

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

JAY NUSSMAN,

*

Petitioner,

*

No. 99-500V

*

Special Master Christian J. Moran

v.

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Filed: January 31, 2008

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

*

Entitlement; hepatitis B vaccine;
seizures; challenge-rechallenge;

*

Respondent.

*

denial of compensation.

*Clifford A. Shoemaker, Shoemaker & Associates, Vienna, Virginia for petitioner;
Voris Johnson, United States Department of Justice, Washington, D.C. for respondent.*

PUBLISHED DECISION DENYING COMPENSATION*

Jay Nussman seeks compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq. (2006). His petition asserts that he received the hepatitis B vaccine on or about December 10, 1992, and April 1, 1993, and was injured as a consequence. Petition (“Pet.”) ¶ 2. During the course of litigation, Mr. Nussman clarified that he suffered seizures and continues to take medication to prevent additional seizures. Pet’r Res. to Resp’t Mot. to Dismiss, filed March 31, 2005.

* Pursuant to 42 U.S.C. § 300aa-12(d)(3)(A), this document constitutes a final “decision.” Unless a motion for review is filed within 30 days, the Clerk of the Court shall enter judgment in accord with this decision.

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.

A preponderance of the evidence establishes that Mr. Nussman is not entitled to compensation. Thus, in the absence of a motion for review, the Clerk's Office is instructed to enter judgment in favor of respondent.

I. Facts

Mr. Nussman was born on August 17, 1978. Exhibit 21 (affidavit of Betty Nussman, signed Dec. 16, 2006) ¶ 2; transcript ("tr.") 158. His father has epilepsy, a fact that is potentially relevant because epilepsy may be linked to genetics. Tr. 114. Mr. Nussman's own early medical history is not consequential. Respondent has not argued that events before Mr. Nussman was approximately 12 years old, affect the outcome of Mr. Nussman's claim. See Resp't Repot, filed March 15, 2005.

In elementary school, Mr. Nussman's performance was very good, but not uniformly excellent. In grades three through six, Mr. Nussman participated in a program for talented and gifted children. Mr. Nussman's academic prowess was reflected in his performance on a standardized test in grade four. Mr. Nussman scored in the 95th percentile or better in almost all areas. Exhibit 25 at 8; see also exhibit 25 at 7 (report card from fourth grade showing mostly A's).

As measured by scores on a standardized test, Mr. Nussman's academic performance peaked in the fourth grade. In the fifth grade, Mr. Nussman scored well, but not as high as he did in fourth grade. Exhibit 25 at 9, 12. His grades also declined slightly. He earned a C in math, and a teacher commented that he needed to improve his organizational skills. Id. at 5-6.

In grade six, school remained somewhat challenging for Mr. Nussman because of problems with organization. Exhibit 23 at 2. Report cards show that he earned mostly A's, some

B's and one C for "observed effort" in math for one marking period. Exhibit 25 at 3-4. His performance on a standardized test was average to above-average. Exhibit 25 at 10. Betty Nussman, Mr. Nussman's mother, attributes some of her son's problems with math in the sixth grade to the inexperience of his teacher. Tr. 218. A teacher in the program for academically talented students stated that creativity was Mr. Nussman's strength. Id. at 15. This program ended after Mr. Nussman completed the sixth grade. Tr. 314.

Although a bit sparse, records from seventh grade are consistent with his performance in fifth and sixth grade. He earned mostly B's in his classes. Exhibit 25 at 13. Mr. Nussman was tutored in math. Exhibit 23 at 2. Mrs. Nussman believes that preparations for his bar mitzvah distracted her son and prevented him from earning higher marks. Tr. 218. The records do not indicate whether Mr. Nussman took a standardized test in seventh grade.

In the fall of 1992, Mr. Nussman started eighth grade. However, the exhibits do not include his grades for the first marking period. His eighth grade report card contains only his final grade. Exhibit 25 at 13.

A preponderance of the evidence establishes that in eighth grade, Mr. Nussman received his first dose of the hepatitis B vaccine on December 10, 1992. The evidence of Mr. Nussman's vaccination is not as strong as it could have been. Usually, a petitioner obtains and files a document created contemporaneously with the vaccination. See 42 U.S.C. § 300aa-25(a) (requiring health care providers to create vaccination records). Here, Mr. Nussman's pediatrician administered the vaccination. Exhibit 21 ¶ 5; tr. 228. As early as May 22, 2002, respondent alerted Mr. Nussman that vaccination records had not been filed. Resp't Status Rep't, filed May 22, 2002. However, it appears that Mrs. Nussman did not request the records until

approximately two years later in 2004.¹ Tr. 302. Dr. Rosen replied that all records had been destroyed after the statute of limitations expired. Exhibit 7. Dr. Rosen's letter does not provide enough information to determine when the records were destroyed. Mr. Nussman stopped going to his pediatrician at age 17. Tr. 199. New Jersey, the state where Dr. Rosen treated Mr. Nussman, tolls the statute of limitations for minors until they reach the age of 21. N.J. Stat. Ann. § 2A:14-21 (1993); Phillips v. Gelpke, 921 A.2d 1067 (N.J. 2007). New Jersey's statute of limitations for filing a medical malpractice action is two years. N.J. Stat. Ann. § 2A:14-2 (1993); Guichardo v. Rubinfeld, 826 A.2d 700 (2003). Therefore, presumably, Dr. Rosen kept Mr. Nussman's records until the final date that Mr. Nussman could have filed a lawsuit against him. That date would have been when Mr. Nussman turned 23, on August 17, 2001, a date that was during this lawsuit.

Without a document created contemporaneously with the vaccination, Mr. Nussman submitted other evidence to prove that he received the vaccination at that time. The evidence that establishes that Mr. Nussman received a vaccination on December 10, 1992, is a history filled out by Mrs. Nussman after August 1993. Exhibit 1 at 2; tr. 303. In addition, Mrs. Nussman averred in a 2006 affidavit that her son received the hepatitis B vaccination on December 10, 1992. Exhibit 21 ¶ 5.

Taken as a whole, the evidence preponderates in favor of a finding that Dr. Rosen administered the first dose of the hepatitis B vaccination on December 10, 1992. As mentioned, Mr. Nussman was in the eighth grade at that time.

¹ Dr. Rosen's response was addressed to Mrs. Nussman, not Mr. Nussman's attorney.

On January 20, 1993, Mr. Nussman and his family attended the Inauguration of President Clinton in Washington, D.C. Exhibit 21 ¶ 5; tr. 200, 229. While returning to New Jersey, Mr. Nussman had a brief episode of confusion. After falling asleep in the car, Mr. Nussman woke up disoriented, not knowing where he was and not remembering what had happened. Mr. Nussman's parents brought him to a hospital's emergency room. The doctor's diagnosis was "confusion of unknown etiology." Exhibit 9 at 11; see also exhibit 21 ¶ 5; tr. 182. There were forty-one days between the hepatitis B vaccination and this event. See tr. 45.

Within three days of returning to their home, Mr. Nussman's parents arranged for him to be seen by a pediatric neurologist. Exhibit 21 ¶ 7; tr. 231; see also exhibit 2 at 1. However, the records from this single visit were not submitted into evidence. It appears that the pediatric neurologist recommended that Mr. Nussman have an electroencephalogram (EEG), because, on February 15, 1993, Mr. Nussman had one.

The February 15, 1993 EEG contained some spikes. Exhibit 28 at 42. Dr. Gold, a neurologist, interpreted the EEG as "mildly abnormal." Exhibit 2 at 1.

Dr. Gold treated Mr. Nussman for several years. Experts retained by both parties here recognize Dr. Gold as an outstanding doctor. Tr. 33, 106. As the treating doctor, Dr. Gold's insights are important.²

Mr. Nussman's first visit to Dr. Gold was on February 17, 1993. Dr. Gold obtained a

² Petitioner's gathering of medical records from Dr. Gold was less than ideal. Acting through counsel, Mr. Nussman filed records of Dr. Gold as exhibit 2 on March 15, 2002. As discussed in the text, the completeness of Dr. Gold's records was questioned during the March 2, 2007 hearing. Consequently, Mr. Nussman was ordered and authorized to issue a subpoena to obtain all records from Dr. Gold. Mr. Nussman, acting through his attorney, filed Dr. Gold's records as exhibit 28 on April 17, 2007. Exhibit 28 contains many more pages of material than exhibit 2.

comprehensive history. After an examination, Dr. Gold stated that Mr. Nussman “showed no evidence of neurologic deficit.” Dr. Gold believed that the January 20, 1993 episode “could represent a partial seizure or might be of psychogenic origin.” Exhibit 28 at 31. “Psychogenic” means “produced or caused by psychological factors.” Dorland’s Illustrated Medical Dictionary (30th ed. 2003) at 1539. Dr. Gold recommended that Mr. Nussman have an MRI. Dr. Gold also explained that Mr. Nussman could be followed without prescribing any anticonvulsants.

Medication would be considered only if Mr. Nussman had subsequent spells. Exhibit 28 at 32.

On February 19, 1993, Mr. Nussman had a second MRI. Dr. Gold stated the results were “completely normal.” Consequently, Dr. Gold confirmed that an anticonvulsant medication would not be introduced. In regards to Mr. Nussman’s academic problems, Dr. Gold stated that his parents should obtain a formal psychoeducational evaluation. Exhibit 28 at 50. By the end of February 1993, the Nussmans were sufficiently concerned about their son’s academic performance that they began the preliminary steps to seek formal assistance for him.

It is difficult to date the beginning of Mr. Nussman’s academic difficulties. Mrs. Nussman believes that his problems started in January of his eighth grade year (or shortly after the seizure, which was 41 days after the first dose of the hepatitis B vaccination). Tr. 232-33, 241-255. However, Mr. Nussman’s report card from eighth grade shows only his grades for the entire year. It does not show grades from individual marking periods which, if available, could show a bright line drop in his performance. Exhibit 25 at 23-27.

On March 6, 1993, Mr. Nussman's academic performance was assessed by Faye Lash.³ Ms. Lash stated that Mr. Nussman's parents were concerned about his "general memory lapses in and out of school." Exhibit 23 at 2. Ms. Lash administered various tests. She concluded that Mr. Nussman "was performing within the average range of academic functioning with definite weakness in the areas of written language and his ability to work quickly while processing all the information needed." Id. at 7. Ms. Lash stated, on March 6, 1993, that Mr. Nussman's strength was creativity. His weaknesses were handwriting, spelling and writing. Id. at 2.

Also in March 1993, Mr. Nussman took "New Jersey Grade 8 Early Warning Test." Exhibit 25 at 57. He scored close to the line dividing "competent" from "superior" on two subjects (reading and writing) and in the middle of the superior range in the third (mathematics). Id.; see also exhibit 102 at 5-7 (explaining proficiency levels).

Mr. Nussman alleges that he received his second dose of the hepatitis B vaccine on April 1, 1993. Pet. at ¶ 3; but see tr. 61-62 (testifying that he did not remember the specific date on which he received the second shot). Once again, no document created contemporaneously with the vaccination was submitted into evidence. However, a preponderance of the evidence establishes that Mr. Nussman received the second vaccine on April 1, 1993.

Records created more than a year after April 1, 1993, give inconsistent dates for the second dose. The earliest record, which is from Dr. Gold in April 1994, notes that Mr. Nussman's father said that the second seizure happened four days after the second vaccination. This record, however, does not give an exact date for either the seizure or the vaccination.

³ The Nussmans sought an evaluation from Ms. Lash because her assessment could support the Nussmans' request that the school evaluate their son. Tr. 258; 34 C.F.R. § 300-503 (1993).

Exhibit 28 at 27. One medical record lists the date of vaccination as April 1, 1993. See, e.g., exhibit 1 at 2 (illegible date). Another medical record states that the vaccination happened on April 4, 1993. Exhibit 14 at 3 (report from Dr. Crane, dated November 13, 2004). Mrs. Nussman's first affidavit says that the vaccination happened on April 4, 1993. Exhibit 21 ¶ 9. However, she also submitted a supplemental affidavit stating that her previous statement was in error; the actual date of the vaccination was April 1, 1993. Mrs. Nussman explained that the vaccination could not have happened on April 4, 1993, because that date was a Sunday. Exhibit 29; tr. 228, 309 (explaining that she knew the appointment was at the end of the week and Dr. Rosen does not see patients on Friday and therefore, she concluded the shot was given on Thursday).

On April 4, 1993, Mr. Nussman had a second event. The more significant assertion is that the vaccination preceded a second event. On some unknown date, Mr. Nussman had an episode in which he seemed to have blacked out and then vomited at a friend's house. The source of this information was Mr. Nussman's friend, Andy, who told Mrs. Nussman about it. Exhibit 21 ¶ 9. Mrs. Nussman did not observe what happened to her son at Andy's house, and Mr. Nussman, himself, does not remember the event. Exhibit 22 ¶ 7 (Mr. Nussman's affidavit, signed December 18, 2006); tr. 189, 202.

This event is not directly reflected in the contemporaneous medical records. Mrs. Nussman stated that she called Dr. Gold to inform him about this event. Tr. 239. Additional persuasive circumstantial evidence of some communication to Dr. Gold is found in Dr. Gold's file. On April 5, 1993, Dr. Gold prescribed Tegretol, a medication to prevent seizures. Exhibit 28 at 5. In light of Dr. Gold's earlier note that anticonvulsant medications would be needed only

if Mr. Nussman experienced a second spell, it is extremely unlikely that Dr. Gold would have prescribed Tegretol without some prompting event. See tr. 101.

In addition, Mr. Nussman had another MRI on April 22, 1993, which was normal. Exhibit 2 at 13; exhibit 28 at 28 (report dated May 7, 1993, discussing the April 22, 1993 MRI). Repeating this study after less than 60 days from the previous MRI strongly suggests some intervening event. Consequently, a preponderance of the evidence establishes that something happened to Mr. Nussman in early April 1993.⁴

Mr. Nussman saw Dr. Gold again on May 7, 1993. Dr. Gold adjusted the amount of Tegretol and planned to check Mr. Nussman in approximately six months. Dr. Gold also referenced recommendations of a Child Study Team in regards to Mr. Nussman's academic difficulties. Exhibit 28 at 28. Later in May 1993, the Child Study Team classified Mr. Nussman as "perceptually impaired." Exhibit 23 at 13; exhibit 25 at 47.

Approximately six months later, Mr. Nussman had another MRI of his brain. The MRI showed no evidence of a demyelinating disease. It also showed a slight asymmetry of the temporal horns and the lateral ventricle. Exhibit 28 at 48 (report dated Dec. 27, 1993). Dr. Gold seemed relatively unconcerned and requested that Mr. Nussman have another evaluation in about six months. Id. at 47.

⁴ In a letter dated March 15, 2007, Dr. Gold states that a "second seizure" was reported on April 3, 1993. Exhibit 28 at 53. This letter holds relatively little persuasive value. It is obviously written nearly 14 years after the "seizure." Nevertheless, Dr. Gold does not explain how he remembers the date of the telephone call. Id. Moreover, Dr. Gold's records do not show any notes from a telephone call on April 3, 1993. See exhibit 28. In addition, Dr. Gold's March 15, 2007 letter contains one statement contradicted by his notes, the date Dr. Gold prescribed Tegretol. Dr. Gold corrected this error in another letter. Exhibit 30. Thus, the March 15, 2007 letter is unreliable.

Mr. Nussman attended ninth grade from 1993 to 1994. In high school, Mr. Nussman earned relatively good grades. Exhibit 25 at 48-49; Exhibit 31 at 7. However, these marks did not come easily. Unlike his participation in an advanced program while in grades 3-6, Mr. Nussman was placed in a middle track in high school. He also had to study very hard to earn good marks. He found memorization to be particularly challenging. Tr. 164, 167, 196.

In April 1994, Mr. Nussman saw Dr. Gold again. Dr. Gold's report begins by describing Mr. Nussman as having a "previously described seizure disorder." Dr. Gold conducted a neurologic evaluation and was "very pleased" because Mr. Nussman had not experienced any seizures. Mr. Nussman was also performing well in school, implementing the recommendations from the Child Study Team. Dr. Gold continued the medication but also raised the possibility of decreasing the Tegretol after a few more months. Dr. Gold also requested another EEG. Exhibit 28 at 26-27.

According to Dr. Gold's report, Mr. Nussman's father believed that the seizures are related to the hepatitis B vaccinations. This comment is the first suggestion of a causal relationship in the medical records, although the suggestion comes from someone who is not a medical expert. Dr. Gold's own statement is that the "time sequence would be highly atypical for a vaccinal encephalopathy." Id. at 27.

The ensuing EEG showed "a mild degree of diffuse cerebral dysfunction." However, "definite epileptiform activity [was] not seen." Exhibit 28 at 45 (report dated April 28, 1994). The results of this EEG did not alarm Dr. Gold. He informed Dr. Rosen that any abnormalities had "questionable significance." Id. at 44. Nothing indicates that Dr. Gold changed Mr. Nussman's course of treatment.

When school resumed in the fall of 2004, Mr. Nussman's Tegretol was tapered. When he reached the midpoint of tapering in October 1994, Mr. Nussman had another EEG. The results were essentially unchanged from the previous EEG. Dr. Gold recommended that the tapering of Tegretol be continued, and then, for the Tegretol to be discontinued entirely. Exhibit 28 at 39-41.

Mr. Nussman stopped taking Tegretol on December 5, 1994. Exhibit 28 at 34. The following day, Mr. Nussman became dizzy in gym class. He felt faint, but did not pass out. Exhibit 2 at 12; exhibit 22 ¶ 8; tr. 310. Mr. Nussman's mother called Dr. Gold and reported that Mr. Nussman was feeling an impulse to hit a wall or a bed. This feeling was similar to how he felt before the seizures. Dr. Gold suggested that Mr. Nussman was having anxiety and should discuss this problem with his psychotherapist. Exhibit 28 at 13, 24.

In the following ten days, Mr. Nussman experienced surges of energy that he could not relieve. When Mr. Nussman's mother reported these complaints to Dr. Gold on December 17, 1994, Dr. Gold, apparently, recommended another EEG. Id. at 13, 24.

The December 17, 1994 EEG was abnormal in some respects. Id. at 37. Dr. Gold restarted Tegretol on that same date. Id. at 13, 24.

Dr. Gold conducted a "detailed and comprehensive neurologic examination" on December 31, 1994. The results were within normal limits. Mr. Nussman had not experienced any more spells after he resumed the Tegretol. Dr. Gold wanted to continue the Tegretol for the time being. Dr. Gold also noted that a placebo trial might be appropriate in the future. Exhibit 28 at 24-25.

After Tegretol was reinstated in December 1994, Mr. Nussman has not had any seizures. Over the course of the following 13 years, he has been examined periodically by various doctors. See exhibit 28 at 22-23 (report of Dr. Gold dated December 31, 1996, stating “seizure free for two years”).

On March 14, 1997, Mr. Nussman, accompanied by his mother, saw a pediatric neurologist, Poorvi Patel. This consultation was prompted by tremors in Mr. Nussman’s hands, which started long before the hepatitis B vaccination. Exhibit 3 at 1. (Mr. Nussman has specifically stated that he is not seeking compensation for this condition. Pet’r Res. to Resp’t Mot. to Dismiss, filed March 31, 2005.)

Dr. Patel discussed Mr. Nussman’s history of seizures. His comments on this point are relevant: “The exact etiology of [his] 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 Jay’s seizures are secondary to Hepatitis B vaccine. No information to support this is available to me at this time.” Exhibit 3 at 4. Ms. Nussman did not bring any literature to Dr. Patel. Tr. 313.

In July 1999, Dr. Gold again recommended tapering Tegretol with a goal of discontinuing it entirely. Exhibit 28 at 20-21. Although Tegretol was discontinued in October 1999, Mr. Nussman reported to Dr. Gold that he was having feelings similar to the surges that he had when he tried to discontinue Tegretol previously. Dr. Gold, therefore, resumed the medication. Id. at 10-11 (handwritten notes).

In March 2000, Dr. Gold wrote a letter supporting Mr. Nussman’s application for the Parke Davis Epilepsy Scholarship Award. According to this letter, Mr. Nussman deserved an award because he was “overcoming the multiple barriers resulting from his epilepsy.” Exhibit 28

at 52. When asked about his application during the hearing, Mr. Nussman stated that he preferred not to think of himself as having epilepsy. Tr. 205.

While this lawsuit was pending, Mr. Nussman attended and graduated from the School of Visual Arts at Syracuse University. Tr. 168. Currently, he works as a graphic designer. Exhibit 22 ¶ 8; tr. 170. He continues to take Tegretol. Tr. 166.

II. Procedural History

Mr. Nussman filed his petition on July 26, 1999. He did not file any medical records with the petition.

After the petition was filed, the case moved slowly. The first set of medical records was filed on March 15, 2002. Respondent filed a status report identifying some missing items and requesting that Mr. Nussman obtain them. Approximately two years later, Mr. Nussman filed additional records. On March 15, 2005, respondent filed its report, pursuant to Vaccine Rule 4, and stated that Mr. Nussman was not entitled to compensation.

Mr. Nussman filed a report from Peter Crain, a psychiatrist and neurologist, on March 25, 2004, as exhibit 14. Dr. Crain had examined Mr. Nussman on November 8, 2004. The purpose of this examination was to determine whether Mr. Nussman “had permanent sequelae as a result of [the] Hepatitis B vaccinations.” Dr. Crain opined that Mr. Nussman’s “encephalopathy with seizure activity and a learning disorder . . . was related entirely to the two Hepatitis B vaccinations.” Exhibit 14 at 10. Although this opinion appears to assist Mr. Nussman, Mr. Nussman did not call Dr. Crain to testify at the hearings.

Following the filing of Dr. Crain's report, respondent filed a report and curriculum vitae from Dr. S. Robert Snodgrass. Dr. Snodgrass believed that the hepatitis B vaccine did not cause a problem for Mr. Nussman. Exhibit A.

After both sides presented reports from their experts, a status conference was held. Mr. Nussman was ordered to file a supplemental report from Dr. Crain. The special master requested that Dr. Crain elaborate on four points: (1) the basis for Dr. Crain's opinion that the first dose of the hepatitis B vaccine caused a seizure more than one month later; (2) the basis for Dr. Crain's opinion that the second dose of the vaccine caused a seizure three days later; (3) his experience and training that qualifies him to offer an opinion about causation; and (4) whether Mr. Nussman's problem was related, if at all, to his father's epilepsy. Order, filed May 19, 2005.

About one month later, Mr. Nussman stated that he was attempting to obtain supplemental reports from an immunologist and a neurologist. Pet'r Status Rep't, filed June 23, 2005. Petitioner's self-selected deadline for filing these reports passed. Eight months later, the special master attempted to schedule a hearing. The case was then transferred to another special master.

Mr. Nussman was allowed additional time to obtain a report from Dr. Marcel Kinsbourne, a pediatric neurologist. Order, dated April 27, 2006. Mr. Nussman did obtain this report and filed it, along with Dr. Kinsbourne's curriculum vitae, on June 19, 2006. Exhibits 17-18. Mr. Nussman also filed literature on which Dr. Kinsbourne relied. Exhibit 19.

Because Mr. Nussman presented a new expert report, respondent obtained a supplemental report from Dr. Snodgrass. Dr. Snodgrass maintained his opinion that there was no causal relationship between the hepatitis B vaccine and Mr. Nussman's seizure disorder. In particular,

Dr. Snodgrass disagreed with Dr. Kinsbourne's assertion that this case was an example of challenge-rechallenge. Exhibit C.

The parties and the special master attempted to schedule the case for a hearing. During a status conference, Mr. Nussman and Mrs. Nussman were ordered to file affidavits. Mr. Nussman filed these affidavits, exhibits 21-22, on December 19, 2006. These submissions were the first time that either Mr. Nussman or his mother presented their statements to the court.

The case was then reassigned to the present special master. After the parties were afforded some time to settle the case, a hearing was set for March 2, 2007. Although Mrs. Nussman was scheduled to testify at the hearing, an illness in her family prevented her from participating. Order, filed February 26, 2007.

The hearing was held on March 2, 2007, during which Mr. Nussman called Dr. Kinsbourne and respondent called Dr. Snodgrass. During the hearing, it became clear that important documents, particularly records from Dr. Gold and Mr. Nussman's elementary school records, were not part of the record. Therefore, Mr. Nussman was ordered to obtain this material.

Mr. Nussman filed additional exhibits in April and May 2007. Respondent, however, maintained that this material did not eliminate confusion about important events (the date of the first dose of the hepatitis B vaccine, the date of the second dose, and the date of the second seizure). Respondent, therefore, requested that a hearing be held to receive testimony from Mr. Nussman, his mother, and Dr. Gold. Resp't Status Rep't, filed May 21, 2007.

A hearing was scheduled for July 19, 2007, for Mr. Nussman and his mother to testify. Mr. Nussman represented that Dr. Gold "had declined to testify" because his records speak for

themselves. In light of Dr. Gold's representation that his testimony could not add to the evidence, respondent decided not to request an authorization to subpoena Dr. Gold to the hearing. Thus, the hearing proceeded without him.

After Mr. Nussman and his mother testified, the parties filed post trial briefs. Respondent acknowledged that a preponderance of the evidence supported a finding that Mr. Nussman received the first dose of the hepatitis B vaccine on December 10, 1992, and a finding that Mr. Nussman received the second dose of this vaccine on April 1, 1992. Resp't Br., filed Oct. 19, 2007, at 24. This agreement is appropriate because a preponderance of the evidence does support these findings. See pages 3-4, 7-8, above. Respondent, however, argued that the evidence is not consistent as to when the second event happened. Resp't Br., filed Oct. 19, 2007, at 25. On this point, respondent's argument misses the mark for the reasons explained above. See pages 8-9, above.

Having resolved the issues of fact, the remaining question is whether Mr. Nussman has established that the hepatitis B vaccines caused his seizures. This decision is ripe for adjudication.

III. Analysis

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

Dr. Kinsbourne believes that the hepatitis B vaccine caused the onset of Mr. Nussman's seizure disorder. The primary, if not exclusive, support for Dr. Kinsbourne's opinion is that Mr. Nussman's case fits a model known as challenge-rechallenge. Dr. Kinsbourne further asserts that this seizure disorder has caused Mr. Nussman's continuing cognitive and emotional problems. Exhibit 20 at 4-5.

In contrast, Dr. Snodgrass opines that the hepatitis B vaccine did not cause Mr. Nussman's seizures. See exhibit A.

The primary point of disagreement between the experts is whether Mr. Nussman's case is an example of challenge-rechallenge. For the reasons set forth at length below in section A, it is found that Mr. Nussman's case is not. This finding underlies the determination in section B that Mr. Nussman does not fulfill the elements stated in Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Finally, although resolution of this issue is not required due to Mr. Nussman's failure to prove that the hepatitis B vaccine caused his seizure disorder, the evidence about the alleged sequela to Mr. Nussman's seizure disorder is discussed in section C.

A. Whether Mr. Nussman's Case Is An Example Of Challenge-Rechallenge

To support his opinion that Mr. Nussman's seizure disorder was caused by the hepatitis B vaccine, Dr. Kinsbourne relies upon a theory of challenge-rechallenge. Although this theory has contributed to petitioners prevailing in this program, see, e.g. Hall v. Sec'y of Health & Human Servs., Fed. Cl. 02-1052V, 2007 WL 3120284 (Spec. Mstr. Sept. 12, 2007); Mr. Nussman's case does not fit within this paradigm.

Challenge-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. See exhibit 20 (report of Dr. Kinsbourne) at 4; see also exhibit G (Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing On Causality 24 (Kathleen R. Stratton et al. eds., 1994) at 5. The second reaction is usually stronger and faster than the first reaction. Tr. 104. A preponderance of the evidence shows that Mr. Nussman does not fulfill the elements of challenge-rechallenge because he did not experience an adverse reaction to the first dose of the hepatitis B vaccine (being challenged) and he did not experience an adverse reaction to the second dose of the hepatitis B vaccine (being rechallenged).

1. First Dose

Mr. Nussman received the first dose of the hepatitis B vaccine on December 10, 1992. He blacked out and lost his memory on January 20, 1993. The evidence that this event was a seizure is mixed. The doctors who examined Mr. Nussman in the emergency room did not diagnose a seizure. Exhibit 9 at 11; tr. 99. Mr. Nussman's regular doctor, Dr. Rosen, recommended that Mr. Nussman see Dr. Gold. Tr. 230. Dr. Gold did not initially diagnose Mr. Nussman as having a seizure. Dr. Gold stated that this episode "could represent a partial seizure or might be of psychogenic etiology." Exhibit 28 at 31.

Whether Mr. Nussman's blackout and memory loss was a seizure is, in some ways, not important. The more relevant question is whether the hepatitis B vaccine caused an adverse reaction. The evidence on this point is weak.

Dr. Kinsbourne hypothesized that Mr. Nussman suffered an autoimmune reaction to the hepatitis B vaccine. Tr. 40-41. Dr. Kinsbourne opined that an autoimmune reaction would

manifest between 5 and 42 days. Tr. 22, 46. Mr. Nussman's blackout (or seizure) happened 41 days after he received the vaccination. Tr. 45. Even if Dr. Kinsbourne's estimate of the temporal limits to an autoimmune reaction were accepted, Mr. Nussman's case barely fits. See tr. 111-12 (testimony of Dr. Snodgrass).

Dr. Kinsbourne provided little basis for his estimate that an adverse reaction to the hepatitis B vaccine could take as long as 42 days. Tr. 45-47. Although Dr. Kinsbourne mentions a report by the Institute of Medicine, Dr. Kinsbourne conceded that, in discussing Guillain-Barre syndrome and acute disseminated encephalomyelitis, the appropriate time frame was 7-21 days. Tr. 45-46. In the context of demyelinating diseases, another special master has determined that the outside limit for an adverse reaction to the hepatitis B vaccine is 30 days. Lovett v. Sec'y of Health & Human Servs., Fed. Cl. No. 98-749V, 2007 WL 852104 (Spec. Mstr. Feb. 8, 2007). Mr. Nussman has provided little persuasive evidence that he had an adverse reaction when "challenged" by the first dose of the hepatitis B vaccine. Thus, a preponderance of the evidence establishes that he did not suffer an adverse reaction from the first vaccine.

2. Second Dose

Mr. Nussman's presentation regarding the "rechallenge" was even less persuasive. As previously discussed, Mr. Nussman's evidence regarding his receipt of the second dose of the hepatitis B vaccination fell short of an ideal. After much extra effort, the evidence supports a finding that Mr. Nussman did receive a second dose of the hepatitis B vaccine on April 1, 1993.

What next happened to Mr. Nussman is even less well-supported. According to Mr. Nussman's friend Andy, Mr. Nussman had an episode in which he vomited. Andy was the only witness to this event. Mr. Nussman does not remember it. Tr. 165, 187-90. Although

Andy was the only witness, he did not testify either orally or through an affidavit. Instead, Mr. Nussman and Mrs. Nussman testified about what Andy told them. Id.; tr. 239, 274.

A preponderance of evidence establishes that Mr. Nussman vomited and blacked out. Two pieces of evidence support this finding: Mrs. Nussman's testimony and Dr. Gold's decision to start Tegretol. Mrs. Nussman's testimony is accepted as persuasive because her demeanor while recounting what Andy told her was credible.⁵

Mrs. Nussman's reliability is enhanced by Dr. Gold's response to her. After bringing her son home from Andy's house, Mrs. Nussman called Dr. Gold. Although no record was created at the time of this call, a preponderance of evidence supports a finding that the call was placed. First, Mrs. Nussman was (and is) a mother concerned about her son. In April 1993, Mr. Nussman was being treated for a possible seizure disorder. If Mr. Nussman experienced anything remotely like a seizure, then it is reasonable to expect his parents to seek medical assistance. Second, Mrs. Nussman called Dr. Gold after normal working hours on a Sunday. If Dr. Gold spoke to Mrs. Nussman while he was not in his office, which is a reasonable inference, then he may not have created a note during his conversation. Third, Dr. Gold's records, which were filed after the first hearing, show that Dr. Gold prescribed Tegretol for Mr. Nussman on April 5, 1993. Exhibit 28 at 5. A reasonable inference is that Dr. Gold did so because of the information that Mrs. Nussman told him. If Dr. Gold is willing to make treatment decisions for Mr. Nussman (prescribe a drug) because of what she told him, then the same information can serve as a predicate for findings of fact in this case.

⁵ The Federal Rules of Evidence do not restrict the admissibility of evidence in Vaccine Program hearings. 42 U.S.C. § 300aa-12(d)(2)(B); Vaccine Rule 8(c). Thus, Federal Rule of Evidence 801 does not prevent Mrs. Nussman from testifying about what Andy told her.

A finding that Mr. Nussman blacked out is a predicate for Dr. Kinsbourne's opinion that Mr. Nussman suffered another adverse event. Until this point, questionable disputed points have been resolved in favor of Mr. Nussman. However, the evidence does not support a finding that the hepatitis B vaccine caused this second event.

The event at Andy's house happened three days after Mr. Nussman received the second dose of the hepatitis B vaccine. Three days is a much different time period than 41 days. Three days falls outside of the temporal window estimated by Dr. Kinsbourne. Tr. 22 (stating adverse reaction could start in five days). However, because Mr. Nussman'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. Tr. 121-22; see also Augustynski v. Sec'y of Health & Human Servs., Fed. Cl. No. 99-611V, 2007 WL 3033614 (Spec. Mstr. Sept. 28, 2007) (a reaction after sensitization can take place in one day).

Nevertheless, a quicker response should be close to the previous response. If Mr. Nussman'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 Mr. Nussman did not have the same reaction.

Dr. Kinsbourne, himself, recognizes that Mr. Nussman's case is difficult and rests his opinion that the hepatitis B vaccine caused neurologic problems on the challenge-rechallenge paradigm. Tr. 43, 57. Dr. Kinsbourne, however, is not persuasive in fitting Mr. Nussman's facts into this pattern. His opinion is an example of an opinion containing "simply too great an

analytical gap between the data and the opinion proffered.” General Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997).

B. Evaluation Of *Althen* Factors

To prove causation in fact, a petitioner must establish at least three elements. The petitioner’s

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

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).

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

Mr. Nussman’s evidence about the medical theory explaining how the hepatitis B vaccine can cause a seizure disorder was not brought forth clearly.⁶ However, with assistance from respondent’s counsel and respondent’s expert, a preponderance of the evidence indicates that a theory — a delayed hypersensitivity reaction — connects the hepatitis B vaccine to the seizure disorder.

⁶ The theory sought here explains how a vaccine caused an injury. It is “a medical theory.” Althen, 418 at 1278 (emphasis added). One example of a commonly presented theory is molecular mimicry. Molecular mimicry offers a hypothesis, based in biology, of how a vaccine can induce an adverse reaction.

The challenge-rechallenge model is not a medical theory. The challenge-rechallenge paradigm is a method, based in logic, that can assist in proving that a vaccine caused an injury. As such, challenge-rechallenge is discussed in the second prong of Althen. The underlying logic can be used in a variety of disciplines, not just medicine.

Before discussing delayed hypersensitivity reactions, it is worthwhile to note the theories initially offered, but then abandoned, by Dr. Kinsbourne. In his report, Dr. Kinsbourne suggested that at least one article showed that the hepatitis B vaccine “can cause manifestations of immune complex disease on the lines of serum sickness.” Exhibit 20 at 4. However, during his testimony, Dr. Kinsbourne specifically stated that Mr. Nussman did not have a reaction like serum sickness. Tr. 50-53.

Dr. Kinsbourne’s report also suggested that an immune complex disease “can cause small vessel vasculopathy . . . and that [the case of] Jay Nussman could plausibly involve isolated small vessel vasculitis of the brain.” Exhibit 20 at 4. “Vasculitis” is “inflammation of a blood vessel.” Dorland’s at 2009; accord tr. 53. Again, during his testimony, Dr. Kinsbourne refrained specifically from stating that Mr. Nussman had vasculitis. Tr. 53.

Instead of maintaining a theory that he presented in his report, Dr. Kinsbourne asserted during cross-examination that Mr. Nussman had a delayed hypersensitivity reaction, which is sometimes referred to as a “type IV” reaction. Tr. 50-52. Dr. Snodgrass, in turn, confirmed that a delayed hypersensitivity reaction was a possible — but unlikely — mechanism. Tr. 107, 124. 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.” Dorland’s at 888.

The testimony about delayed hypersensitivity reaction allows Mr. Nussman to fulfill, by a preponderance of the evidence, the first prong from Althen. Dr. Kinsbourne’s testimony on cross-examination and Dr. Snodgrass’s testimony establishes a theoretical link between the hepatitis B vaccine and Mr. Nussman’s seizures.

Mr. Nussman's burden is to "provid[e]" a medical theory. Althen, 418 F.3d at 1278. A petitioner does not have to prove the theory by establishing the biological mechanism. See Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994). Pursuant to this standard, Mr. Nussman has met the first element of his case.

Although Mr. Nussman met his burden on the first prong, the relative weakness of his evidence has ramifications for other aspects of his case. 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. Tr. 44, 81; exhibit 19, tabs 1, 3, 4, & 7. After Dr. Kinsbourne withdrew these theories, the relevance of these articles decreased greatly. Mr. Nussman 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. See tr. 117-18 (testimony of Dr. Snodgrass stating that the medical community has not researched a connection between the hepatitis B vaccine and either a single seizure or epilepsy).

These flaws diminish Dr. Kinsbourne's persuasiveness, which is important in evaluating Dr. Kinsbourne's opinion for the next two prongs of Althen. However, they do not detract from finding that Mr. Nussman has fulfilled the first prong of Althen. Through Dr. Kinsbourne, Mr. Nussman has provided a medical theory that respondent's expert, Dr. Snodgrass, finds possible, but unlikely. Therefore, a preponderance of the evidence establishes a medical theory connecting the hepatitis B vaccine to Mr. Nussman's seizures.

2. Logical Sequence of Cause and Effect Showing that the Vaccination Was The Reason for The Injury

The second prong of Althen requires Mr. Nussman to establish, by a preponderance of the evidence, a logical sequence of cause and effect showing that the hepatitis B vaccine was the reason for his seizures. Mr. Nussman's evidence fails for two reasons. First, as set forth above, Mr. Nussman's case is not an example of challenge-rechallenge, which is the primary (if not sole) reason offered in support of his claim. Second, the opinion of his treating doctor suggests that the hepatitis B vaccine did not cause the seizures.

Dr. Kinsbourne relies almost exclusively upon Mr. Nussman's presentation as an example of challenge-rechallenge. Tr. 24, 43, 81. But, Dr. Kinsbourne's opinion is not persuasive. Without establishing this point, no other evidence shows that the hepatitis B vaccine was the reason for Mr. Nussman's injury.

As a matter of fact, the evidence from Mr. Nussman's treating neurologist, Dr. Gold, is that the hepatitis B vaccine did not cause the seizures. Opinions of treating doctors are to be considered in determining whether a vaccine caused an injury. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Even without the instruction in Capizzano to consider the opinion of treating doctors, consideration of Dr. Gold's opinion is appropriate. Dr. Gold is well-positioned to evaluate whether the hepatitis B vaccine caused Mr. Nussman's seizure disorder. He specializes in treating seizure disorders and epilepsy. Both Dr. Kinsbourne and Dr. Snodgrass recognized his reputation in this field. Tr. 33, 106. Thus, if medical researchers were exploring whether the hepatitis B vaccine could cause a seizure disorder, then Dr. Gold would likely know about this research. His expertise in the field of seizure disorders means his opinion should be weighed carefully.

Prompted by Mr. Nussman's father, Dr. Gold considered the possibility the hepatitis B vaccine caused an adverse effect on Mr. Nussman. Dr. Gold stated that the sequence of events for Mr. Nussman "would be highly atypical for a vaccinal encephalopathy." Exhibit 28 at 27 (letter dated April 2, 1994). Thus, Dr. Gold's opinion supports the proposition that the hepatitis B vaccine did not cause Mr. Nussman's seizures.

Dr. Gold knew the sequence of events in Mr. Nussman's case. Presumably, Dr. Gold also is aware of the challenge-rechallenge paradigm. Dr. Gold's indication that Mr. Nussman likely did not have a problem caused by a vaccine reinforces the rejection of Dr. Kinsbourne's offering of the challenge-rechallenge paradigm.

Considered as a whole, the evidence that Mr. Nussman's disorder was caused by the hepatitis B vaccine is not persuasive. Thus, Mr. Nussman is not entitled to compensation.

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

Mr. Nussman, as the petitioner, bears the burden of presenting evidence about the appropriate temporal relationship between his vaccination and the onset of any problems for which he claims compensation. Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1358 (Fed. Cir. 2006), cert. denied, ___ U.S. ___, 127 S. Ct. 2909 (2007).

For the same reasons that Mr. Nussman does not fit the challenge-rechallenge pattern, he also does not establish the appropriate temporal relationship. Evidence on the temporal relationship is sparse, but it preponderates in favor of a finding that the hepatitis B vaccine, if it caused seizures, would cause the seizures within 30 days.

Both experts presented some testimony about the timing for an adverse reaction. Dr. Kinsbourne asserted that an unspecified type of an immune-mediated reaction would occur within 5-42 days. Exhibit 20 at 4; tr. 22. In the context of discussing a delayed hypersensitivity reaction, Dr. Kinsbourne opined that the reaction may not take place until six or eight weeks after the vaccination. Tr. 51-52. Dr. Snodgrass, on the other hand, believed a reaction would more appropriately take place 15-17 days after the vaccination. Tr. 112.

In addition to his testimony, Dr. Kinsbourne also presented literature. This literature, however, sheds little light on determining the outer range of a delayed hypersensitivity reaction.

One article is a case report of a man who presented with a seizure approximately 30 days after learning he was exposed to the wild hepatitis B virus and given human serum globulin. Exhibit 19, tab 2 (Benjamin R. Brooks, Viral Hepatitis Type B Presenting with Seizure, 237 J Amer. Med. Ass’n 427 (1977)). The persuasive value of this article is limited because (a) it reports a single case, so excluding coincidence is impossible, and (b) it concerns the hepatitis B

virus, not the hepatitis B vaccine. Tr. 87. However, to the extent that it is relevant, the article indicates that the reaction would develop in approximately 30 days.

Tab 3 and tab 4 of exhibit 19 contain the same letter to the editor, S. Hartman, Convulsion Associated with Fever Following Hepatitis B Vaccination, 26 J. Paediatric. Child Health 65 (1990). The author describes a febrile seizure that developed within one hour after the first dose of the hepatitis B vaccine. This incident is not a delayed hypersensitivity reaction, which requires at least a few days to develop. Therefore, it does not assist in determining the expected temporal relationship in Mr. Nussman's case.

Another article presented by Dr. Kinsbourne is Louis Reik, Jr., Disseminated Vasculomyelinopathy: An Immune Complex Disease, 7 Ann. Neurol. 291 (1980). Dr. Reik offers a hypothesis in which demyelination occurs without a "delayed hypersensitivity reaction." Exhibit 19, tab 7 at 292. In describing immune complex vasculitis, Dr. Reik notes that the onset is usually one to three weeks. Id. at 293. This article provides no direct evidence for how long a delayed hypersensitivity reaction is expected to take in Mr. Nussman because the article hypothesizes a mechanism that lacks a delayed hypersensitivity reaction. Mr. Nussman, in contrast, is asserted to have this reaction. See tr. 123. But, if the article could be construed as providing some information about the time expected for a hypersensitivity reaction, then the inference is that a reaction would be expected to occur between 7 and 21 days.

Finally, Thaschawee Arkachaisri, Serum Sickness and Hepatitis B Vaccine Including Review of the Literature, 85 (Suppl. 2) J Med. Assoc. Thai S607 (2002), discusses serum-sickness type reactions. Exhibit 19 at tab 1. Whether this article provides information relevant

to Mr. Nussman's case is not clear because this article reports on serum sickness and, according to Dr. Kinsbourne, Mr. Nussman did not have a serum sickness type reaction. Tr. 50-53.

However, to the extent that the timing of a delayed hypersensitivity reaction is roughly analogous to the timing of a serum sickness reaction, then the article provides some support for a proposition that the time might extend until 42 days. Of 32 reported possible cases, only six happened more than 22 days after a dose of the hepatitis B vaccine was administered. Of these six cases, four happened either on day 28 (one case) or on day 30 (three cases), leaving only two cases. The last two cases occurred with the greatest number of days of delay (42 days and 90 days) and were both reactions to the third dose of the vaccine. Exhibit 19 at tab 1 at S609.

This article provides relatively little support for Dr. Kinsbourne's assertion. The one case that began on day 90 is so far removed from the other cases that any relationship between the hepatitis B vaccine and the serum sickness reaction is more likely to be coincidental, rather than causal. When this case is eliminated, only in one of 31 cases did the serum sickness begin more than 30 days after the date of vaccination. Therefore, this article, which discusses a serum sickness reaction that Mr. Nussman did not have, is entitled to little persuasive weight.

Other articles presented by Dr. Kinsbourne do not address the expected temporal sequence when a vaccine causes an adverse reaction. Instead, they discuss how seizure disorders can affect someone. See exhibit 19, tabs 5, 6, & 8.

In sum, the evidence supporting Mr. Nussman's position consists of Dr. Kinsbourne's testimony plus, to some extent, the Arkachaisri article. Although not a prerequisite for admissibility, medical articles may be considered in evaluating the persuasiveness of an expert's opinion. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593-94 (1993); Merck &

Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364, 1374 (Fed. Cir. 2005); Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (affirming special master’s use of Daubert in vaccine program cases); Libas v. United States, 193 F.3d 1361, 1366-67 (Fed. Cir. 1999); see also Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 354 (5th Cir. 2007) (stating a lack of textual support may “go to the weight, not the admissibility” of the expert's testimony); Waleryszak v. Sec’y of Health & Human Servs., 45 Fed. Cl. 573, 578-79 (1999), appeal dismissed, 250 F.3d 753 (Fed. Cir. 2000).

Even if Dr. Kinsbourne’s opinion were the only evidence on timing, crediting his testimony is not required. Rohm & Haas Co. v. Brotech Corp., 127 F.3d 1089, 1092 (Fed. Cir. 1997); U.S. Philips Corp. v. Windmere Corp., 861 F.2d 695, 704 (Fed. Cir. 1988). But, Dr. Kinsbourne’s testimony is not the only evidence. Dr. Snodgrass disagreed with his opinion.

Considering all the evidence, including the demeanor of the experts when they testified, the 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, Mr. Nussman has failed to meet his burden of presenting persuasive evidence that his seizure occurred within an appropriate time frame. See Burns, 3 F.3d at 417; Bradley v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993); Andrew Corp. v. Gabriel Electronics, Inc., 847 F.2d 819, 824 (Fed. Cir. 1988) (authorizing finder of fact to consider expert’s demeanor when analyzing the persuasiveness of their testimony).

Mr. Nussman’s has failed to establish that his alleged reaction to the hepatitis B vaccine took place in a medically appropriate time. Thus, he is not entitled to compensation.

C. Sequela

Finally, because Mr. Nussman 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 Mr. Nussman’s claims and his evidence are warranted.

Mr. Nussman alleges that the hepatitis B vaccine caused him to develop a form of epilepsy known as a complex partial seizure disorder. Exhibit 19, tab 8 (Jen Schoenfeld et al., Neuropsychological and behavioral status of children with complex partial seizures, 41 Developmental Medicine & Child Neurology 724, 724 (1999); see tr. 17, 19 (testimony of Dr. Kinsbourne), 98 (testimony of Dr. Snodgrass). Mr. Nussman contends that the complex partial seizure disorder (or epilepsy) caused him to perform poorly in school because he has a problem with memorization. Tr. 25-27 (testimony of Dr. Kinsbourne), 209 (testimony of Mr. Nussman).

Mr. Nussman’s only evidence linking a complex partial seizure disorder to an impairment in cognitive abilities was the opinion of Dr. Kinsbourne.⁷ Unfortunately, Dr. Kinsbourne’s

⁷ Mr. Nussman also submitted a statement from his treating psychologist, David Thaler. Dr. Thaler does not connect Mr. Nussman’s problems with “interpersonal relationships and job

opinion was conclusory, based upon mistaken information, and showed little appreciation for the nuances in Mr. Nussman's case.

The lack of analysis supporting Dr. Kinsbourne's opinion regarding the sequela of a seizure is reflected in the little attention this issue received. Dr. Kinsbourne's report addresses the consequences of a seizure disorder in one paragraph and cites four articles. Exhibit 20 at 5. Dr. Kinsbourne's testimony was two pages and did not discuss the articles that he submitted at all. Tr. 25-27. Mr. Nussman did not elicit any testimony from Dr. Snodgrass as to whether partial complex seizures can cause learning disorders. See tr. 120-43. As set forth below, a more extensive presentation of the basis for Dr. Kinsbourne's testimony would have been appropriate.

A foundation for Dr. Kinsbourne's opinion was the change in Mr. Nussman's academic performance in the eighth grade, shortly after he received the first dose of the hepatitis B vaccine. Tr. 25-27, 72. The best evidence of Mr. Nussman's academic performance is, of course, his school records.

When Dr. Kinsbourne presented his opinion in his written report, and, again when he testified orally, Dr. Kinsbourne did not have Mr. Nussman's school records. Tr. 150-51; order, dated March 8, 2007. After Dr. Kinsbourne testified, Mr. Nussman filed copies of his grammar school records that his mother retained. See order, dated June 27, 2007. Consequently, Mr. Nussman was given an opportunity to present either an expert report from a new expert or a supplemental report from Dr. Kinsbourne. Id. Mr. Nussman declined this opportunity. Tr. 319-20.

issues" to the effect of the hepatitis B vaccine. Dr. Thaler merely notes that these problems "are at least in part due to his unique medical and neurological history." Exhibit 26 at 1. This statement does not identify a specific event in Mr. Nussman's "medical and neurological history" that caused his problems.

Dr. Kinsbourne's credibility would have been enhanced if, in light of the additional information, he reasserted that Mr. Nussman's decline in academic performance began in eighth grade. However, Mr. Nussman's report card shows that he fell short of the highest grade in several subjects in sixth and seventh grade. Exhibit 25 at 3-4, 15. Another example is that Dr. Kinsbourne asserts that Mr. Nussman remained in a program for academically gifted students until the eighth grade when "he had to be removed to mainstream classes." Exhibit 20 at 3. Actually, Mr. Nussman left the academically gifted program in sixth grade because the program terminated at that level. Tr. 314. These discrepancies are significant because if Mr. Nussman's academic problems began in the sixth or seventh grade, then the hepatitis B vaccine, which Mr. Nussman received in the eighth grade, could not have caused the problems.

Dr. Kinsbourne makes another mistake. He stated that Mr. Nussman began having anxiety after eighth grade and attributes that change in Mr. Nussman's personality to a reaction to the hepatitis B vaccine. Exhibit 20 at 5. In fact, Mr. Nussman saw a counselor for anxiety in both the sixth and seventh grades. Exhibit 3 at 2. Dr. Kinsbourne was not aware of this treatment. Tr. 73-76.

Dr. Kinsbourne's opinions about the effects of Mr. Nussman's seizure disorder are not well-grounded in fact. The persuasive value is, therefore, diminished. nCube Corp. v. Seachange Intern., Inc., 436 F.3d 1317, 1323 (Fed. Cir. 2006); Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994).

Moreover, Dr. Kinsbourne did not address the specific circumstances of Mr. Nussman's case. Mr. Nussman's case essentially rests upon a proposition that a single 20 minute episode of memory loss on January 20, 1993 when Mr. Nussman was 14 years old, constituted a seizure that

caused a lifelong cognitive dysfunction. Even adding the incident in April 1994 and the incident in December 1994, Mr. Nussman experienced only three incidents that can be remotely characterized as seizures. While it is possible for seizures to cause lifelong damage, Mr. Nussman has not proved that these events were, in fact, seizures causing this type of permanent damage.

Moreover, the vaccinations, seizures, and changes in academic performance were taking place in the context of Mr. Nussman's puberty. Early adolescence is well-noted for being a time in which people's personality change in response to different environments, responsibilities, and interests. For example, a psychological evaluation from May 3, 1993, shortly after Mr. Nussman received the second vaccination, indicated that Mr. Nussman was "currently experiencing many age-typical adolescent feelings and impulses." Exhibit 10 at 2. While it is conceivable that a pharmaceutical product, like the hepatitis B vaccine, can cause personality changes in an adolescent, a petitioner should present more evidence on this point.

Dr. Kinsbourne did not address these circumstances. The literature that Dr. Kinsbourne supplied indicates that other factors can affect the long-term outcome of a person with a seizure disorder. "Age of onset of recurrent was the strongest and most consistent predictor of adequacy of cognitive functioning; earlier age of onset was associate with poorer cognitive status." Exhibit 19, tab 8 (Jen Schoenfeld et al., Neuropsychological and behavioral status of children with complex partial seizures, 41 *Developmental Medicine & Child Neurology* 724, 724 (1999). "It is now appreciated that sociodemographic/family characteristics are significantly associated with neuropsychological status and emotional/behavioral adjustments. Therefore, these factors need

to be controlled to obtain a clear understanding of the effects of epilepsy on cognition and behavior.” Id. (citations omitted).

Dr. Kinsbourne did not explain whether he considered Mr. Nussman’s age, relative infrequency of seizure-type events, and sociodemographic characteristics in concluding that the hepatitis B vaccine ultimately caused an impairment in cognitive function. Dr. Kinsbourne may not have addressed them explicitly because his expertise is not in treating seizure disorders. See tr. 31, 81-82. Someone who treats seizure disorders or a specialist in cognitive impairments, such as a neuropsychiatrist, may have shown how these factors did or did not affect Mr. Nussman.

Ultimately, these criticisms about Mr. Nussman’s evidence and Dr. Kinsbourne’s opinion affect the outcome of this case only to the extent that they reinforce the finding that Dr. Kinsbourne’s opinion is not well-founded. Whether Mr. Nussman established any sequela to his seizure disorder is not relevant to the more fundamental question of whether Mr. Nussman established, by a preponderance of the evidence, that the hepatitis B vaccine caused his seizure disorder. Because Mr. Nussman has not established, by a preponderance of the evidence, that the hepatitis B vaccine caused his seizure disorder, there is no need to resolve the question of what are the sequela to that disorder.

IV. Conclusion

In some respects, Mr. Nussman’s case could have and should have been presented better. The gathering and filing of documents created contemporaneously with his December 1992 vaccination, his April 1993 vaccination, and Dr. Gold’s records could have been accomplished more efficiently. Dr. Kinsbourne could have disclosed the medical theory that connected the

hepatitis B vaccine to Mr. Nussman's seizure disorder in his written report. Dr. Kinsbourne's opinion regarding sequela could have been based upon a more accurate account of Mr. Nussman's academic history.

These flaws, however, do not affect the outcome of Mr. Nussman's case. At its core, the question is whether Mr. Nussman's case fits within the challenge-rechallenge paradigm. It does not.

Because Mr. Nussman has not established by a preponderance of the evidence that the hepatitis B vaccine caused a seizure disorder, he is not entitled to compensation. Absent a motion for review, the Clerk's Office is instructed to enter judgment in favor of respondent.

IT IS SO ORDERED.

S/ Christian J. Moran

Christian J. Moran
Special Master