 2 at 11. At mid-dosage, on October 29, 2004, petitioner underwent another EEG, which was "very mildly abnormal due to rhythmical generalized slowing[,] but at no time were there epileptiform discharges." Ex. 2 at 11; accord Ex. 28 at 39, 41. Thus, Dr. Gold recommended a continuation of the Tegretol tapering, with a repeat EEG to be done one month after the Tegretol had been discontinued. Ex. 28 at 39.

Petitioner stopped taking Tegretol on December 5, 1994. Ex. 2 at 11. Petitioner asserts that the next day, he felt dizzy and faint in gym class, but did not pass out. Ex. 22 at ¶ 8; see also Ex. 21 at ¶ 11 (indicating, in an affidavit prepared by petitioner's mother, that petitioner "had another seizure" on December 6, 1994). In addition, petitioner reported that upon the discontinuation of the Tegretol, he began to have impulses to hit a wall or the bed, a feeling petitioner recalled experiencing "prior to a seizure." Ex. 2 at 11; accord Ex. 28 at 13. Further, petitioner experienced surges of energy that he could not relieve. Ex. 2 at 11; Ex. 28 at 13. In a December 9, 1994 telephone conversation with petitioner's mother, Dr. Gold suggested that petitioner's impulses were an anxiety reaction. Ex. 2 at 11; Ex. 28 at 13. Subsequently, on December 17, 1994, petitioner underwent another EEG, which recorded "2 single spike and slow wave complexes in generalized distribution during drowsiness," which "had a duration of less than 1 second and were not associated with any clinical change." Ex. 2 at 11; accord id. at 17.

Based upon petitioner's history and the EEG results, Dr. Gold opted to restart petitioner on Tegretol on December 17, 1994. Ex. 2 at 11; Ex. 28 at 13. During a December 31, 1994 physical examination, Dr. Gold found petitioner to be within normal neurological limits. Ex. 2 at 11. Dr. Gold also noted that petitioner had not had any "spells" since restarting the Tegretol. Id. Thus, Dr. Gold opted to maintain the current Tegretol regimen, but suggested that a placebo trial might be appropriate in the future. Id. at 11-12. Dr. Gold recommended further evaluation in April 1995. Id. at 12.

Dr. Gold continued to treat petitioner through at least October 1999. See Ex. 28 at 10-11 (containing Dr. Gold's handwritten notes of telephone conversations with petitioner and petitioner's mother in October 1999). Petitioner has also been seen by other physicians since December 1994. For example, petitioner saw Dr. Patel on March 14, 1997, for his hand tremors. Ex. 3 at 1. Of note in Dr. Patel's report of the examination is the following passage:

> The exact etiology of partial complex seizure is unclear to me. There is family history of seizures in his father. The mother has done extensive research to ascertain if [petitioner]'s seizures are secondary to Hepatitis B vaccine. No information to support this is available to me at this time.

Id. at 4.

Having graduated from the School of Visual Arts at Syracuse University, petitioner presently works as a graphic designer. Ex. 22 at ¶ 8. Petitioner continues to have "difficulty remembering information, direction, details, [and] names . . . ." Id. In addition, petitioner continues to take Tegretol and see a neurologist and a psychologist. Id.

B. Procedural History

Petitioner filed his petition for compensation on July 26, 1999. As noted by the special master, "[a]fter the petition was filed, the case moved slowly." Nussman, 2008 WL 449656, at

*7. The reasons for the slow pace of the proceedings are clearly detailed by the special master and need not be repeated here. See id. at *7-8. Eventually, both parties submitted expert reports from pediatric neurologists–Marcel Kinsbourne, M.D. for petitioner and S. Robert Snodgrass, M.D. for respondent–and hearings were conducted on March 2 and July 19, 2007. Id. The special master issued his ruling on January 31, 2008, denying petitioner's claim for compensation. Id. at *19. Specifically, the special master concluded that a preponderance of evidence showed that (1) petitioner did not fit within the "challenge-rechallenge" paradigm because petitioner did not experience adverse reactions to either hepatitis B vaccination, id. at *9; and (2) there was a medical theory–a delayed hypersensitivity reaction–causally connecting the vaccinations and petitioner's episodes, id. at *12-13. However, the special master found that petitioner failed to prove by a preponderance of evidence that (1) there existed a logical sequence of cause and effect connecting the hepatitis B vaccinations to petitioner's episodes, id. at *13-14; and (2) petitioner's episodes occurred within a medically acceptable period of time postvaccination, id. at *14-17. Petitioner filed a motion for review on March 3, 2008, to which respondent responded on April 2, 2008. The court heard argument on July 2, 2008, and the case is now ripe for decision.

II. DISCUSSION

The United States Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master, and upon such review, may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). In the instant case, petitioner enumerates, pursuant to Vaccine Rule 24, three objections to the special master's decision. First, petitioner asserts that the special master held him to an elevated burden of proof by requiring him to prove that his case fit within the challenge-rechallenge paradigm, contrary to the decision of the Federal Circuit in Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Mot. Review ("Mot.") 2. Second, petitioner contends that by virtue of the special master's findings, he has proven causation pursuant to Althen. Id. Third, petitioner argues that the special master improperly discussed the extent of the sequelae of his injury. Id. The court discusses petitioner's first two objections together, and then addresses petitioner's third objection.

A. Proving Causation Under the Vaccine Act

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if petitioner proves, by a preponderance of evidence, all of the elements set forth in 42 U.S.C. § 300aa-11(c)(1) and that the illness is not due to factors unrelated to the administration of the vaccine.[9] A petitioner in the Vaccine Program can recover in one of two ways: either by proving an injury listed on the Table or by proving causation-in-fact. See 42 U.S.C. §§ 300aa-11(c)(1)(C), -13(a)(1). In this case, petitioner did not attempt to prove a Table injury because even though the hepatitis B vaccine is listed on the Table, petitioner's alleged injuries are not. Thus, petitioner proceeded on a causation-in-fact theory.

In Althen, the Federal Circuit articulated a three-part test, based on prior precedent, explaining what a petitioner must show to prove causation-in-fact under the Vaccine Act:

> [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.

418 F.3d 1278. The first prong seeks to demonstrate whether "'the vaccine(s) at issue cause the type of injury alleged.'" Pafford, 451 F.3d at 1355-56 (quoting the decision of the special master as recited by the trial court). The second prong requires a petitioner to show "that the vaccine was the 'but for' cause of the harm," id. at 1356, or, in other words, "'that the vaccine actually caused the alleged symptoms in [the] particular case,'" id. (quoting the decision of the special master as recited by the trial court). Although probative, proof of the third prong is insufficient to prove causation. Althen, 418 F.3d at 1278.

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[9] Subsection (c)(1) requires, among other things, that the following elements be satisfied: (1) that the vaccine in question is set forth in the Vaccine Injury Table ("Table"); (2) that the vaccine was received in the United States or in its trust territories; (3) that the injured person either sustained an injury as a result of the administration of a Table-designated vaccine for a period of more than six months after the administration of the vaccine, suffered illness, disability, injury, or condition from the vaccine that resulted in inpatient hospitalization and surgical intervention, or died from the administration of the vaccine; and (4) that the petitioner has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury or death. 42 U.S.C. § 300aa-11(c)(1).

1. The Court Finds No Error in the Special Master's Conclusion That Petitioner Established the First Althen Prong–"A Medical Theory Causally Connecting the Vaccination and the Injury"

Petitioner offered the expert opinion and testimony of Dr. Kinsbourne to supply a medical theory that explained how the hepatitis B vaccination could cause seizure disorders. See generally Ex. 20 (expert report); Hr'g Tr. 11-89, 148-49, Mar. 2, 2007 ("Mar. Tr.") (testimony). In his report, Dr. Kinsbourne posited both that the hepatitis B vaccine could cause serum sickness, which in turn could cause seizures, and that the hepatitis B vaccine could cause small vessel vasculitis of the brain, which also could cause seizures. Ex. 20 at 4. These were the only theories proffered by Dr. Kinsbourne in his report explaining how the hepatitis B vaccine could cause a seizure. However, at hearing, Dr. Kinsbourne explained that he only offered those theories to support the biological plausibility that the hepatitis B vaccine could cause a seizure, and did not believe that either mechanism applied to petitioner. Mar. Tr. 42-44. Specifically, Dr. Kinsbourne agreed that petitioner "probably" did not suffer from "a serum sickness-type illness based on the fact that [petitioner] didn't experience any of the symptoms that one would expect to see with serum sickness," id. at 52, and confirmed that no objective tests, such as an MRI scan, showed any inflammation of the blood vessels around petitioner's brain, id. at 53-55. It was not until he was being cross-examined at hearing by respondent's attorney that Dr. Kinsbourne raised the possibility of a delayed hypersensitivity reaction. Id. at 49-52. Dr. Kinsbourne explained that there were four types of hypersensitivity reactions, and that based solely on the timing of petitioner's first vaccination and episode, petitioner experienced a "type IV" delayed hypersensitivity reaction, "which is the hypersensitivity that can take weeks and weeks to evolve." Id. at 50.

The special master found Dr. Kinsbourne's evidence regarding a possible medical theory to be both "weak[]" and "flaw[ed]." Nussman, 2008 WL 449656, at *13. Specifically, the special master explained:

> In Dr. Kinsbourne's report, he identified two other theories, an immune complex disease causing serum sickness and an immune complex disease causing vasculitis. Dr. Kinsbourne supplied literature to buttress his opinion and to show his theory that the hepatitis B vaccine can cause a seizure disorder was biologically plausible. After Dr. Kinsbourne withdrew these theories, the relevance of these articles decreased greatly. [Petitioner] did not offer any supplemental exhibits discussing hepatitis B vaccine causing a delayed hypersensitivity reaction following Dr. Kinsbourne's testimony.
>
> It should be noted that Dr. Kinsbourne backed away from the two theories identified in his own report. Dr. Kinsbourne's resort to a third choice suggests a lack of critical thinking in his report and calls into question the accuracy of his theory. If delayed hypersensitivity were a theory that scientists were exploring to explain an alleged association between the hepatitis B vaccine and seizures, then

> Dr. Kinsbourne would probably have presented this theory in his report and discussed it prominently.

Id. (citations omitted). The special master found that "[t]hese flaws diminish[ed] Dr. Kinsbourne's persuasiveness," which the special master would take into account when evaluating the remainder of Dr. Kinsbourne's evidence. Id.

The weakness of Dr. Kinsbourne's evidence notwithstanding, the special master concluded that petitioner satisfied the first prong of Althen. Respondent's expert, Dr. Snodgrass, opined that while it was "possible" for a hepatitis B vaccination to cause a delayed hypersensitivity reaction, which might manifest as a seizure, he did not find it that it was "likely" or "probable" in this case. Mar. Tr. 107, 124. As noted by the special master, a petitioner is not required to prove the proffered medical theory. Nussman, 2008 WL 449656, at *13 (citing Knudsen ex rel. Knudsen v. Sec'y of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994)). Thus, based upon the testimony of Dr. Kinsbourne and Dr. Snodgrass, the special master concluded that petitioner had established, by a preponderance of evidence, a medical theory that could explain how the hepatitis B vaccine could cause petitioner's episodes. Id. Neither party challenges the special master's conclusion, and the court does not find the conclusion "to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

2. The Court Finds No Error in the Special Master's Conclusion That Petitioner Did Not Establish the Second Althen Prong–"A Logical Sequence of Cause and Effect Showing That the Vaccination Was the Reason for the Injury"

The special master found that petitioner failed to establish, by a preponderance of evidence, a logical sequence of cause and effect linking the hepatitis B vaccinations to his two episodes, and identified two reasons for the failure. Id. First, the special master held that petitioner had not proven that his case was one of challenge-rechallenge, the theory proposed by Dr. Kinsbourne to explain how the hepatitis B vaccinations did cause petitioner's episodes. Id. Second, the special master noted that petitioner's treating physician, Dr. Gold, did not believe that the vaccinations caused petitioner's episodes. Id. The court addresses each basis for the special master's conclusion in turn.

a. The Court Finds No Error in the Special Master's Conclusion That Petitioner Did Not Establish That Petitioner Fit Within the Challenge-Rechallenge Paradigm

The special master explained that "[c]hallenge-rechallenge happens when a person (1) is exposed to one antigen, (2) reacts to that antigen in a particular way, (3) is given the same antigen again, and (4) reacts to that antigen similarly." Id. at *9. Typically, the second reaction is faster and more severe. Id. (citing Mar. Tr. 104); Mar. Tr. 88, 122. As the special master noted throughout his decision, petitioner, through Dr. Kinsbourne, relied heavily on the proposition that petitioner fit within the challenge-rechallenge paradigm. See Nussman, 2008 WL 449656, at *9 ("The primary, if not exclusive, support for Dr. Kinsbourne's opinion is that

[petitioner]'s case fits a model known as challenge-rechallenge."), *13 ("[C]hallenge-rechallenge . . . is the primary (if not sole) reason offered in support of his claim."), *14 ("Dr. Kinsbourne relies almost exclusively upon [petitioner]'s presentation as an example of challenge-rechallenge."), *19 ("At its core, the question is whether [petitioner]'s case fits within the challenge-rechallenge paradigm."). Such reliance was evident in Dr. Kinsbourne's testimony. See Mar. Tr. 23 (noting that the timing of the second episode "enable[d] me to testify to a causal relationship between the vaccine and the seizures"), 23-24 (indicating that petitioner's second episode "puts the clinical picture into the context of the challenge/rechallenge phenomenon, and that is really the basis on which I make my causation opinion"), 44 (asserting that "[i]n [petitioner's] case, my evidence is the challenge/rechallenge"), 57 (noting that he was "relying on rechallenge").

With respect to petitioner's first episode, which occurred forty-one days postvaccination, the special master found that petitioner "provided little persuasive evidence that he had an adverse reaction when 'challenged' by the first dose of the hepatitis B vaccine." Nussman, 2008 WL 449656, at *10. The special master explained that although Dr. Kinsbourne testified that an immune-mediated neurological "reaction would manifest between 5 and 42 days," id. (citing Mar. Tr. 22, 46), he "provided little basis for his estimate that an adverse reaction to the hepatitis B vaccine could take as long as 42 days," id. (citing Mar. Tr. 45-47). Thus, the special master concluded that petitioner had not shown, by a preponderance of evidence, that petitioner "suffer[ed] from an adverse reaction from" the December 10, 1992 hepatitis B vaccination. Id.

The special master found the evidence presented in support of rechallenge "even less persuasive." Id. First, petitioner's second episode occurred no more than three days postvaccination. See supra note 6. As noted by the special master, a three-day interval between vaccination and injury "falls outside the temporal window estimated by Dr. Kinsbourne." Nussman, 2008 WL 449656, at *11. Although the special master indicated that "because [petitioner]'s alleged adverse response is to his second exposure to the hepatitis B vaccine, it is conceivable that his response could have been somewhat quicker," the special master concluded:

> [A] quicker response should be close to the previous response. If [petitioner]'s body followed the same immune process after receiving both the first and second doses, then the second reaction would have taken approximately the same amount of time. Although the second reaction may be faster, the second reaction should not be 13 times quicker. The great discrepancy between the timing of the two events suggests that [petitioner] did not have the same reaction.

Id.

The court finds no error in the special master's conclusion that petitioner did not adversely react to the December 10, 1992 vaccination. The special master found petitioner's evidence on this point to be minimal, and the court agrees. Furthermore, petitioner does not challenge this conclusion. See Mot. 8 ("For the purposes of this motion for review, Petitioner

will assume that 42 days is too long and that whatever happened after the first dose of vaccine was a different event and had nothing to do with vaccines."[10]). On the other hand, the court finds that the special master's rationale for finding that petitioner did not have an adverse reaction to the April 1, 1993 vaccination was arbitrary. In so finding, the court is not ruling that petitioner suffered from an adverse reaction to the April 1, 1993 vaccination because, as explained in the next paragraph, such a ruling would be of no import given petitioner's failure to prove an initial challenge and associated adverse reaction. Instead, the court is merely noting that the special master did not cite, and the court could not locate, any support from any medical record, expert report, expert testimony, or medical literature for the propositions that (1) a second reaction should take "approximately the same amount of time" as the initial reaction or (2) a second reaction cannot occur thirteen times as fast as the first reaction.[11] The special master may be correct on these points, but the conclusions should be supported by the evidence in the record.

However, the special master's error is of little consequence to his ultimate finding that petitioner does not fit the challenge-rechallenge model. There can only be rechallenge if there was an initial challenge and associated adverse reaction. See Nussman, 2008 WL 449656, at *9. Because the court upholds the special master's determination that petitioner has not proven by a preponderance of evidence that petitioner adversely reacted to the December 10, 1992 vaccine, the issue of the existence of rechallenge is moot.

Furthermore, the objection raised by petitioner to the special master's focus on the challenge-rechallenge model lacks merit. Petitioner argues that the special master required him to prove that he fit within the challenge-rechallenge paradigm, which would improperly elevate petitioner's burden of proof. Mot. 5-9. Specifically, petitioner asserts:

> No case in the program has ever required that Petitioner demonstrate "challenge-rechallenge." Such a requirement would be an absurdity, particularly for someone who has an obvious reaction to one vaccination. No one would suggest that, in order to prevail in the program, the person should be required to get another vaccination in order to demonstrate "challenge-rechallenge." And yet the Special Master's decision is clearly based, almost entirely, upon a failure to fit this case "within the challenge-rechallenge paradigm."

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[10] The court notes that "42" is a typographical error. In the previous paragraph, petitioner asserted that the special master "determined that the onset was 42 days." Mot. 8. However, the special master actually determined that onset was at forty-one days postvaccination. See Nussman, 2008 WL 449656, at *10 ("[Petitioner]'s blackout (or seizure) happened 41 days after he received the vaccination.").

[11] While there was preponderant evidence that the second reaction in the challenge-rechallenge model generally occurs faster than the first reaction, it appears that neither party presented evidence regarding how much faster the second reaction would occur.

Id. at 5. Despite petitioner's charges, the court is unable to discern where in his decision that the special master "required" petitioner to demonstrate "challenge-rechallenge" as a condition for receiving compensation. As explained below, petitioner's assignment of error is wholly unfounded.

First, the challenge-rechallenge model was proffered by petitioner as evidence that the hepatitis B vaccinations did cause his episodes, i.e., that there was a logical sequence of cause and effect connecting the vaccinations and the episodes. Indeed, at hearing, Dr. Kinsbourne repeatedly stated that his theory of causation was dependant on the existence of a challenge and rechallenge. See Mar. Tr. 23 (noting that the timing of the second episode "enable[d] me to testify to a causal relationship between the vaccine and the seizures"), 23-24 (indicating that petitioner's second episode "puts the clinical picture into the context of the challenge/rechallenge phenomenon, and that is really the basis on which I make my causation opinion"), 44 (asserting that "[i]n [petitioner's] case, my evidence is the challenge/rechallenge"), 57 (noting that he was "relying on rechallenge"). As the foregoing citations to Dr. Kinsbourne's testimony demonstrate, it was petitioner, and not the special master, who placed such heavy emphasis on the challenge-rechallenge paradigm.

Second, petitioner's argument is unavailing because he conflates the first two prongs of the Althen analysis. In his motion, petitioner contends:

> While [evidence of challenge-rechallenge] was the evidence that Petitioner was hoping the Special Master would accept in support of there being a medical theory causally connecting the hepatitis B vaccination with a seizure disorder, such evidence proved not to be necessary, since, as the Special Master pointed out, a medical theory WAS proven, albeit with the assistance of respondent's counsel and respondent's expert.

Mot. 7. In fact, the medical theory accepted by the special master–a delayed hypersensitivity reaction–satisfied only the first prong of Althen. Petitioner remained obligated to establish Althen's second prong, see Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1327 (Fed. Cir. 2006) (noting that Althen's second prong "is not without meaning"), and he thus offered the challenge-rechallenge model to make the required showing. Proof of a medical theory explaining how a vaccine could cause an injury is analytically distinct from proof that a vaccine actually did cause the injury.

Ultimately, petitioner was required to establish the second prong of Althen–that there was a logical sequence of cause and effect linking the hepatitis B vaccinations to his two episodes. Thus, it was well within the special master's discretion to fully consider the challenge-rechallenge model proposed by petitioner to demonstrate the logical sequence of cause and effect. The court finds no error in the special master's analysis of petitioner's proposed challenge-rechallenge model.

b. The Court Finds No Error in the Special Master's Consideration of Dr. Gold's Records in Considering Whether the Hepatitis B Vaccinations Caused Petitioner's Episodes

Because petitioner was unable to establish the second Althen prong using the challenge-rechallenge model, it was necessary for him to find an another means to demonstrate the logical sequence of cause and effect connecting the hepatitis B vaccinations to his episodes. Petitioner opted not to present any additional expert testimony on causation, so the special master looked to the records of petitioner's treating neurologist–Dr. Gold. See Nussman, 2008 WL 449656, at *14. As the binding precedent of the Federal Circuit makes abundantly clear, the medical records and medical opinion of treating physicians are valuable in vaccine cases because "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). Thus, the special master was well within his discretion to evaluate Dr. Gold's position.

From February 1993, when Dr. Gold began treating petitioner, until early 1994, there is no mention in any of Dr. Gold's records that either he, petitioner, or petitioner's parents linked petitioner's episodes to the hepatitis B vaccinations. In fact, it was not until April 1994 that the hepatitis B vaccinations were mentioned, and only because the issue had been raised by petitioner's father. See Ex. 2 at 6 ("Relative to seizures[, petitioner]'s father believes that they are related to the hepatitis B vaccination in that the initial seizure occurred three weeks after the first immunization and the second seizure four days after the second vaccination."). Significantly, Dr. Gold dismissed such a relationship, writing: "This time sequence would be highly atypical for a vaccinal encephalopathy." Id. Because petitioner's treating neurologist–the physician in the best position to reach a conclusion about the cause of petitioner's episodes–rejected a causal relationship, the special master was justified in concluding that petitioner had not established Althen's second prong. Moreover, had the special master rejected Dr. Gold's written comment as unpersuasive,[12] petitioner's case would not have improved because he would still lack any evidence of a logical sequence of cause and effect linking the hepatitis B vaccinations to his episodes. Thus, petitioner's contention that the special master should not have relied upon Dr. Gold's conclusion because the basis for his conclusion–that petitioner's first episode occurred three weeks postvaccination–was incorrect, Mot. 7, is of no moment. Petitioner would still be without proof of a logical sequence of cause and effect connecting the hepatitis B vaccinations to his episodes.

[12] Such a finding would have been unlikely because, as the special master noted, both Dr. Kinsbourne and Dr. Snodgrass testified to Dr. Gold's excellent reputation in treating seizure disorders. See Nussman, 2008 WL 449656, at *14 (citing Mar. Tr. 33, 106).

3. The Court Finds No Error in the Special Master's Conclusion That Petitioner Did Not Establish the Third Althen Prong–"A Showing of a Proximate Temporal Relationship Between Vaccination and Injury"

As noted by the special master, petitioner bears the burden of proving, by a preponderance of evidence, a medically appropriate temporal relationship between his hepatitis B vaccinations and his subsequent episodes. See Nussman, 2008 WL 449656, at *14 (citing Pafford, 451 F.3d at 1358); see also Althen, 418 F.3d 1274 (requiring a petitioner to prove a "proximate temporal relationship between vaccination and injury"). Thus, petitioner presented evidence of an appropriate temporal relationship via the report and testimony of Dr. Kinsbourne and certain medical literature relied upon by Dr. Kinsbourne. Nussman, 2008 WL 449656, at *15-16. In his report and testimony, Dr. Kinsbourne indicated that immune-mediated neurological injuries typically occur between five and forty-two days after the first "exposure to the causative agent," Mar. Tr. 22, and that a three-day interval between a second exposure and subsequent injury is consistent with rechallenge, id. at 23-24; Ex. 20 at 4. Dr. Kinsbourne further testified that a delayed hypersensitivity reaction could, in some cases, "take six or eight weeks or two months." Mar. Tr. 52; see also id. at 50 (noting that "delayed hypersensitivity. . . can take weeks and weeks to evolve").

The literature cited by Dr. Kinsbourne included a case report concerning a seizure occurring thirty days after exposure to the wild hepatitis B virus, and not the hepatitis B vaccination; a letter to the editor describing a febrile seizure developing within one hour postvaccination, which due to its timing could not be a delayed hypersensitivity reaction; an article hypothesizing that certain neurological conditions following infection or vaccination by between one and three weeks may occur as a result of a humoral response instead of a delayed hypersensitivity reaction;[13] and a case report and literature review describing thirty-two serum sickness-type reactions, not delayed hypersensitivity reactions, only two of which occurred more than forty-one days postvaccination. See Ex. 19 at 2-12, 20-24, cited in Nussman, 2008 WL 449656, at *15-16 (noting also that the remaining articles provided by Dr. Kinsbourne did "not address the expected temporal sequence when a vaccine causes an adverse reaction").

The special master found none of the literature supplied by Dr. Kinsbourne on petitioner's behalf to be persuasive on the issue of a temporal relationship, because there was very little similarity between the disease processes described in the literature and petitioner's proposed medical theory of a delayed hypersensitivity reaction.[14] Nussman, 2008 WL 449656, at

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[13] As explained by Dr. Snodgrass in his testimony, a humoral response refers to the immune system's production of antibodies in response to the introduction of an antigen, while a delayed hypersensitivity reaction is the immune system's production of T lymphocytes (i.e., T-cells) in response to an antigen. Mar. Tr. 115. The responses are entirely distinct. Id.

[14] The court notes that although petitioner presented medical literature to support his proffered temporal relationship and the special master considered that medical literature,

*15-16. In other words, none of the articles explicitly addressed the appropriate temporal relationship between an injury caused by a delayed hypersensitivity reaction to a hepatitis B vaccination. Thus, the special master gave no weight to any of the literature, with one exception, to which he ascribed "little persuasive weight." Id. at *16. In the absence of persuasive medical literature, the special master was left with only Dr. Kinsbourne's opinion of an appropriate temporal relationship on petitioner's behalf. Id. Further weakening petitioner's evidence, in the eyes of the special master, was Dr. Snodgrass's testimony that there was a "low probability" that a seizure could be caused by a hepatitis B vaccination forty-one days earlier, and that he would instead "be much more interested in something happening on Day 15 or Day 17." Mar. Tr. 111-12.

Based on the expert reports, expert testimony, and medical literature, the special master concluded:

> [T]he record does not support a finding that a delayed hypersensitivity reaction to the first dose of the hepatitis B vaccine would occur as many as 41 days after the receipt of the vaccine. Dr. Kinsbourne was not persuasive on this point for several reasons. He admitted that the precise number of days was not critical to his opinion. Tr. 71. Originally, he miscalculated the number of days between the first dose of the hepatitis B vaccine and the episode on January 20, 1993. Tr. 22, 45. He raised the idea of a possible delayed hypersensitivity reaction during cross-examination only after he withdrew two other possible mechanisms–a serum sickness reaction and a vasculitis. Then, when Dr. Kinsbourne introduced the theory of a delayed hypersensitivity reaction, he stretched the limit from six weeks to eight weeks. Tr. 52. Because Dr. Kinsbourne changed his theory several times, none of the theories he presented on this point are persuasive. Therefore, [petitioner] has failed to meet his burden of presenting persuasive evidence that his seizure occurred within an appropriate time frame.

Nussman, 2008 WL 449656, at *16; see also id. at *14 ("Evidence on the temporal relationship is sparse, but it preponderates in favor of finding that the hepatitis B vaccine, if it caused seizures, would cause seizures within 30 days."). The court finds no error in the special master's conclusion.

Furthermore, as noted above, the special master concluded that although a three-day interval between vaccination and injury "falls outside the temporal window estimated by Dr. Kinsbourne[,] . . . because [petitioner]'s alleged adverse response is to his second exposure to the hepatitis B vaccine, it is conceivable that his response could have been somewhat quicker." Id. at *11 (citing Mar. Tr. 121-22 (containing Dr. Snodgrass's testimony that petitioner's second episode occurred between one and seven days postvaccination); Augustynski v. Sec'y of HHS,

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petitioners are not required to provide or cite medical literature to prove causation. Althen, 418 F.3d at 1279-80.

No. 99-611V, 2007 WL 3033614, at *4-5 (Fed. Cl. Spec. Mstr. Sept. 28, 2007) (concluding that a T-cell response could occur within twenty-four hours of a second hepatitis B vaccination because the petitioner had already been challenged by his first hepatitis B vaccination)). Although the special master ultimately concluded that petitioner did not have an adverse reaction to the April 1, 1993 vaccination, the court has rejected the rationale for that conclusion as unsupported by the record. Thus, the court allows to stand the special master's statement that an adverse response to a second hepatitis B vaccination could occur sooner than five days.

In addition, the court notes that there was evidence presented by Dr. Kinsbourne on the appropriateness of a three-day interval. In his expert report, Dr. Kinsbourne opined: "Coincidence is virtually ruled out by the timing of the second seizure, which occurred three days after the second Hepatitis B vaccination. This time interval is consistent with an accelerated (anamnestic) immune-mediated reaction to an antigen to which the immune system has previously been sensitized." Ex. 20 at 4. Dr. Kinsbourne also testified that with the second episode following the second vaccination by a few days, he was able to opine that there was a causal relationship, based on the challenge-rechallenge model. Mar. Tr. 23-24. Yet, all of the evidence makes it clear that the alleged three-day interval was reasonable only if the second vaccination was a rechallenge.[15] Because the special master found that petitioner did not adversely react to the December 10, 1992 vaccination, it follows that the April 1, 1993 vaccination cannot be a rechallenge pursuant to the definition articulated by the special master, Nussman, 2008 WL 449656, at *9, and, therefore, petitioner has not established by a preponderance of evidence that a three-day interval is an appropriate time period for his alleged reaction to the April 1, 1993 hepatitis B vaccination. To the extent that the special master has reached this conclusion by rejecting petitioner's claim of rechallenge, the court finds no error.

4. Petitioner Has Waived His New Argument Isolating the Second Vaccination From the First Vaccination and, in any Event, Petitioner Cannot Prevail on That Argument

Petitioner has failed to prove, as required by Federal Circuit precedent, that taken together, his hepatitis B vaccinations caused his two episodes.[16] Accordingly, in his motion for

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[15] The special master only briefly referred to the alleged three-day interval outside of the challenge-rechallenge paradigm. First, the special master quoted the definition of "delayed hypersensitivity reaction" from a medical dictionary: "A delayed hypersensitivity reaction is a reaction 'initiated by antigen-specific T lymphocytes; unlike forms of hypersensitivity mediated by antibodies, it takes one or more days to develop.'" Nussman, 2008 WL 449656, at *12 (quoting Dorland's Illustrated Medical Dictionary 888 (30th ed. 2003)). Next, the special master asserted, without citation to the record, that "a delayed hypersensitivity reaction . . . requires at least a few days to develop." Id. at *15. The statements, considered together or in isolation, do not amount to preponderant evidence of a temporal relationship.

[16] Accordingly, the burden did not shift to respondent to prove an alternative cause for petitioner's episodes, as petitioner suggests. See Mot. 11 (noting that because petitioner had met

review, petitioner raises a new argument: that pursuant to statements in the special master's decision, he has proven causation with respect to the April 1, 1993 hepatitis B vaccination and subsequent episode, when examined in isolation from the December 10, 1992 vaccination and January 20, 1993 episode. See Mot. 8 ("[T]he seizure that Petitioner experienced after the second vaccination fits a logical sequence of cause and effect, even according to the Special Master and the respondent's expert."); see also id. at 10 (arguing that because the special master noted that a reaction after being sensitized to a vaccine can occur in one day, petitioner has "describe[d] a logical sequence of cause and effect"). Respondent argues that pursuant to Vaccine Rule 8(f), petitioner has waived this argument. Resp. 16. Vaccine Rule 8(f) provides:

> Any fact or argument not raised specifically in the record before the special master shall be considered waived and cannot be raised by either party in proceedings on review of a special master's decision. This rule shall not apply to legal arguments raised by the party that stands in the role of the appellee on review.

Respondent is correct–petitioner waived its new argument by not raising it before the special master. See also Weddel v. Sec'y of HHS, 23 F.3d 388, 390 n.2 (Fed. Cir. 1994) (noting that "Congress has expressly forbidden" the Federal Circuit from considering two arguments that petitioners did not raise before the special master); Jay v. Sec'y of HHS, 998 F.2d 979, 983 & n.4 (Fed. Cir. 1993) (holding that petitioners had abandoned an argument that they "did not pursue or defend . . . either in their case in chief or on the motions for summary judgment" and that it would not consider a legally complex, alternative argument that was first raised on appeal). However, the court will briefly address the argument for petitioner's benefit.

Initially, the court notes that even if the court found that the alleged three-day interval between the April 1, 1993 vaccination and the subsequent episode was medically appropriate, petitioner has still failed to establish a logical sequence of cause and effect connecting the vaccination and the episode. Obviously, petitioner cannot rely on the challenge-rechallenge model when only one vaccination is being considered, and petitioner has not proffered any evidence of causation that is not dependant upon petitioner fitting within the challenge-rechallenge model. To the extent that petitioner argues that proof of a medical theory (i.e., a delayed hypersensitivity reaction) plus an appropriate temporal relationship (i.e., a three-day interval) is tantamount to proving causation, see Mot. 10, the court directs petitioner to the following passage from the Federal Circuit's decision in Capizzano:

> The second prong of the Althen III test is not without meaning. There may well be a circumstance where it is found that a vaccine can cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine

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its burden to show causation, the burden to prove an alternative cause shifted to respondent).

> caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

440 F.3d at 1327. Such is the case here. Neither the medical records nor the proffered medical opinion suggest that the April 1, 1993 hepatitis B vaccination actually caused petitioner's second episode. Thus, petitioner's new argument concerning causation, if not waived, would fail.

B. Sequelae

The special master concluded his decision with a section entitled "Sequela," which addresses the evidence concerning the impairment to petitioner's cognitive abilities. Nussman, 2008 WL 449656, at *17-19. Petitioner's third objection in his motion for review is to the special master's entire discussion of sequelae, which petitioner finds to be wholly inappropriate. Mot. 12-14. Specifically, petitioner asserts that a discussion of sequelae is an issue for the damages stage of proceedings, and has no place in an entitlement decision. Id. Respondent counters that evidence of sequelae is relevant to more than just damages, also bearing upon the Vaccine Act's six-month duration of injury requirement and the credibility of Dr. Kinsbourne. Resp. 17-18. Although the special master provides no indication that he was addressing petitioner's sequelae in relation to the six-month requirement, he was well within his discretion to include a discussion of sequelae in his decision.

First, the special master made it abundantly clear that his discussion of sequelae was not probative to his causation decision. See Nussman, 2008 WL 449656, at *9 ("[A]lthough resolution of this issue is not required due to [petitioner]'s failure to prove that the hepatitis B vaccine caused his seizure disorder, the evidence about the alleged sequela to [petitioner]'s seizure disorder is discussed in section C."), *17 ("Finally, because [petitioner] has not established, by a preponderance of the evidence, that the hepatitis B vaccine caused any adverse effect, the question of sequela does not need to be resolved. Nevertheless, some comments about [petitioner]'s claims and his evidence are warranted."), *19 ("Whether [petitioner] established any sequela to his seizure disorder is not relevant to the more fundamental question of whether [petitioner] established, by a preponderance of the evidence, that the hepatitis B vaccine caused his seizure disorder."). In essence, the special master's discussion constituted dicta. Second, there is no provision in the Vaccine Act that prevents a special master from commenting upon evidence presented by the parties. Indeed, it was petitioner, not the special master, who raised the issue of cognitive impairment–manifesting as memory, concentration, and academic difficulties. See Ex. 20 at 2-3, 5; see also Pet'r Posthr'g Br. 9 (discussing the evidence petitioner presented regarding sequelae); supra Part I.A (recounting some of petitioner's difficulties). It is absurd for petitioner to now complain about the special master discussing the issues petitioner first pressed. Third, as noted by respondent, the special master indicated that his discussion of sequelae "reinforce[d] the finding that Dr. Kinsbourne's opinion [was] not well-founded." Nussman, 2008 WL 449656, at *19. For these reasons, the special master did not abuse his discretion by discussing sequelae.

III. CONCLUSION

The special master correctly applied the legal standards set forth in the Vaccine Act and Federal Circuit precedent. The court concurs with the special master that petitioner did not satisfy the second or third prongs of the Althen analysis because he failed to prove, by a preponderance of evidence, either a logical sequence of cause and effect or a proximate temporal relationship between the hepatitis B vaccinations and his two episodes. Thus, for the reasons set forth above, the court **SUSTAINS** the decision of the special master and **DENIES** petitioner's motion for review. The clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Margaret M. Sweeney
MARGARET M. SWEENEY
Judge