IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

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RICHARD ABBOTT, JR., a minor	*	
by his mother and natural guardian,	*	
WANDA BUNCH,	*	No. 99-497V
	*	Special Master Christian J. Moran
Petitioner,	*	
	*	
v.	*	Filed: June 28, 2010
	*	
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	Entitlement, hepatitis B vaccine,
	*	seizure disorder, immune system of
Respondent.	*	newborn, herpes simplex virus
** *		

David L. Terzian, Esq., Rawls & McNelis, P.C., Richmond, Virginia, for petitioner;
Darryl R. Wishard, Esq., United States Department of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[*]

Wanda Bunch alleged that the hepatitis B vaccine caused her son, Richard Abbott, Jr. ("Ricky"), to suffer a seizure disorder. She sought compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa–10 et seq. (2006).

Ms. Bunch has failed to establish that she is entitled to compensation. In particular, Ms. Bunch has failed to establish, by a preponderance of the evidence, that the theories offered by her expert provide a reliable explanation of how the hepatitis B vaccine can cause a seizure disorder

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

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

in a child less than six weeks old. Additionally, Ms. Bunch has failed to establish, by a preponderance of the evidence, that Ricky responded to the hepatitis B vaccine in the way predicted by her expert. Specifically, although the theories offered by Ms. Bunch's expert involve the hepatitis B vaccine leading to an attack on myelin, the evidence, including testimony from Ms. Bunch's expert, shows that Ricky did not experience demyelination. Consequently, the Clerk's Office is instructed to enter judgment in favor of respondent. The reasons for this decision follow.

I. Facts

Ms. Bunch's health while pregnant with Ricky is one issue in this case. Ms. Bunch's obstetrician was Barbara Doty, who also was Ricky's pediatrician. Dr. Doty's records show that Ms. Bunch was generally healthy, except for some nausea and vomiting during her pregnancy. The records do not show that Dr. Doty tested to see whether Ms. Bunch was infected with a herpes simplex virus. See exhibit 26 (pre-natal records).[1] This lack of information about Ms. Bunch allows respondent to propose that a herpes simplex virus, transmitted to Ricky during his birth, caused his seizure disorder during his birth.

Ms. Bunch gave birth to Ricky on June 2, 1994. Exhibit 8. Ms. Bunch's delivery of Ricky did not proceed smoothly. The doctors eventually used vacuum extraction. Exhibit 26 at 8; exhibit 4 at 1 (record dated Dec. 13, 1994); exhibit 5 at 1 (record dated Jan. 25, 1995); tr. 13-14. Immediately after birth, Ricky's Apgar scores were seven and nine. He was treated with oxygen for transient rapid and labored breathing. Four hours after being born, Ricky was breast-feeding well.

Ricky received the first dose of the hepatitis B vaccination on June 3, 1994, the day after he was born. Although Ms. Bunch testified that she initially had resisted efforts to consent to Ricky's vaccination; tr. 15; tr. 26; her testimony on this point is not material. Her (lack of) consent does not affect the outcome of this claim because petitioners are not required to establish any breach of the duty of care with regard to informed consent. Ricky was discharged from the hospital later on June 3, 1994.

On June 13, 1994, Dr. Doty examined Ricky. She determined that he was growing appropriately. She also observed that there were pustules on his scalp. She prescribed Bactroban, an antibiotic ointment. Exhibit 6 at 7.

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[1] Ms. Bunch testified that she was checked for viral infections. Tr. 15-16. However, she later testified that she was tested for being infected with hepatitis B and assumed that she was also tested for herpes simplex virus. Tr. 29-30. Due to the lack of persuasive evidence from either Ms. Bunch's testimony or the prenatal records from Dr. Doty, Ms. Bunch has not established that she was tested for herpes simplex viruses while pregnant with Ricky.

On July 5, 1994, Ricky received the second dose of the hepatitis B vaccine. Exhibit 6 at 4, 7; tr. 18. For approximately 36 hours after receiving this vaccination, Ricky's health was normal. Exhibit 6 at 6 (report dated July 8, 1994, stating "infant was well yesterday").

In the morning on July 8, 1994, Ms. Bunch observed that Ricky was "twitching and crying in spurts." She called Dr. Doty's office to report her observations. Exhibit 6 at 6; tr. 18-19; tr. 33; tr. 46. Staff at Dr. Doty's office told Ms. Bunch that Ricky's reaction was normal.

Notwithstanding this reassurance from the staff at Dr. Doty's office, Ms. Bunch sought additional care for Ricky at Alaska Regional Hospital. Tr. 20. Ms. Bunch reported that earlier that day, Ricky began twitching on his right side and that vomiting occurred with the twitches. The doctor at Alaska Regional Hospital, Dr. Emilio Avilia, observed that Ricky was having tonic and clonic seizures. Dr. Avilia admitted Ricky to the hospital and prescribed phenobarbital, an anti-seizure medication. Exhibit 1 at 8-10.

Dr. Avilia ordered certain tests for Ricky. A lumbar puncture was done. The results showed that his cerebrospinal fluid contained 157 white blood cells, 42 red blood cells, 100 lymphocytes, 0 polymorphs, 36 gluclose and 110 protein. Exhibit 1 at 28.

Ricky's brain was also tested. An electroencephalogram (EEG) did not show signs of seizure activity, although the doctor noted that a barbiturate (phenobarbital) suppresses any seizure activity. Exhibit 1 at 14-15. A CT scan with and without contrast of Ricky's brain showed that his brain was "normal in appearance with no evidence of cerebral swelling, intra- and extra-axial hemorrhage, or any mass effect." Dr. Cruz, who interpreted the CT scan, noted one "rounded, slightly hypodense focus," but Dr. Cruz indicated that this was not likely to be "some form of inflammatory or neoplastic process." Exhibit 1 at 16; see also tr. 91-92 (Dr. Steinman discussing this CT scan).

Dr. Avilia discharged Ricky on July 11, 1994. Dr. Avilia diagnosed Ricky as suffering from a "seizure disorder" but the etiology was to be determined. Dr. Avilia noted that the results from the lumbar puncture were consistent with an encephalopathy caused by a virus. Dr. Avilia stated that Ricky's most recent neurological examination was normal. Dr. Avilia also recommended that Ricky not receive the pertussis vaccine. Exhibit 1 at 20.

After Ricky's discharge on July 11, 1994, his health appeared normal. Dr. Doty examined him again on August 10, 1994, and specifically noted that Ricky had "had no further episodes of any type of seizure disorder." Exhibit 6 at 10; accord exhibit 1 at 36. During the April 2009 hearing, Ms. Bunch testified that between July and October 1994, Ricky continued to have abnormal movements, specifically that his head dropped and his arms thrust forward. Tr. 266. This testimony is not consistent with the record created by Dr. Doty on August 10, 1994, is presumed to reflect accurately Ricky's health through August 10, 1994. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993); Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991) (explaining that a specific recording that nothing was wrong is a stronger indication than an absence of a notation), aff'd, 968 F.2d 1226 (Fed. Cir.

1992). Given that more than 10 years elapsed, Ms. Bunch's ability to recall exactly when Ricky was having these movements is questionable. See tr. 20. Further, Ms. Bunch appeared to be a conscientious, attentive, and loving mother, who would have reported a problem to Dr. Doty if Ms. Bunch had observed one.

On August 22, 1994, Dr. Doty referred Ricky to an Infant Learning Program. Dr. Doty stated that Ricky had a "seizure disorder felt secondary to a virus and possibly related to a vaccination with hepatitis B." Dr. Doty made the referral because although Ricky was "doing well," Dr. Doty wanted "to make sure that he progresses on track." Exhibit 6 at 9.

On October 18, 1994, Ricky pulled his legs upward and curled his upper body forward on three occasions. He made a similar movement again on October 19, 1994. Ms. Bunch brought him to the emergency room at Valley Hospital, where the doctors diagnosed Ricky as having a seizure. Exhibit 7 at 1; exhibit 1 at 36. Ricky was transferred to Alaska Regional Hospital, where he had been cared for three months earlier. Ricky stayed in Alaska Regional Hospital for one week.

While in the hospital, the doctors ordered various tests on Ricky. An EEG was abnormal and was consistent with epilepsy. Exhibit 1 at 40. In addition to the EEG, Ricky also had an MRI. The MRI showed that Ricky, who was approximately four months old, had appropriate myelination. There was, however, an abnormality suggesting some loss of neuronal bulk. Exhibit 1 at 41. (The significance of this MRI is one of the primary disputes between the experts. See tr. 93-94 (testimony of Dr. Steinman); tr. 317-318 (testimony of Dr. MacDonald).)

Ricky was discharged on October 21, 1994. The discharging physician, Dr. Jeff Brand, recommended that Ricky continue to receive phenobarbital. Dr. Brand also recommended that Ricky not receive the pertussis vaccination. Exhibit 1 at 71.

In December 1994, Ms. Bunch, Ricky's father, and Ricky traveled from their home in Alaska and saw Jerrold Milstein, a pediatric neurologist at the University of Washington in Seattle, Washington. Dr. Milstein noted that Ricky had chronic and indolent lesions on his scalp. Dr. Milstein assessed Ricky's development as occurring within normal time, except for some right-handed skills. Dr. Milstein also stated that Ricky's earlier hospitalization was consistent with an "acquired encephalitis." Dr. Milstein suggested that a herpes virus or an echovirus may have caused the encephalitis. Dr. Milstein recommended that Ricky continue to take phenobarbital for two more years. Exhibit 4; see also tr. 154 (Dr. Steinman commenting on Dr. Milstein's report).

During the following month, Ricky resumed having seizures. Starting on January 16, 1995, Ricky had three to five seizures per day and the average duration of these seizures was less than one minute. Ricky's doctors prescribed Tegretol, an anti-seizure medication. Exhibit 2 at 2; exhibit 3 at 1.

On January 30, 1995, Ricky saw another pediatric neurologist in Seattle, Dr. George Makari. Dr. Makari obtained a detailed medical history from Ricky's parents, which is consistent with the history recounted above. Dr. Makari determined that Ricky's development was normal, except for a history of mild weakness on his right side and the history of focal seizures. For the etiology of these problems, Dr. Makari stated that the cause was "not 100 percent clear. It may be related to the hepatitis vaccination or a viral encephalitis." Dr. Makari requested an MRI and continued Ricky on Tegretol. Dr. Makari also requested an opportunity to review Ricky's old medical records. Exhibit 3 at 2; see also exhibit 2 at 3.

While Ricky was taking Tegretol, the seizures diminished. Dr. Wright, a naturopath in Alaska, also suggested modifying Ricky's diet. Exhibit 5 at 4 (report dated Mar. 8, 1995).

Ricky had a follow-up appointment with Dr. Makari on April 27, 1995. Dr. Makari stated that Ricky had done well in his development. Dr. Makari also examined Ricky and found that the neurological examination was normal. However, a recent EEG was abnormal. Dr. Makari recommended that Ricky take Klonopin, another medication for seizures. In terms of causation, Dr. Makari commented that "I do not think that this is related to the hepatitis immunization (it has not been reported that encephalitis would occur with hepatitis vaccination.)" Exhibit 3 at 4.

After 1995, Ricky continued to have seizures periodically and received care from various neurologists and pediatric neurologists. The details of these visits, with some exceptions, generally do not provide any information that is useful in determining whether the hepatitis B vaccine caused Ricky's seizures.

A potentially important fact was learned in 2003. A test from this year showed that Ricky had been infected with the herpes simplex virus, type II. This test also indicated that Ricky had not been infected with herpes simplex virus, type I. Exhibit 21 at 14.

Also, in May 2003, Ricky had another MRI of his brain. The results were normal. Exhibit 21 at 19-20; see also tr. 98-99 (Dr. Steinman).

At the time of the hearing, Ricky attended school. Although Ricky was 15 years old, he attended the fifth grade and his academic functioning was at the level appropriate for a child in the second or third grade. He experiences seizures every day. Tr. 24-25.

II. Procedural History

A petition was filed on Ricky's behalf on July 26, 1999. The petition listed Ricky's father, Richard Abbott, Sr., as the petitioner. No medical records were filed with the petition.

Nearly three years later, Mr. Abbott filed the first set of medical records as exhibits 1-8. In February 2003, a special master stayed this case. Although not reflected on the docket, the stay reflected efforts to develop a method to resolve the numerous cases in which petitioners

alleged that the hepatitis B vaccine caused them an injury. Ultimately, these attempts did not succeed.

In February 2006, after it became apparent that this case needed to be developed, the case was transferred to the undersigned. The stay was lifted and the case proceeded.

At a status conference, Mr. Abbott's counsel, Mr. Clifford Shoemaker, indicated that he was attempting to find a different attorney to be counsel of record for the petitioner. This process eventually led to an order designating Ms. Bunch as petitioner. Order, dated Sept. 18, 2006; order, dated Feb. 14, 2007. After Ms. Bunch became the petitioner, she consented to a change in attorneys from Mr. Shoemaker to Mr. David Terzian. See order, filed March 7, 2007. Mr. Terzian has represented Ms. Bunch and acted as counsel of record after March 7, 2007.

Before Mr. Shoemaker stopped working on this case, he filed additional medical records. Mr. Terzian filed one remaining medical record on March 14, 2007. After all medical records were filed, Ms. Bunch sought an expert. She filed a report from Dr. Lawrence Steinman as exhibit 28 on March 5, 2008. Ms. Bunch also filed literature on which Dr. Steinman relied and Dr. Steinman's curriculum vitae.

Dr. Steinman's opinion, at least with regard to the condition affecting Ricky, evolved. Initially, Dr. Steinman's report stated that Ricky "developed a post-immunization meningoencephalitis." Exhibit 27 at 1-2. Dr. Steinman connected the hepatitis B vaccine to Ricky's condition by explaining that Ricky's immune system cross-reacted with myelin. This initial report also indicated that Ricky may have had a "post-immunization encephalomyelitis, as no infectious basis was found for the meningoencephalitis." Id. at 4. A supplemental report referenced "post-vaccination encephalomyelitis, which is a form of acute disseminated encephalomyelitis." Exhibit 48 at 1.

Regardless of the name assigned to Ricky's condition, Dr. Steinman opined that the hepatitis B vaccine caused harm to Ricky's neurological functioning. Exhibit 27 at 4; exhibit 48 at 2; tr. 59. Dr. Steinman offered the theory of molecular mimicry to explain how the hepatitis B vaccine can cause neurological damage. According to Dr. Steinman, a portion of the hepatitis B vaccine contains a sequence of molecules that resembles (or mimics) a sequence of molecules in myelin. Exhibit 27 at 3-4. Dr. Steinman also opined that other causes for Ricky's seizures had been excluded. Exhibit 27 at 2, 4; exhibit 48 at 2.

Respondent filed her report on June 18, 2008, and asserted that Ms. Bunch had failed to establish that she was entitled to compensation. Respondent also filed the report of Dr. John MacDonald (a pediatric neurologist), his curriculum vitae, and the literature on which he relied. Exhibits A-L. The basic thrust of Dr. MacDonald's report was that Ricky's "clinical picture here is classical for viral encephalitis." Exhibit A at 5.

After receiving Dr. MacDonald's report, respondent requested an opportunity to present the report from another expert, Dr. Richard Stiehm (a pediatric immunologist), and this request

was granted. Respondent filed Dr. Stiehm's report, curriculum vitae, and literature associated with Dr. Stiehm's report. Exhibits M-AA. Dr. Stiehm challenged two portions of Dr. Steinman's opinion. Similar to Dr. MacDonald, Dr. Stiehm opined that Ricky's neurologic disorder "was due to viral encephalitis." Dr. Stiehm went one step further than Dr. MacDonald in that Dr. Stiehm identified the specific virus – herpes simplex virus type 2. Exhibit M at 6.

In addition, Dr. Stiehm disagreed with a theory that a six-week-old child's immune system could attack his own nervous system. According Dr. Stiehm, cross reactivity of hepatitis B virus and myelin "at such an early age is highly unlikely since the infant's immune response, particularly a T-cell response necessary to cause demyelination, is developmentally immature, antigenically inexperienced, and functionally deficient." Exhibit M at 7; tr. 164.

At a status conference on September 19, 2008, Ms. Bunch indicated that she wanted to file a supplemental expert report from Dr. Steinman. Ms. Bunch did so and also filed medical literature on December 17, 2008. Exhibits 48-52. Dr. Steinman's supplemental report stated that Ricky suffered from "post-vaccination encephalomyelitis, which is a form of acute disseminated encephalomyelitis." Exhibit 48 at 1. Dr. Steinman also stated that Ricky's symptoms, which Dr. MacDonald and Dr. Stiehm had linked to a virus, were also "classical for a post-immunization encephalomyelitis." Id. at 2. Responding to Dr. Stiehm's comment about an infant's immune system, Dr. Steinman also stated that Ricky's receipt of a hepatitis B vaccination, which was consistent with the recommendation of the American Academy of Pediatrics, demonstrates that Ricky's immune system was not functionally deficient. Id.

After the parties filed these reports, a hearing was held on April 15, 2009, in San Francisco, California. During this hearing, Ms. Bunch, who resides in Alaska; Dr. Steinman, who works in Stanford, California; and Dr. Stiehm, who works in Los Angeles, California; testified in person. Following the hearing, Ms. Bunch requested an opportunity to obtain a report from a specialist in pediatric infectious diseases. This request was deferred. A second hearing was held on June 4, 2009, in Washington, D.C. Dr. MacDonald and Dr. Steinman (in rebuttal) testified. Dr. Stiehm participated by telephone.

After the hearing, Ms. Bunch renewed her request to obtain a report from a specialist in pediatric infectious diseases. Ms. Bunch wanted to rebut Dr. Stiehm's opinion that the herpes simplex virus caused Ricky's encephalitis. This issue was again deferred, pending a determination about whether Ms. Bunch had established, by a preponderance of the evidence, that the hepatitis B vaccine can cause a seizure disorder in a child less than six weeks old as stated by Dr. Steinman. If Ms. Bunch had failed to meet her burden, then exploring other potential causes for Ricky's seizures, such as the herpes simplex virus, would not be necessary. See Doe v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1358 (Fed. Cir. 2010).

In an unrecorded status conference held on June 24, 2009, the undersigned agreed to present a draft decision to the parties. The intended purpose of the draft decision was to allow the experts to address the undersigned's presentation of medical science. On September 2, 2009,

a final (not draft) decision was mistakenly filed. Ms. Bunch filed a motion to vacate this decision, which was granted on September 4, 2009.

After September 2009, the parties have filed a series of reports from Dr. Steinman, Dr. MacDonald, and Dr. Stiehm. The parties have also filed additional medical articles cited by their experts. This process concluded on April 28, 2010, when Ms. Bunch filed the last report from Dr. Steinman. In a May 18, 2010 status conference, both parties stated that the evidentiary record was closed and neither requested an additional hearing. See Vaccine Rule 8(d) (stating "The special master may decide a case on the basis of written submissions without conducting an evidentiary hearing.). Both parties declined the opportunity to file briefs. Thus, the case is ready for adjudication.

III. Standards for Adjudication

There are at least three distinct parts to evaluating whether a petitioner is entitled to compensation. One part is to articulate the elements of the petitioner's case. These elements are "what" petitioner must establish. A separate part of the analysis is the quantum of evidence that a petitioner must introduce, which is the burden of proof. A final aspect is the process of weighing or evaluating the evidence that is submitted. These three portions are discussed separately.

A. Elements of Petitioner's Case

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

When a petitioner proceeds on a causation-in-fact theory, a petitioner must establish three elements. The petitioner's

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

Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

B. Burden of Proof

For the elements that petitioners are required to prove, their burden of proof is a preponderance of the evidence. 42 U.S.C. § 300aa–13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

C. How to Weigh Evidence

The preceding sections explain what a petitioner is required to establish and what level of proof satisfies the petitioner's obligation. The remaining issue is how to evaluate evidence submitted to meet the standard of proof on those elements. Three authorities generally instruct special masters in how to evaluate evidence. They are Congress, the United States Court of Federal Claims, and the United States Court of Appeals for the Federal Circuit.

Congress is the first authority for instructions about how to weigh evidence. In enacting the National Vaccine Injury Compensation Act, specifically section 13, Congress provided some instructions about how special masters should analyze the evidence. Among other provisions, section 13 dictates that the special master should consider "the record as a whole." Section 13 also provides that the special master shall consider "any diagnosis, conclusion, medical judgment or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition or death." Nevertheless, "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court."

The second authority is the United States Court of Federal Claims. Congress authorized the Court of Federal Claims to promulgate rules of procedure for cases in the Vaccine Program. 42 U.S.C. § 300aa–12(d)(2). Collectively, the judges of the Court of Federal Claims have issued the Vaccine Rules. The Vaccine Rules, in turn, provide that the special master "must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties." Vaccine Rule 8(b)(1).

The third authority is the United States Court of Appeals for the Federal Circuit. Decisions by the Federal Circuit are binding precedent. 42 U.S.C. § 300aa–12(e). In regard to

weighing evidence, some Federal Circuit cases that reviewed decisions of special masters were relatively silent about how special masters should evaluate evidence in deciding whether a vaccine caused an injury. E.g. Lampe, 219 F.3d at 1359-62; Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (reviewing special master's evidentiary determination under the abuse of discretion standard). These decisions are in accord with how the Federal Circuit has reviewed challenges to causation in contexts outside of the Vaccine Program. See Southern California Fed. Sav. & Loan Ass'n v. United States, 422 F.3d 1319, 1337 (Fed. Cir. 2005) (affirming trial court's finding, despite some evidence to the contrary, that FIRREA caused the bank's recapitalization). Within the Vaccine Program, the Federal Circuit expected that special masters would "consider[] the relevant evidence of record, draw[] plausible inferences and articulate[] a rational basis for the decision." Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991).

A particular topic on which the Federal Circuit has guided special masters is the process for evaluating the testimony of expert witnesses. In the Vaccine Program, an expert's opinion may be evaluated according to the factors identified by the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Terran, 195 F.3d at 1316. As recognized in Terran, the Daubert factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and, (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2, citing Daubert, 509 U.S. at 592-95.

After Terran, decisions from judges of the Court of Federal Claims have consistently cited to Daubert. E.g. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 742-45 (2009); Cedillo v. Sec'y of Health & Human Servs., 89 Fed. Cl. 158, 182 (2009), appeal docketed, No. 2009-5004 (Fed. Cir. Oct. 7, 2009); De Bazan v. Sec'y of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2006) ("A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness's testimony regarding causation."), rev'd on other grounds, 539 F.3d 1347 (Fed. Cir. 2008); Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006); Piscopo v. Sec'y of Health & Human Servs., 66 Fed. Cl. 49, 54 (2005).

The reliability of the expert's theory is not presumed. A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly, 592 F.3d at 1324. Furthermore, the reliability of an expert's theory affects the persuasiveness of the evidence. Special masters may "inquir[e] into the reliability of testimony from expert witnesses. Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special

masters have that responsibility in Vaccine Act cases." Id. at 1325. The finding that an expert's opinion passes a minimal standard of reliability does not require acceptance of that expert's theory because "disputes about the degree of relevance or accuracy (above this minimum threshold [of reliability]) may go to the testimony's weight." i4i Ltd. Partnership v. Microsoft Corp., 598 F.3d 831, 852 (Fed. Cir. 2010).

In evaluating expert testimony and scientific literature, special masters should analyze scientific literature "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." Andreu, 569 F.3d at 1379. "In other words, a finding of causation in the medical community may require a much higher level of certainty than that required by the Vaccine Act to establish a prima facie case. The special master must take these differences into account when reviewing the scientific evidence." Broekelschen v. Sec'y of Health & Human Servs., 89 Fed. Cl. 336, 343 (2009), appeal docketed, No. 2009-5132 (Fed. Cir. Sept. 28, 2009).

Generally, the Federal Circuit expects that a special master will present a reasonable basis for rejecting the opinion of one expert. Lampe, 219 F.3d 1361; Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

These standards will be used to determine whether Ms. Bunch has established that she is entitled to compensation. For reasons explained in the following section, Ms. Bunch has not met her burden of proof. Therefore, she is not entitled to compensation.

IV. Analysis

The parties have presented competing theories to explain what caused Ricky's seizure disorder. Ms. Bunch claims that the hepatitis B vaccine did so. The evidence relating to the hepatitis B vaccine is discussed in section A below. Respondent claims that the causative agent was the herpes simplex virus, type 2. The evidence on this separate factor is discussed in section B.[2]

A. Whether the Hepatitis B Vaccince Caused Ricky's Seizures

To be entitled to compensation, Ms. Bunch must establish the three elements required by Althen, which are set forth above. Each of these elements are reviewed in the following sections. The dispositive findings are presented for the first and second prongs.

[2] Evidence about whether a herpes simplex virus caused Ricky to suffer an encephalopathy was not considered in determining whether Ms. Bunch has established the Althen factors. This separation does not prejudice Ms. Bunch because evaluating any causal contribution by a herpes simplex virus would only make Ms. Bunch's case more difficult.

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

The first element in Ms. Bunch's case is "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278. This theory must "pertain[] specifically to the petitioner's case." Moberly, 592 F.3d at 1322. Ms. Bunch has not met her burden on this element.

Ms. Bunch's evidence on this element comes from Dr. Steinman. Drawing upon his background as a doctor with board certification in neurology and as the head of the immunology program at Stanford Medical School; tr. 53, exhibit 28; Dr. Steinman presented different, but related, theories explaining how the hepatitis B vaccine can cause seizures. His two written pre-trial reports and a majority of his testimony presented the theory that the hepatitis B vaccine can cause demyelination and demyelination can lead to seizures. In this regard, Dr. Steinman discussed two different components of the immune system: T-cells and B-cells. During the hearing, Dr. Steinman also briefly opined that the hepatitis B vaccine can cause an injury to neurons. Because all of Dr. Steinman's theories involve the hepatitis B vaccine activating the immune system in a way that causes damage to the nervous system, immunology and neurology are discussed first. This summary provides a context for the subsequent evaluation of Dr. Steinman's theories.

a. Basic Immunology and Neurology

Because vaccines are intended to stimulate the immune system, special masters frequently hear testimony about the immune system. See Snyder v. Sec'y of Health & Human Servs., No. 01-162V, 2009 WL 332044, at *52-57 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), motion for review denied, 88 Fed. Cl. 706 (2009); Tosches v. Sec'y of Health & Human Servs., No. 06-192V, 2008 WL 440285, at *4-5 (Fed. Cl. Spec. Mstr. Jan 31, 2008). The following summary, about which there is no dispute, provides a context for the different opinions of Dr. Stiehm and Dr. Steinman.

The body's adaptive immune system has two components. One portion produces antibodies and is sometimes referred to as the B-cell system. Tr. 163. The hepatitis B vaccine primarily stimulates a response from the B-cell side. Tr. 250.

The other portion of the adaptive immune system is known as the T-cell system. The T-cell system produces various types of cells that have different functions. Some T-cells are known as "helper" cells because they assist the B-cells in responding to an antigen. Other T-cells are known as effector cells because they attack (kill) some invading pathogens like viruses. Tr. 163; see also tr. 270 (Dr. Steinman discussing T-helper cells).

Dr. Steinman suggests that in certain people, either the antibodies or the T-cells are misdirected. Instead of attacking and destroying a foreign substance, antibodies or the T-cells turn against the constituent parts of the body. In Ricky's case, Dr. Steinman identified two body parts as the possible targets for the errant T-cells or antibodies, either myelin or neurons.

Myelin and neurons are both parts of the nervous system. Myelin is like the plastic insulation around a wire. Tr. 133. Neurons that transmit information. See tr. 133; Dorland's Illustrated Medical Dictionary, (30th Ed. 2003) at 1256.

As mentioned previously, Dr. Steinman's theory begins with the proposition that some portion of the hepatitis B virus has a molecular structure that resembles (or mimics) some portion of myelin. When two substances have similarities in their molecular structure, they are said to be "homologous." The homology between myelin basic protein and a portion of the hepatitis B virus, known as the viral polymerase, was reported in 1985. See exhibit 34 (RS Fujinami et al., Amino Acid Homology Between the Encephalitogenic Site of Myelin Basic Protein and Virus: Mechanism for Autoimmunity, 230 Science 1043 (1985)). The hepatitis B viral polymerase, which was studied by Doctors Fujinami and Oldstone, is not found in the hepatitis B vaccine. The hepatitis B vaccine was the subject of another study, which was conducted by Dr. Bogdanos. Dr. Bogdanos observed that compared to controls, people who received the hepatitis B vaccine developed auto-antibodies directed against several myelin antigens at an increased rate. Exhibit 33 (Dimitrios-Petrou Bogdanos, A Study of Molecular Mimicry and Immunological Cross-reactivity Between Hepatitis B Surface Antigen and Myelin Mimics, 12(3) Clin. Dev. Immunol. 217, 222 (2005)).[3]

From the idea that the hepatitis B vaccine shares molecular structure with a part of the nervous system, Dr. Steinman offered a theory to explain how the hepatitis B vaccine can cause a neurological problem. Dr. Steinman explained that the hepatitis B vaccine, like all vaccines, is designed to trigger an immune response. The body responds to the hepatitis B vaccine by attacking it. According to the theory offered by Dr. Steinman, the immune system becomes misdirected. Instead of focusing on the hepatitis B vaccine, the immune system recognizes the body's myelin as a foreign substance and attacks and destroys some portion of the myelin. This entire process – beginning with the homology between two substances and concluding with an auto-immune attack on some part of the body – is frequently referred to as "molecular mimicry."

Within the medical literature, molecular mimicry has been offered as a theory to explain many autoimmune diseases. Molecular mimicry has also been proposed by petitioners and experts retained by petitioners in the Vaccine Program as a theory that causally connects a vaccine to the petitioner's injury. When petitioners have asserted molecular mimicry, respondent has often challenged its reliability. Special masters' evaluations of molecular mimicry have varied. See, e.g., Schmidt v. Sec'y of Health & Human Servs., No. 07-20V, 2009 WL 5196169, at *5, 7, 11 (Fed. Cl. Spec. Mstr. Dec. 17, 2009) (discussing whether flu vaccine can cause transverse myelitis via molecular mimicry); Shaw v. Sec'y of Health & Human Servs., No. 01-707V, 2009 WL 3007729, at *23 (Fed. Cl. Spec. Mstr. Aug. 31, 2009) (petitioner's expert asserted that the hepatitis B vaccine can cause demyelination by molecular mimicry), mot. for review granted in part and remanded, 91 Fed. Cl. 715 (2010).

[3] The participants in Dr. Bogdanos's study did not develop any auto-immune disease.

b. Molecular Mimicry between the Hepatitis B Vaccine and Myelin

Dr. Steinman's primary theory is that the hepatitis B vaccine caused damage to Ricky's myelin. In his two reports filed before trial, Dr. Steinman discussed "myelin" extensively. For example, Dr. Steinman stated that "[i]t is known that Hepatitis A and Hepatitis B viruses share chemical sequences in their composition that are identical or highly similar to myelin proteins." Dr. Steinman also stated that: "[t]here is extensive cross reactivity between Hepatitis A and B viruses and myelin antigens." Exhibit 27 at 3. Dr. Steinman extended this point from the hepatitis B virus to the hepatitis B vaccine and, again, mentioned myelin. He stated that "immunization with Hepatitis B vaccine can evoke in some patients an immune response that is cross-reactive to myelin proteins." Exhibit 27 at 4, citing exhibit 33 (Bogdanos). In Dr. Steinman's supplemental report, which addressed the opinions expressed by Dr. Stiehm and Dr. MacDonald, Dr. Steinman again referred to "myelin mimics." Exhibit 48 at 1.

Myelin, in theory, can be attacked by either T-cells or B-cells. Initially, Dr. Steinman was understood to be focusing on T-cells and the withdrawn September 2, 2009 decision discussed T-cells extensively. The September 2, 2009 decision found that Ms. Bunch had failed to establish that a newborn's T-cell system is sufficiently robust to damage myelin. That analysis is essentially repeated in section (1) below.

After reviewing the September 2, 2009 decision, Ms. Bunch and Dr. Steinman argued that the analysis of T-cells was mistaken. Dr. Steinman maintained that B-cells, not T-cells, were acting. The analysis for B-cells in newborns is set forth in section (2) below.

(1) Molecular Mimicry via T-cells in Newborns

Neither of Dr. Steinman's pre-trial reports disclosed whether Dr. Steinman believed that T-cells or antibodies caused the damage to myelin. See exhibit 27, exhibit 48. Dr. Steinman's testimony on direct examination was ambiguous. He stated that the damage was caused by white blood cells, known as lymphocytes. Tr. 64; tr. 70; tr. 84. White blood cells include both T-cells and antibodies. Dorland's at 1077. When questioned on cross-examination about what part of the immune system was causative, Dr. Steinman responded "There's a predominance of T-cells." Tr. 112.[4]

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[4] Later, after the hearing, Dr. Steinman stated that "molecular mimicry is relevant without any T cell response" because antibodies (B-cells) are sufficient. Exhibit 55 at 1. The effectiveness of a newborn's B-cells is taken up in the section IV.A.1.b(2) below.

Dr. Steinman's statement that T-cells are not necessary for molecular mimicry has not prompted Ms. Bunch to abandon or waive formally the T-cell theory. Because Dr. Steinman's testimony about T-cells remains part of the record, it must be considered. See 42 U.S.C. § 300aa–13(a) (instructing special masters to consider the "record as a whole.").

The remainder of the first day of the hearing emphasized the effectiveness of T-cells. Dr. Stiehm testified that he interpreted Dr. Steinman's theory as involving a response from T-cells. Tr. 248-50. One of the two themes of Dr. Stiehm's testimony was that the T-cells of a newborn cannot damage the baby via an attack against self. Tr. 164-196. (Dr. Stiehm's other theme was that Ricky's seizures were caused by herpes simplex virus, type II.) Dr. Steinman, in turn, defended his opinion by testifying on rebuttal that T-cells in newborns actually are strong enough to cause harm. Tr. 270-75. Thus, through at least the conclusion of the first day of the hearing, Dr. Steinman was opining that the hepatitis B vaccine can cause a seizure disorder through molecular mimicry mediated by T-cells.

The reliability of Dr. Steinman's theory was challenged in a narrow sense: assuming that molecular mimicry is a reliable theory to explain how a vaccine can cause an autoimmune disease in some people, does a two-month-old child have a sufficiently robust immune system to cause an autoimmune disease? This more limited question is important because the petitioner's theory must "pertain[] specifically to the petitioner's case." Moberly, 592 F.3d at 1322. According to Dr. Stiehm, the immunologic damage to the myelin as described by Dr. Steinman is a T-cell mediated event. Dr. Stiehm stated that young infants cannot manufacture a T-cell mediated immune attack that is strong enough to harm their own body. Tr. 248-50.

The distinction between a newborn's B-cell system and T-cell system is important to Dr. Stiehm's critique of Dr. Steinman's opinion. In a newborn, the B-cell part of the immune system is functioning in some capacity. It functions effectively enough that a newborn will produce an antibody in response to receiving the hepatitis B vaccine. However, the antibody response is diminished such that doctors give booster vaccinations when the child's immune system is more mature. Tr. 164-65 (testimony of Dr. Stiehm).

Dr. Stiehm contrasted the B-cell system, which functions at reduced effectiveness, to the T-cell system, which, according to Dr. Stiehm, does not function effectively for newborns. Tr. 164-66. At one-month-old, a newborn's T-cell system is functioning at approximately 5 to 10 percent. Tr. 260. The more limited functioning of the T-cell system explains why vaccines that prompt a T-cell response are delayed until the baby reaches at least one year. Tr. 254-55; see also tr. 261-63. According to Dr. Stiehm, because the T-cells that are present in a newborn are not functioning as effectively as they do in adults, the damage to myelin cannot occur as postulated by Dr. Steinman. Tr. 197. Dr. Stiehm also stated that there are virtually no cases of any autoimmune diseases, of any type, occurring in the first six months of life because most autoimmune diseases are T-cell mediated. Tr. 166.

During the hearing, Dr. Steinman appeared, initially, not to dispute that the T-cells are the part of the immune system that elicits the demyelinating response. Dr. Steinman also agreed that the T-cell system of a newborn functions at a diminished capacity. However, Dr. Steinman stated that even at a diminished capacity, Ricky's T-cell response was strong enough to create damage to his myelin. Tr. 270; tr. 275-6. Dr. Stiehm refuted this assertion by stating that the T-cell's "helper" function – the way some T-cells assist the B cells in producing a weak antibody

response – does function at a very diminished capacity. It is the T-cell's effector function – the T-cell's ability to cause the damage to the myelin – that does not function in newborns. Tr. 291.

On this point, Dr. Stiehm's opinion was more persuasive than Dr. Steinman's. Ms. Bunch has not established that molecular mimicry is a reliable theory for a child who was six weeks old. A preponderance of the evidence supports a finding that because Ricky was less than two-months-old, he could not react in a way postulated by Dr. Steinman, that is, Ricky could not mount a sufficiently robust attack by T-effector cells to harm his own neurological system. Several factors support this finding.

First, Dr. Stiehm's expertise is a primary consideration. Dr. Stiehm has studied the immune system of newborn children for approximately 40 years. He has written more than 80 publications about the immune system of newborns. He is the editor of a leading textbook about the immune system of newborns. Exhibit N (curriculum vitae of Dr. Stiehm); tr. 156-61. Dr. Steinman acknowledged that Dr. Stiehm "has studied neonatal immunology probably as deeply as anyone in the world." Tr. 270.[5]

Second, Dr. Stiehm's opinion is supported by medical literature filed in this case. One article, which summarized three presentations given during a symposium on neonatal immunology conducted by the Pediatric Academic Societies, stated that newborn infants have "an immune system capable of reacting, albeit not completely, to foreign antigen and microbes." The article continued and stated that "[c]linical observations indicate that the human fetus and neonate are more vulnerable than are older children to pathogens that require T-cells for their optimal control, including enteroviruses, [and] herpesviruses." Exhibit AA (David B. Lewis et al., Newborn Immunology: Relevance to the Clinician, Curr. Probl. Pediatr. Adolesc. Health Care, May/June 2006) at 189. The authors of this study particularly noted that young infants can

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[5] In submissions made after the hearing, Dr. Steinman asserted that his expertise was worth more than Dr. Stiehm's experience because Dr. Steinman is board-certified in both immunology and neurology. According to Dr. Steinman, his background lets him see the whole picture better than Dr. Stiehm, who is knowledgeable about immunology (but not neurology) and better than Dr. MacDonald, who is knowledgeable about neurology (but not immunology). Exhibit 55 at 6; exhibit 56 at 4-5.

Dr. Stiehm's experience is specific to the exact question being examined – what are the capabilities of a newborn's immune system. This specificity makes Dr. Stiehm's opinion on this particular question more persuasive. A finder of fact may consider the qualifications of an expert when weighing competing opinions. See Dura Auto Sys. of Indiana , Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002) (explaining that a theoretical economist should not be permitted to testify regarding an econometric study if the expert did not have a background in econometrics); Waleryszak v. Sec'y of Health & Human Servs., 45 Fed. Cl. 573, 578 (1999), appeal dismissed, 250 F.3d 753 (Fed. Cir. 2000) (table); cf. Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 782 (3d Cir. 1996) (stating "witnesses may be competent to testify as experts even though they may not, in the court's eyes, be the 'best' qualified. Who is 'best' qualified is a matter of weight.")

respond to the hepatitis B vaccine, but lack the capacity to manufacture T-cells to fight the herpes simplex virus. Id. at 190-91; see also tr. 257-59 (Dr. Stiehm's testimony about this article).

Third, various examples from relatively common experiences also support an opinion that the T-effector-cell system in newborns is not powerful. Newborns are relatively vulnerable to being infected with viruses, such as the viruses that cause the common cold. Newborns are also particularly at risk to being infected by the herpes simplex virus. Tr. 167. (Whether Ricky was infected with the herpes simplex virus is discussed in section IV.B below).[6]

The strength of the newborn's immune system is also reflected in the recommended vaccination schedule. The American Academy of Pediatrics recommends that some vaccines be administered after a child reaches two-years-old. Tr. 260-63.

The fourth and least important factor is that Dr. Stiehm's opinion about the relative weakness of a newborn's T-effector cells matches what is known about acute disseminated encephalomyelitis ("ADEM"). ADEM is relevant because that is the disease that Dr. Steinman stated the hepatitis B vaccine caused. Exhibit 48 at 1. No medical article in the record in this case indicates that ADEM affects children as young as two months of age.

The medical articles that were filed indicate that the earliest age of onset for ADEM is older than Ricky was in July 1994. In a study of 84 pediatric cases of ADEM, the "age of presentation ranged from 0.4 [4.8 months] to 16 years, with a mean age of 5.3 ± 3.9 years and a median of 4.5 years." Exhibit EE (Silvia Tenembaum et al., Acute disseminated encephalomyelitis: A long-term follow-up study of 84 pediatric patients, 59(2) Neurology 1224, 1225 (2002)).[7] A smaller study (14 patients) reported that the average age was 6.5 ± 4.8 years. Exhibit 50 (Takaai Ishizy et al., CSF cytokine and chemokine profiles in acute disseminated encephalomyelitis, 175 J of Neuroimmunology 52, 53 (Table 1) (2006)). A third study, which also involved 14 patients, reported that the age of onset was 10 months to 18 years. Exhibit 51 (John A. D. Leake, Acute Disseminated Encephalomyelitis in Childhood: Epidemiologic, Clinical and Laboratory Features, 23 Pediatr Infect Dis J 756, 758 (2004)). In sum, the youngest child reported to have ADEM in the articles filed into this record was nearly five months old. Most children seem to be at least three years old.

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[6] After the hearing, Ms. Bunch filed, as exhibit 54, an article published in 2004. Martin O.C. Ota et al., Hepatitis B immunisation induces higher antibody and memory Th2 responses in new-borns than in adults, 22 Vaccine 511 (2004). Given that Dr. Stiehm's report raised the question about a neonate's ability to respond to the hepatitis B vaccine, Ms. Bunch should have submitted this article before the hearing.

In any event, this article does not assist Ms. Bunch in refuting Dr. Stiehm's opinion that infants less than six weeks old do not produce a robust response of T-effector cells. The article mentions "helper" T-cells, which are the type of T-cells that assist in the production of antibodies. The article appears not to discuss T-effector cells.

[7] A duplicate of this article was filed as exhibit 49.

As to why no child as young as Ricky has been reported to have been affected by ADEM, Dr. Steinman offered an explanation, which was not very persuasive. According to Dr. Steinman, the articles may suffer from "ascertainment bias" in that the researchers were not looking for cases of neo-natal ADEM. Tr. 75. Both Dr. Stiehm and Dr. MacDonald disagreed with the assertion that ascertainment bias prevented researchers from finding cases of ADEM in younger infants. Tr. 225-26 (Dr. Stiehm); tr. 377-78 (Dr. MacDonald). Of course, it is possible that a very young child has developed ADEM and this case was not reported anywhere. But, this situation is not likely. It seems more reasonable to find that ADEM has not been reported in very young children because ADEM cannot happen in very young children for the reasons explained by Dr. Stiehm.

Ultimately, the age at which ADEM has been recognized to commence is just one point of evidence supporting Dr. Stiehm's opinion that molecular mimicry cannot explain what happened to Ricky. Other supporting pieces of evidence include Dr. Stiehm's experience and reputation, statements in medical articles, and the common observation that young children are more vulnerable to viruses.

For these reasons, Ms. Bunch has failed to establish, by a preponderance of the evidence, the reliability of a theory in which a vaccine stimulates T-cells to cause an autoimmune attack in an infant who is less than two months. This finding is limited to newly born children.[8]

(2) Molecular Mimicry via B-cells in Newborns

The theory that B-cells, rather than T-cells, can cause an autoimmune reaction in newborns was presented circuitously. The pre-trial reports did not discuss B-cells explicitly. As mentioned earlier, Dr. Steinman's first report did not explain whether the activated part of the adaptive immune system was T-cells or B-cells. See exhibit 27. Dr. Stiehm appears to have understood that Dr. Steinman's opinion was predicated upon T-cells because Dr. Stiehm's pre-hearing report stated that "a major reaction following a vaccine at such an early age is highly unlikely since the infant's immune response, particularly a T-cell response necessary to cause demyelinization, is developmentally immature, antigenically inexperienced, and functionally deficient." Exhibit M, filed Sept. 3, 2008, at 6. Dr. Steinman's supplemental report provided him an opportunity to review Dr. Stiehm's opinion and to explain that his theory did not rely upon T-cells. Dr. Steinman did not say that his theory relied upon B-cells. See exhibit 48 at 2.

During the hearing, the experts did not devote much attention to B-cells explicitly. Dr. Steinman's direct testimony talked about white blood cells. Tr. 64. This term is sufficiently broad to include antibodies, but, the overall context of Dr. Steinman's testimony suggested that Dr. Steinman was discussing T-cells, not B-cells. See tr. 112. Dr. Stiehm explained why he believed that T-cells could not cause the harm as postulated by Dr. Steinman.

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[8] Outside of the context of newborns, Dr. Stiehm stated that in general, molecular mimicry "is a very likely cause of cross-reactive autoimmunity." Tr. 250.

In his rebuttal testimony, for the first time, Dr. Steinman talked about antibodies explicitly. Dr. Steinman stated: "So inflammation is largely mediated by the cellular arm of the immune system, T cells. But inflammation is also mediated in acute disseminated encephalomyelitis and encephalitis by antibodies. And these antibodies are of a type called immunoglobulin G." Tr. 270. Similarly, Dr. Steinman testified that "T cells are very much a part of the theory, but so is antibody." Tr. 274. These references to antibodies are relatively insubstantial. The focus of the rebuttal phase of the first day of the hearing was on T-cells. See tr. 270- 94.

On the second day of the hearing, Dr. Steinman's testimony focused on responding to Dr. MacDonald's and Dr. Stiehm's theory that Ricky suffered from a viral encephalitis. According to Dr. Steinman, there is nothing in the record that supports a diagnosis of a viral encephalitis. Tr. 408-13. Dr. Steinman did not discuss B-cells or antibodies during the second day of hearing.

Under these circumstances, the withdrawn September 2, 2009 decision discussed why T-cells did not function in the way postulated by Dr. Steinman. To the extent that Dr. Steinman had intended to express the idea that his opinion was predicated upon B-cells, that portion of Dr. Steinman's opinion was not understood. After the September 2, 2009 decision was withdrawn, Ms. Bunch presented additional reports from Dr. Steinman.[9]

In a post-hearing report, Dr. Steinman stated that "an antibody response is precisely what can and does break tolerance to myelin." Exhibit 55 at 7. He also stated "Molecular mimicry is fully operative at the B cell level." Id. at 8. Dr. Steinman relied primarily upon three articles, written by Wucherpfennig, Bogdanos, and Robinson. Exhibit 30 (Kai Wucherpfennig et al., Recognition of the Immunodominant Myelin Basic Protein Peptide by Autoantibodies and HLA-DR2-restricted T Cell Clones from Multiple Sclerosis Patients, 100 J. Clin. Invest., No. 5, 114 (1997)); exhibit 33 (Dimitrios-Petrou Bogdanos et al., A Study of Molecular Mimicry and Immunological Cross-Reactivity Between Hepatitis B Surface Antigen and Myelin Mimics, 12(3) Clinical & Developmental Immunology, 217 (2005)); exhibit 37 (William H. Robinson et al., Protein Microarrays Guide Tolerizing DNA Vaccine Treatment of Autoimmune Encephalomyelitis, 21 No. 9 Nature Biotechnology 1033 (2003)). Why Dr. Steinman emphasized T-cells during the hearing and B-cells after the hearing is not especially clear.[10] Consistently presenting one theory is more persuasive because consistency avoids the impression that a later-presented theory is merely an afterthought. See Weisgram v. Marley Co., 528 U.S. 440, 455 (2000) (stating "It is implausible to suggest, post-Daubert, that parties will initially present less than their best expert evidence in the expectation of a second chance should their

[9] The September 2, 2009 decision was withdrawn for procedural reasons, not because Dr. Steinman's testimony was unclear.

[10] Dr. Steinman indicated that the pending publication of article by Dr. Derfuss et al. for which he served as a peer-reviewer prevented an earlier discussion. See exhibit 55 at 1-2. This article, which was filed as exhibit KK, develops the concepts presented in the three earlier articles.

first try fail."). Regardless of how the theory that in newborns, the hepatitis B vaccine can stimulate the production of antibodies that can cause an autoimmune attack on the nervous system entered the case, it is part of the record and will be evaluated.

In their responses to Dr. Steinman's post-hearing report, Dr. Stiehm and Dr. MacDonald generally do not challenge the proposition that antibodies can cause damage. See exhibit JJ and exhibit RR. Dr. MacDonald challenges Dr. Steinman's proposition that molecular mimicry is relevant to causation without a response from the T-cells. Exhibit RR. Dr. Stiehm, again, objects to the assertion that autoimmunity can develop in a newborn. According to Dr. Stiehm, autoimmune diseases do not develop in newborns for two reasons. First, the newborn's B-cell system does not produce cross-reactive antibodies in the first six months. Exhibit JJ at 3. Second, autoimmune diseases against tissues are "nearly always T-cell mediated." Exhibit JJ at 4.

Dr. Stiehm's second point (about T-cells mediating autoimmune diseases) has been discussed above. Therefore, the remaining question is whether Ms. Bunch has established the reliability of the theory that B-cells in a newborn can lead to an autoimmune attack on the nervous system. A preponderance of the evidence fails to support the reliability of this theory.

Many reasons for finding a lack of support for the B-cell theory overlap with the reasons for finding a lack of support for the T-cell theory. For example, Dr. Stiehm has studied the immune system of neonatal children extensively. In addition to editing a leading textbook on this subject, Dr. Stiehm has written a chapter on the B-cell system. Tr. 161. Thus, even within the subspecialty of neonatal immunology, Dr. Stiehm possesses knowledge about the very precise question here. On the question about a neonatal infant's immune system, Dr. Steinman does not have comparable expertise.

Second, information in the record is inconsistent with Dr. Steinman's assertion that B-cells can cause autoimmunity in a newborn. Dr. Steinman testified that the type of antibody that causes autoimmunity is immunoglobulin G, which is commonly abbreviated IgG. Tr. 270. A newborn's production of IgG is diminished. Exhibit AA (Lewis: Newborn Immunology) at 198; exhibit BB (David B. Lewis and Wenwei Tu, The Physiologic Immunodeficiency of Immaturity (Chapter 22) in Immunologic Disorders in Infants & Children (5th ed. 2004) (E. Richard Stiehm et al., eds)) at 723-24. The reduced capability in producing IgG explains why newborns who receive the hepatitis B vaccination at birth must receive booster doses. See Exhibit BB at 720; see also tr. 260 (Dr. Stiehm discussing vaccination schedule).

Dr. Stiehm explained that infants develop the ability to produce cross-reactive antigens through the first six months. In early life, the newborn's "immune responses are initially antigen specific." Exhibit JJ at 3. This means that a newborn, like Ricky, will produce a response to the hepatitis B vaccine, but that this response will not affect how the newborn responds to other substances. Dr. Steinman did not challenge this explanation. See exhibit 56.

Dr. Steinman's response attempted to present examples of antibody diseases that are manifested as seizures in the neonatal period. Exhibit 56 at 3-4. This response was not persuasive because Dr. Stiehm demonstrated why the diseases identified by Dr. Steinman are not comparable to the theory proposed to explain how the hepatitis B vaccine caused seizures in Ricky. Exhibit WW at 2. Again, Dr. Stiehm's greater experience in the field of neonatal immunology adds weight to his opinion and increases the persuasive value of it.

A third reason for finding that Ms. Bunch has failed to establish the reliability of the theory that B-cells can cause autoimmune diseases in a newborn is the example of ADEM. As discussed in connection with the assertion that T-cells can cause autoimmune disease, reports of ADEM in infants as young as six weeks have not been found. The absence of reports supports an inference that ADEM does not occur in infants this young. Dr. Stiehm's opinion reinforces this logic by explaining that the newborn's immune system makes the onset of ADEM at this age biologically implausible.

Consequently, for these reasons, Ms. Bunch has not established the reliability of the theory that the hepatitis B vaccine can induce B-cells to cause autoimmune disease in the central nervous system of a newborn. Much like the assessment regarding T-cell immaturity, the finding that a newborn's B-cell system cannot lead to an autoimmune disease via molecular mimicry is limited to infants less than six months old. As Dr. Steinman recognized, the Wucherfennig article, on which he relied heavily, does not "have any bearing on whether children at one or two months of age are immunologically competent." Tr. 421.

c. Molecular Mimicry between the Hepatitis B Vaccine and Neurons

As discussed in the preceding two sections, Dr. Steinman's theory shifted from initially being a theory based on T-cells to a theory based on B-cells. A similar change occurred with respect to the part of Ricky's body that a component of the immune system attacked. In his two pre-trial reports, Dr. Steinman identified myelin. At the hearing, Dr. Steinman discussed neurons. See tr. 76 ("the brunt of [Ricky's] inflammation was directed to neurons"). However, after the hearing and after reviewing the withdrawn September 2, 2009 decision, Dr. Steinman returned to myelin.

The problems with Dr. Steinman's idea that Ricky's myelin was damaged are discussed in section IV.A.2 below. The present section explains why Ms. Bunch has failed to establish, by a preponderance of the evidence, that the hepatitis B vaccine can induce an autoimmune attack on neurons. As discussed in the withdrawn September 2, 2009 decision, there are three problems with this theory.

First, the theory appears to have been raised to address the evidence showing that Ricky did not experience demyelination. (This evidence is discussed in section IV.A.2) As pointed out on cross-examination, Dr. Steinman's two reports did not discuss damage to neurons. Tr. 94-95; see also exhibit 28, exhibit 48. In testimony, Dr. Steinman indicated that too much attention was

being placed on the results of the MRI. Tr. 94. Dr. Steinman stated that the more important diagnostic test was the EEG. Tr. 77-78. This testimony contradicts Dr. Steinman's implicit evaluation of the medical records because Dr. Steinman's written reports did not refer to the EEG. Tr. 106; see also exhibit 28; exhibit 48.

Second, evidence supporting a theory that the body's response to the hepatitis B vaccine cross-reacts with neurons was absent. Ms. Bunch presented no evidence to show that the molecular structure of the hepatitis B vaccine mimics the molecular structure of neurons. Dr. Steinman recognized that no evidence shows a similarity between the hepatitis B vaccine and neurons. Tr. 134. At best, Dr. Steinman speculated that the hepatitis B vaccine shares some molecular structure with neurons. Tr. 432 ("a molecule that targets white matter and portion of the myelin sheath may also target gray matter [neurons]."") (emphasis added). Without some showing of homology, the theory of molecular mimicry between the hepatitis B vaccine and neurons is much less reliable than the theory of molecular mimicry between the hepatitis B vaccine and myelin. The latter theory is supported, to some degree, by the article by Bogdanos and the article by Fujinami and Oldstone.

Third, even if the body could mount a cross-reaction on neurons, such an attack would be mediated through either T-cells or B-cells. See tr. 186 (Dr. Stiehm addressing T-cells). For the reasons explained above, Dr. Stiehm persuasively explained that newborns lack a sufficiently robust immune system to allow an autoimmune attack on neurons.

These three reasons for finding a lack of reliability in Dr. Steinman's theory that the hepatitis B vaccine led to a direct autoimmune attack on Ricky's neurons were provided in the withdrawn September 2, 2009 decision. Dr. Steinman had an opportunity to review this decision and did little to controvert points one and two. See exhibit 56. Instead, Dr. Steinman explained how demyelination can lead to a problem in neurons. Exhibit 56 at 8-10.[11] A lack of rebuttal on points one and two suggest that they are sound.

In sum, Dr. Steinman has proposed various theories or one theory with variations. The hepatitis B vaccine caused an immune response – either T-cells or B-cells – that attacked some portion of the central nervous system – either myelin or neurons. Regardless of the precise formulation, no theory has been established as reliable in this case primarily because of Ricky's age. Ms. Bunch's failure to meet her burden of proof on the first element of Althen means that she is not entitled to compensation. Nevertheless, the remaining two prongs from Althen are discussed below.

[11] Evidence about demyelination in Ricky, to repeat, is discussed in section IV.A.2 below.

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

Ms. Bunch failed to establish, by a preponderance of the evidence, the second prong from Althen, which is "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Even if Ms. Bunch had established that a theory proposed by Dr. Steinman were reliable for explaining how the hepatitis B vaccine can cause an injury in newborns, a preponderance of the evidence establishes that Ricky did not act in a way predicted by Dr. Steinman's theory.

To recapitulate, Dr. Steinman primarily offered the theory that the hepatitis B vaccine cross-reacts with myelin. Exhibit 27 at 3-4, exhibit 48 at 1; tr. 59-62; tr. 102-03; tr. 124-25. Dr. Steinman postulated the idea that the structure of the hepatitis B vaccine resembles the myelin component of the nervous system. His initial report refers to "myelin" at least four times. Dr. Steinman also stated that the evidence favored "a post-immunization encephalomyelitis." Exhibit 27 at 4. Dr. Steinman continued to advance "post-immunization encephalomyelitis" in his supplemental report. Exhibit 48 at 2. There is a cohesiveness to Dr. Steinman's opinion, as presented in his reports, in that Dr. Steinman opined that a component of the hepatitis B vaccine mimics some part of myelin and Ricky suffered from inflammation in his myelin.

After the hearing and after reviewing the withdrawn September 2, 2009 decision, Dr. Steinman opined about the process by which "an immune response to myelin could lead to an immune attack against the neuron." Exhibit 56 at 9, citing exhibit 53 (Lawrence Steinman, The Gray Aspects of White Matter Disease in Multiple Sclerosis, 106 PNAS No. 60, 8083 (2009)). As a matter of theory, this opinion seems reasonable insofar as saying what "could" happen and respondent's expert in neurology, Dr. MacDonald, did not challenge this particular opinion. See exhibit RR.

The problem is that the evidence does not show that Ricky suffered any problem with his myelin. Some evidence affirmatively shows that Ricky's myelin was normal. Exhibit 1 at 41. After questioning from respondent's counsel, Dr. Steinman recognized that Ricky's myelin may not have been affected. Tr. 119-20. During the second hearing, Dr. Steinman was even more direct: "Ricky did not have a demyelinating disorder or a d[y]smyelinating disorder." Tr. 429. This concession undermines most of Dr. Steinman's opinions.

Before making this concession, Dr. Steinman attempted to minimize the results of the October 21, 1994 MRI. But, Dr. Steinman's opinion was not persuasive.[12] Dr. Steinman

[12] Dr. Stiehm, to some extent, agreed with Dr. Steinman's assertion that Ricky may have experienced demyelination but the MRIs did not detect the demyelination. Tr. 210-12. Dr. Stiehm's opinion on this point is not persuasive because Dr. Stiehm, in his words, is "not an expert" on whether demyelination appears on an MRI or CT scan. Tr. 212; accord tr. 254 (Dr. Stiehm stating he does not know enough about myelin to distinguish between the myelinization of a two-month-old and the myelinization of a four-month-old).

suggested that the equipment used in an MRI was not sensitive enough to detect any changes in myelin. Tr. 136. Dr. Steinman suggested that if the vaccination in July 1994 had caused demyelination, then it would not necessarily appear on an MRI performed in October 1994. Tr. 94; tr. 412; tr. 426-28. According to Dr. Steinman, Ricky's age was such that the brain in a normal six-week-old child has such little myelin that the MRI cannot detect any deficits in myelin. Tr. 76-77; tr. 115-16.

After the hearing, the maturity of Ricky's myelin continued to be discussed. Dr. Steinman maintained that Ricky's "myelin was too immature to show the classical signs of ADEM," and "[l]ack of evidence of demyelination does not mean that Ricky's immune system had not made a cross-reactive immune response to the myelin proteins present in his brain." Exhibit 55 at 8-9.

Dr. MacDonald effectively rebutted Dr. Steinman's opinion. A preponderance of the evidence establishes that if Ricky had experienced demyelination as a result of his July 5, 1994 vaccination, then the demyelination would have appeared on the October 21, 1994 MRI. Tr. 316-17; tr. 365-71. Dr. MacDonald's opinion is consistent with the treatment given by Ricky's doctors. The doctor's decision to order an MRI in October 1994, suggests that the doctors believed that the MRI could reveal inflammation in Ricky's brain if inflammation existed in Ricky. Otherwise, the doctor would not have ordered a test that could not show a positive result. Furthermore, the radiologist who read the MRI appears to have taken into account Dr. Steinman's concern about Ricky's age. The radiologist stated the MRI showed "[t]he degree of myelination is appropriate for the patient's age." Exhibit 1 at 41; accord tr. 93 (testimony of Dr. Steinman about this report).

Whether an MRI would show demyelination in a child less than one year old has been discussed in an earlier case, involving Ms. Bunch's attorney, Dr. Steinman, and Dr. MacDonald.[13] The testimony and medical articles in that earlier case supported a finding that an MRI given to a six-week-old infant in 1999 would show demyelination if it existed. Veglia v. Sec'y of Health & Human Servs., No. 02-397V, 2009 WL 515407, at *8 (Fed. Cl. Spec. Mstr. Feb. 10, 2009). Despite addressing an MRI given five years after the MRI given to Ricky, Veglia provides some additional support for the proposition that MRIs are useful diagnostic tools for children less than one year old.[14]

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[13] Referring to an earlier case is appropriate because special masters may use their "accumulated expertise" to understand the evidence presented in a particular case. Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1362 (Fed. Cir. 2000), quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Ultimo v. Sec'y of Health & Human Servs., 28 Fed. Cl. 148, 152-53 (1993).

[14] Dr. MacDonald's post-hearing report cited two articles to support the proposition that MRIs can detect changes in myelin (sometimes, referred to as white matter) in newly born infants. Although these articles do support the proposition for which they were cited, the articles are not definitive because the articles discuss MRIs, which were done in 2004 or more recently.

A basis of Dr. Steinman's opinion is that portions of the hepatitis B vaccine resemble the structure of myelin. See exhibit 55 at 10 ("The vaccination leads to a break in tolerance to myelin."). In theory, this similarity permits the body to attack itself. Even if this underlying theory were valid, there is not a preponderance of evidence that Ricky's experience matched what Dr. Steinman's theory seems to suggest. The October 21, 1994 MRI failed to detect any demyelination. Thus, Ms. Bunch has not offered a "logical sequence," as required by the second prong of Althen.

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

The third prong from Althen is "a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278. Whether Ms. Bunch met her burden of proof on this element is not clear.

In this case, the interval between the vaccination and the onset of symptoms for Ricky was approximately three days. Determining whether this interval is appropriate is difficult due to the ambiguity in Dr. Steinman's theory. The appropriate amount of time seems to vary as to whether T-cells or B-cells are acting.

Dr. Steinman offered T-cells as the causative agent as part of his direct testimony. In this context, Dr. Steinman stated that a time of three days "fits . . . [a] vigorous cellular secondary recall booster reaction precisely." Tr. 68. The term "cellular" refers to T-cells, which are distinguished from antibodies.

Dr. MacDonald did not dispute that assuming that the hepatitis B vaccine caused an autoimmune response, three days was an appropriate interval. Dr. MacDonald's testimony appears to have been given in the context of discussing T-cells. Tr. 382-83. If Dr. Steinman's theory were based in T-cells, then a preponderance of the evidence supports the temporal association.

However, Dr. Steinman's most recent iteration of his theory involves B-cells. Exhibit 55 (stating Ricky's "neurons were damaged via an antibody mediated reaction."). The particular type of antibody is known as IgG. Tr. 270. Dr. Steinman has not opined about the appropriate amount of time for a B-cell (as opposed to a T-cell) reaction to take place. A clear statement from Dr. Steinman would have been helpful because IgG develops after the body produces other types of antibodies, such as IgM. See exhibit AA (Lewis) at 198; exhibit BB (Lewis) at 721-24. This delay in production of IgG suggests that three days may not be a medically appropriate interval for IgG to cause damage.

These more recent MRIs may be more capable of displaying demyelination than the equipment used on Ricky in 1994.

If proof for the appropriate temporal relationship determined whether Ms. Bunch were entitled to compensation, additional evidence could be sought. Seeking more evidence is not necessary because Ms. Bunch has not established the other two prongs from Althen. Even if Ms. Bunch satisfied the temporal relationship prong, she would not be entitled to compensation. See Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (holding that compensation may not be awarded in off-Table causes merely because the injury developed after the vaccination).

4. Summary Regarding Three *Althen* Factors

The preceding analysis has discussed evidence relating to the hepatitis B vaccine and seizure disorders in newborns. For the reasons explained above, Ms. Bunch has failed to establish the first and second prongs from Althen. Therefore, she is not entitled to compensation even if she may have satisfied the third prong.

B. Whether the Herpes Simplex Virus Caused Ricky's Seizures

In addition to the evidence about the hepatitis B vaccine causing Ricky's seizures, the record contains evidence that a herpes simplex virus caused Ricky's problems. This point is briefly discussed in this section.

Beginning with Dr. Stiehm's initial report, respondent presented a plausible case that the herpes simplex virus type 2 caused Ricky's seizure disorder, based upon the evidence that he tested positive for that virus when he was approximately 9 years old; that the herpes simplex virus type 2 is almost always transmitted either during sex or during birth; and if he were exposed to the virus during birth, then his immune system could not have fought off the attack. Exhibit M at 5-6; tr. 167; tr. 172-79; tr. 200 (summary of Dr. Stiehm's opinion); tr. 235-45; tr. 263-64; tr. 400-02.

Dr. Stiehm's opinion was addressed by Dr. Steinman. In his supplemental written report, Dr. Steinman discussed whether a virus, including a herpes simplex virus, caused Ricky's condition. Exhibit 48 at 2. On the first day of the hearing, Dr. Steinman also explained why he believes that a virus did not cause Ricky's seizures in his testimony. Tr. 80-84; tr. 106-11; tr. 126-29; tr. 137-39; tr. 149-53; tr. 278-87 (rebuttal testimony).

After Dr. Stiehm testified on April 15, 2009, Ms. Bunch requested, during an unrecorded status conference on June 1, 2009, an opportunity to obtain a report from a specialist in treating pediatric infectious diseases. This request was deferred pending the testimony on the second day of the hearing. During the second day, Dr. Steinman again contested respondent's theory that a virus caused Ricky's seizure disorder. Tr. 412; tr. 437-40. At the end of the hearing, Ms. Bunch reiterated her request to obtain another expert. Tr. 449. Ms. Bunch argued that a specialist in pediatric infectious diseases would assist Ms. Bunch in challenging the reliability of Dr. Stiehm's opinion regarding the herpes simplex virus.

Assuming that Ms. Bunch made a timely request for an opportunity to obtain another report, her request is denied.[15] A report from a pediatric infectious disease specialist is not necessary. The need to determine whether the herpes simplex virus caused Ricky's seizures arises only after Ms. Bunch establishes, by a preponderance of the evidence, the three factors from Althen. Doe v Sec'y of Health & Human Servs., 601 f.3d 1349, 1358 (Fed. Cir. 2010) (stating "because [the petitioner] never established a prima facie case, . . . the burden (and attendant restrictions on what 'factors unrelated' the government could argue) never shifted."). Because Ms. Bunch has not established her predicate showing for the reasons explained in section IV.A., further investigation of the herpes simplex virus would not serve any purpose.[16]

V. Conclusion

Ms. Bunch has failed to establish all the elements required by Althen. Therefore, she is not entitled to compensation. The Clerk's Office is instructed to enter judgment for respondent unless a motion for review is filed.

IT IS SO ORDERED.

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

[15] In September 2008, Ms. Bunch was placed on notice that the herpes simplex virus was an issue in this case when respondent disclosed Dr. Stiehm's report, which stated that the herpes simplex virus caused Ricky's seizure disorder. Exhibit M. After this disclosure, Ms. Bunch produced a supplemental report from Dr. Steinman that discussed the herpes simplex virus in December 2008. Exhibit 48. Ms. Bunch expressed an interest in obtaining a specialist in pediatric infectious diseases only after Dr. Steinman and Dr. Stiehm testified during the April 15, 2009 hearing. Under these circumstances, fair questions include whether Ms. Bunch delayed too long in seeking an additional expert, see Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 721-24 (2009) (denying motion for review that argued that special master erred in admitting evidence that petitioner did not have an opportunity to rebut); and whether one party's retention of an expert witness after the hearing has begun prejudices the other party, see Vaccine Rule 8(b)(1) (instructing special masters to consider evidence "governed by principles of fundamental fairness to both parties").

[16] Of course, if Ms. Bunch were found to have established the three Althen factors, then an evaluation of the herpes simplex virus would be necessary before determining that Ms. Bunch were entitled to compensation.