

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS  
OFFICE OF SPECIAL MASTERS**

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THOMAS WALTER RICCI, a minor,	*	
through his parents and natural guardians,	*	
DANIEL RICCI and EVA RICCI,	*	No. 99-524V
	*	Special Master Christian J. Moran
Petitioners,	*	
	*	
v.	*	Filed: May 16, 2011
	*	
SECRETARY OF HEALTH	*	entitlement, hepatitis B vaccine,
AND HUMAN SERVICES,	*	seizure disorder, encephalitis
	*	
Respondent.	*	

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David L. Terzian, Rawls & McNelis P.C., Richmond, VA., for petitioners;  
Michael P. Milmoie, United States Dep't of Justice, Washington, D.C. for  
respondent.

**PUBLISHED DECISION DENYING ENTITLEMENT TO COMPENSATION<sup>1</sup>**

Daniel and Eva Ricci allege that the hepatitis B vaccine caused their son, Thomas, to develop “an encephalopathy and/or encephalitis and/or

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<sup>1</sup> Because this 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 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 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).

meningoencephalitis. . . and that this injury has left Thomas with a residual seizure disorder.” Pet’r Br., filed Nov. 12, 2010, at 1-2. The Riccis seek compensation pursuant to the National Childhood Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 et seq. (2006).

The Riccis have failed to establish that they are entitled to compensation. Their expert, Dr. Lawrence Steinman, offered a theory to explain how the hepatitis B vaccine can cause Thomas’s injury. The parties dispute whether the Riccis have carried their burden as to reliability of Dr. Steinman’s theory but these arguments are largely immaterial. Instead, the dispositive evidence shows that Thomas did not react in a way posited by Dr. Steinman’s theory. Thus, the Riccis have not persuasively established that the hepatitis B vaccine harmed Thomas. The Clerk’s Office is instructed to enter judgment in favor of respondent.

## **I. Facts**

The parties agree that the medical records created contemporaneously with the events that they describe are accurate. The pertinent parts of Thomas’s history are set forth below.

Ms. Ricci was healthy during her pregnancy preceding Thomas’s birth. After 38 weeks of gestation, Thomas was born on July 8, 1992. He weighed 8 pounds and 15 ounces. His Apgar score was eight at one minute and nine at five minutes. Exhibit 1 (Affidavit of Eva Ricci, dated June 20, 2006) at 1.

On approximately September 10, 1992, Thomas had a cold. His pediatrician, Dr. Ofelia Ayuste, diagnosed him as having an ear infection. Exhibit 6 at 7 (record dated Sept. 24, 1992). Thomas returned for a check of his ears on October 8, 1992. On this date, he received the first dose of the hepatitis B vaccine. Exhibit 6 at 2, 7.

On October 13, 1992, Thomas’s arm jerked. His mother reported his behavior to a colleague of Dr. Ayuste. However, the colleague did not request additional evaluation for Thomas. Exhibit 1 at 1; tr. 10-11; see also exhibit 3 at 92 (discharge summary prepared on October 21, 1992); exhibit 4 at 22 (report given on Nov. 6, 1992). In retrospect, it appears that this arm jerking constituted a seizure.

On October 15, 1992, Ms. Ricci brought Thomas to see Dr. Ayuste. Dr. Ayuste obtained a history from Ms. Ricci, saw Thomas's arm jerking, and directed Ms. Ricci to bring Thomas to a local hospital, Hinsdale Hospital. Exhibit 3 at 98; Exhibit 1 at 1.

Thomas stayed in Hinsdale Hospital from October 15 through October 21, 1992. Exhibit 3 at 92-94. Thomas was treated by a pediatric neurologist, Dr. Thomas Sullivan. Following a neurologic evaluation, Dr. Sullivan described Thomas as "alert, attentive." Exhibit 3 at 98-99. While hospitalized, Thomas had various tests were performed on him. Important tests that are discussed in detail below include tests of Thomas's cerebrospinal fluid, an electroencephalogram ("EEG"), a computed tomography ("CT") scan with contrast, and magnetic resonance imaging ("MRI") of the brain. When Thomas was discharged, the doctor diagnosed him as suffering from "[i]nfantile seizure disorder of undetermined etiology." The doctors prescribed phenobarbital and a trial of pyridoxine. *Id.* at 92-93.

After discharge from Hinsdale Hospital, Thomas continued to have seizures. He was admitted to Loyola Hospital on November 6, 1992. He was seen by another pediatric neurologist, Dr. Steven Coker. Dr. Coker ordered, among other tests, a lumbar puncture, a CT of Thomas's brain, and another EEG. The CT scan was essentially normal. Exhibit 4 at 21. The EEG on November 9, 1992, was also normal. *Id.* at 20. Thomas was discharged from Loyola Hospital on November 11, 1992. His diagnosis remained seizures. His medication was changed to Klonopin, and ACTH. Exhibit 4 at 99-100.

Since 1992, Thomas has continued to have seizures. The Riccis have consulted many doctors in Chicago and have brought Thomas to see a doctor at Johns Hopkins University. Tr. 16-17. These doctors have not been able to determine a cause for Thomas's seizures. Tr. 12-13.<sup>2</sup> In 2009 (when Thomas was almost 17 years old), he functioned like an infant who was three to six months old. Tr. 20.

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<sup>2</sup> None of these doctors, some of whom Dr. Steinman described as "outstanding," attributed Thomas's problem to the hepatitis B vaccine. Tr. 74-75.

## II. Procedural History

Mr. and Ms. Ricci filed a petition on July 28, 1999, which was near the last day petitions alleging that a hepatitis B vaccine caused an injury before August 6, 1997 could be filed. See 42 U.S.C. § 300aa-16(b); 63 Fed. Reg. 25777, 25778 (clarifying the date on which the hepatitis B vaccine was added to the vaccine injury compensation table). They alleged that the hepatitis B vaccine, which Thomas received on October 8, 1992, caused an “adverse reaction.” Pet. ¶ 3. The Riccis did not file any medical records or exhibits with their petition.

Along with many other cases involving the hepatitis B vaccine, this case was informally stayed for several years. Attorneys representing petitioners with similar claims, attorneys representing the government, and the Office of Special Masters attempted to establish a structure for resolving these cases efficiently. Despite good faith efforts, they were not entirely successful. When it became apparent that this case needed to be resolved individually, the case was transferred to the undersigned in 2006 and the case resumed.

In 2006, the Riccis filed Thomas’s medical records. Afterwards, respondent filed her report pursuant to Vaccine Rule 4. Respondent maintained that the Riccis were not entitled to compensation because the Riccis had not offered an expert to support their claim. Resp’t Rep’t, filed Feb. 1, 2007, at 4.

The Riccis attempted to fill this gap. In August 2007, the Riccis filed the report from and curriculum vitae of Dr. Lawrence Steinman. Dr. Steinman has a lengthy list of accomplishments. He is a professor in Stanford University’s Departments of Neurology, Pediatrics, and Genetics. He is also the chair of the same institution’s program in immunology. He has been board-certified in neurology since 1984. He has written more than 300 articles, including numerous articles in leading journals. Dr. Steinman’s particular area of focus is multiple sclerosis. Exhibit 10 (curriculum vitae).

While this case was pending, Dr. Steinman received two honors that reflect his accomplishments. First, Dr. Steinman was elected to the Institute of Medicine. Tr. 298-99; tr. 304-05. The Institute of Medicine often prepares reports on medical issues for the federal government. King v. Sec’y of Health & Human Servs., No. 03-584V, 2010 WL 892296, at \*75 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). Second, Dr. Steinman was selected to receive the 2011 Charcot Award, which is given every two years to a person for lifetime achievement in research relating to multiple sclerosis. Pet’r Reply, filed Feb. 28, 2011, at 4-5.

Dr. Steinman presented the opinion that “Thomas Ricci developed neurological damage from his immunization with recombinant Hepatitis B on October 13, 1992. He developed a post-immunization encephalopathy, with evidence of a mild meningoencephalitis.” Exhibit 9 at 2. Dr. Steinman proposed that due to the similarities between the hepatitis B virus and myelin, the hepatitis B vaccine “elicited an immune response that [led] to neurological damage.” *Id.* at 3. This theory is often described as “molecular mimicry.” The Riccis filed medical articles on which Dr. Steinman relied.

Respondent, in turn, presented a report from and the curriculum vitae of Dr. Max Wiznitzer. Dr. Wiznitzer currently works as an associate professor in neurology at the University Hospital in Cleveland, Ohio. He became board-certified in pediatrics in 1982, in neurology with special competence in child neurology in 1986, and in neurodevelopmental disabilities in 2004. He has written approximately 50 articles for peer-reviewed journals. Dr. Wiznitzer’s particular area of focus is epilepsy, developmental disabilities, and autism. Exhibit B (curriculum vitae).

Dr. Wiznitzer disagreed with Dr. Steinman’s ultimate opinion that the hepatitis B vaccine harmed Thomas. Dr. Wiznitzer disagreed with the diagnosis reached by Dr. Steinman and maintained that “There is no evidence of an encephalopathy with associated meningoencephalitis at the time of [Thomas’s] hospital admission of 10/15/92.” Dr. Wiznitzer also discounted the theory proposed by Dr. Steinman because Thomas’s diagnosis did not match the diseases discussed in the articles cited by Dr. Steinman. Exhibit A at 4.

After both sides presented these reports, the process for scheduling a hearing began. This process took longer than usual for various reasons. While the parties were trying to arrange a mutually convenient time for the hearing, they continued to file documents. The Riccis submitted updated medical records, a supplemental expert report from Dr. Steinman, and more medical articles. The respondent filed three supplemental reports from Dr. Wiznitzer and additional medical articles.

Ultimately, the first session of the hearing took place on May 11, 2009, in Chicago, Illinois. Thomas’s mother (Eva Ricci) and Dr. Steinman testified. Unfortunately, conflicts in schedules prevented Dr. Wiznitzer from participating. Thus, another session of the hearing was required.

The scheduling of the second hearing, too, was problematic. During this interlude, the parties, again, filed more medical records, supplemental expert reports, and medical articles. The second (and final) day of the hearing was December 15, 2009. At this hearing, both Dr. Steinman and Dr. Wiznitzer testified.

During the hearing, the Riccis attempted to undermine Dr. Wiznitzer's credibility. Tr. 219-30, tr. 261-72, tr. 376-83. This argument started the parties on a course that included several status conferences, a motion to exclude evidence, and the submission of briefs on this point. This issue concluded with an order filed August 13, 2010, granting in part and denying in part respondent's motion to exclude evidence.

After this order, the parties were directed to file briefs. The Riccis submitted a primary brief and a reply brief. Respondent presented her arguments in a single brief. The case is ready for adjudication.

### **III. Standards for Adjudication**

Petitioners are required to prove their cases by 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). In this regard, "close calls regarding causation are resolved in favor of injured claimants." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005).

The Riccis' claim is not based upon the Vaccine Injury Table. Therefore, they must establish that the vaccine was the cause in fact of Thomas's injury. See Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1335 (Fed. Cir. 2010).

The elements for an off-Table case are: “(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, 418 F.3d at 1278.

#### **IV. Analysis**

The foundation for evaluating this case is Dr. Steinman’s theory explaining how the hepatitis B vaccine harmed Thomas. Dr. Steinman explained that the hepatitis B vaccine can stimulate an immune response, that this immune response can damage myelin, that this immune response would be manifest as inflammation, and that, after the myelin is damaged, the neurons suffer. Section A, below, expands this summary and presents certain challenges to the theory offered by Dr. Wiznitzer. No determination about Dr. Steinman’s theory is reached here because such evaluation is not necessary.

Even if Dr. Steinman presented a persuasive theory of what can happen, the evidence about Thomas does not match what Dr. Steinman’s theory predicts would happen as discussed in section B. Most notably, Dr. Steinman’s theory postulates that Thomas would suffer inflammation in his central nervous system. Relevant tests produced normal results and the doctors who treated Thomas in the relevant time did not diagnose Thomas as suffering from inflammation. Although Dr. Steinman discussed this evidence, his explanations were not persuasive. Consequently, the evidence about Thomas is in conflict with Dr. Steinman’s theory and the Riccis cannot establish the second prong of Althen. Given section B’s conclusion, the third prong of Althen is discussed only briefly in section C.

##### **A. Althen Prong 1**

On behalf of the Riccis, Dr. Steinman presented a theory known as molecular mimicry.<sup>3</sup> Molecular mimicry is based upon a similarity in the structure

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<sup>3</sup> Dr. Steinman has presented this theory in other cases. See Abbott ex rel. Bunch v. Sec’y of Health & Human Servs., No. 99-497V, 2010 WL 3186269, at \*12-19 (Fed. Cl. Spec. Mstr. June 28, 2010); Veglia v. Sec’y of Health & Human Servs., No. 02-397V, 2009 WL 515407, at \*6 (Fed. Cl. Spec. Mstr. Feb. 10, 2009); Broekelschen v. Sec’y of Health & Human Servs., No. 07-137V, 2009 WL 440624, at \*22 (Fed. Cl. Spec. Mstr. Feb. 4, 2009), motion for review denied, 89 Fed. Cl. 336 (2009), aff’d, 618 F.3d 1339 (Fed. Cir. 2010).

between substances that enter the body from the outside, known as antigens, and tissues that occur in the body. In the process of responding to an antigen, the body's immune system becomes confused and attacks its own tissue. This process leads to the development of autoimmune diseases. Tr. 35, tr. 46. On this general level, it appears that Dr. Wiznitzer accepts the validity of molecular mimicry to explain how some autoimmune diseases occur. See tr. 163.

For Thomas Ricci, the relevant antigen is the hepatitis B vaccine. The relevant host tissue is myelin. Exhibit 9 (Dr. Steinman's report) at 3. Myelin wraps nerves like insulation wraps a wire, tr. 36, and myelin is often referred to as "white matter," see Dorland's Illustrated Medical Dictionary (31st ed. 2007) at 1130 (defining "matter, white") & 1819 (defining "substantia alba"). Relying upon a paper by Dr. Bogdanos, Dr. Steinman opined that the hepatitis B vaccine has been shown to cause an increased production of antibodies that react with myelin. Tr. 76; tr. 285-91, discussing exhibit 15 (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)).

When the immune system attacks myelin, inflammation results.<sup>4</sup> Dr. Steinman conceded that "without inflammation I couldn't make these arguments." Tr. 346.

Dr. Steinman extends the molecular mimicry theory a step beyond the attack on myelin. According to Dr. Steinman, once the myelin has been damaged, the immune system's response can spread to the gray matter of the brain. (Gray matter represents the nerve cells in the brain.) To support this step, Dr. Steinman cited an editorial that he wrote for the Proceedings of the National Academy of Sciences. Tr. 44; tr. 64; tr. 287, discussing exhibit 44 (Lawrence Steinman, "The gray aspects of white matter disease in multiple sclerosis," 105 (20) Proceedings of the National Academy of Science, 8083 (2009)). As discussed below, Dr. Steinman stated that

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<sup>4</sup> The medical term for inflammation in the brain is "encephalitis." Dorland's at 619; accord tr. 58. "Meningitis" means inflammation of the meninges, the lining of the brain and spinal cord. Dorland's at 1149-50. "Meningoencephalitis" is inflammation in the meninges (the lining of the brain) and the brain itself. Dorland's at 1151; accord tr. 37. Dr. Steinman stated that Thomas had a mild meningoencephalitis. Tr. 276-78; exhibit 9 at 2.

this theory (hepatitis B vaccine leads to an immune response, the immune response attacks the myelin producing inflammation, and the immune response damages nerve cells) explains what happened to Thomas.

Dr. Witnitzer challenged various aspects of the theory presented by Dr. Steinman. Dr. Witnitzer stated that molecular mimicry has not been proffered as a theory to explain epilepsy, the disease that he thinks Thomas has. Tr. 209. Dr. Witnitzer also argued that this theory is not “biologically plausible” to happen in a child who was three months old. Tr. 165; see also tr. 215 (stating that no articles have associated hepatitis B vaccine with seizures in infants). Relatedly, Dr. Witnitzer maintained that the Bogdanos article was not relevant because Bogdanos studied adults, not children. Tr. 209-11; tr. 367-68.

It is not necessary to weigh the evidence that supports or detracts from Dr. Steinman’s theory. It is sufficient to note that Dr. Steinman maintained the reliability of this theory in response to Dr. Wiznitzer’s criticisms. See, e.g., tr. 286-93. If the persuasiveness of Dr. Steinman’s theory determined whether the Riccis were entitled to compensation, then the evidence about molecular mimicry in a three month old could be examined. However, such analysis is not needed in this case because the Riccis have failed to show that Thomas responded to the hepatitis B vaccine in a way that is consistent with Dr. Steinman’s theory.<sup>5</sup>

## **B. Althen Prong 2**

The preceding exposition of Dr. Steinman’s theory of how the hepatitis B vaccine can cause a seizure disorder is the basis for the second prong of Althen, which asks whether the vaccine did cause harm to the vaccinee. See Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir. 2006) (affirming special master’s use of “can cause” and “did cause” test as consistent with the Althen test). The answer is that a preponderance of the evidence shows that Thomas did not react to the hepatitis B vaccine in a way consistent with Dr. Steinman’s theory.

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<sup>5</sup> If the evidence on Althen prong 1 were weighed, Dr. Steinman’s expertise in researching the immune system would be one factor to consider. There was considerable dispute about whether Dr. Wiznitzer is qualified to argue against a theory that explains how the immune system interacts with the neurological system. Tr. 156-60; Pet’r Br. at 11-12, 25-29; Pet’r Reply at 4, 8. Further comment on the relative strengths and weaknesses of Dr. Wiznitzer’s ability is not needed because this decision assumes that Dr. Steinman’s theory is persuasive.

An essential part of Dr. Steinman's theory is that the person would experience inflammation in his brain. Tr. 37 (stating "so there was inflammation and it [led] to seizures"); tr. 346. Thus, the critical issue is whether Thomas showed any signs or symptoms of inflammation. Dr. Steinman maintains that Thomas showed signs of inflammation but Dr. Wiznitzer disagreed.<sup>6</sup>

When a special master is confronted with competing opinions from well-credentialed experts, the special master may consider the underlying basis for an expert's opinion in determining whether that opinion is persuasive. See Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1347-49 (Fed. Cir. 2010); Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating "An expert opinion is no better than the soundness of the reasons supporting it."). Here, Dr. Steinman's assertion that Thomas suffered inflammation is almost entirely without support. In contrast, abundant evidence supports Dr. Wiznitzer's conclusion. The evidence that supports Dr. Wiznitzer's conclusion includes: (1) laboratory studies of Thomas's cerebrospinal fluid, (2) imaging studies of his brain, (3) his clinical appearance, and (4) comments of his treating doctors.

- Studies of Thomas's Cerebrospinal Fluid

When asked to explain what evidence supported his opinion that Thomas suffered inflammation, Dr. Steinman stated that "the best argument I can make on behalf of Thomas" is based on results from two laboratory tests, the white blood count and protein count from Thomas's cerebrospinal fluid. Tr. 309. According to Dr. Steinman, the meaning of these two studies in combination supports a finding that Thomas had inflammation in his central nervous system.

It is very important to begin the discussion of the white blood count and protein count with the statement that results from these two tests were listed as normal on the reports themselves. Although Dr. Steinman argues that they were "really pushing the edge" of normal, tr. 340, the tests were normal. Thomas's white blood count was 5 and a normal result, according to the Hinsdale Hospital laboratory, is 0-9. Thomas's protein was 44 and a normal result, again according to Hinsdale Hospital, is 15-45. Exhibit 3 at 102-03.

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<sup>6</sup> The Riccis have specifically conceded that Dr. Wiznitzer has the expertise to offer an opinion as to whether Thomas suffered from encephalitis. Tr. 206; see also tr. 158 (Dr. Wiznitzer's discussion of his ability to diagnose encephalitis).

Despite the ostensibly normal results, Dr. Steinman opined during the first hearing that Thomas's spinal fluid showed inflammation. This opinion raised a question about what results are "normal." Tr. 40-41; tr. 62; tr. 102-05.

The hiatus between sessions of the hearing allowed both parties to submit evidence explaining what tests on a normal three-month-old child in 1992 would show. See exhibit 49 (supplemental report of Dr. Steinman); exhibit M (supplemental report of Dr. Wiznitzer). Consequently, a significant portion of the testimony on the second day of the hearing focused on these articles.<sup>7</sup> See tr. 191-204 (Dr. Wiznitzer), tr. 273-77 (Dr. Steinman), tr. 309-11 (same), tr. 319-25 (same), tr. 340 (same), tr. 352 (Dr. Wiznitzer). In the final analysis, neither the Riccis nor Dr. Steinman presented a persuasive reason for changing the meaning of what Hinsdale Hospital reported as normal. Hinsdale Hospital's values are supported by published articles and a reference in a leading textbook on neurology. Given this abundant support, it would be highly unusual to dispute what so many authorities have said.

Thus, the evidence shows that Thomas's protein and WBC were normal. Dr. Steinman emphasizes that the tests were above the mean. Tr. 273-77; tr. 347-48. Dr. Steinman places further importance on the fact that the almost abnormal results appeared in two tests. Tr. 309. In contrast, Dr. Wiznitzer finds that two normal tests are just that – two normal tests. Dr. Wiznitzer compared the situation to baseball in which a batter hits consecutive pitches outside of (but close to) the foul

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<sup>7</sup> The most pertinent articles about protein counts were exhibit 46 (Daniel Biou et al., "Cerebrospinal Fluid Protein Concentrations in Children: Age-related Values in Patients without Disorders of the Central Nervous System," 46:3 Clinical Chemistry 399 (2000)) and exhibit 47 (Michael Wong et al., "Cerebrospinal Fluid Protein Concentration in Pediatric Patients: Defining Clinically Relevant Reference Values," 154 Arch. Pediatr. Adolesc. Med. 827 (2000)). The most relevant articles about white blood counts were exhibit 48 (Jay M. Portnoy and Lloyd C. Olson, "Normal Cerebrospinal Fluid Values in Children: Another Look," 75 Pediatrics 484 (1985)) and exhibit N (David J. Michelson "Spinal Fluid Examination" in Pediatric Neurology Principles & Practice (4th ed. Kenneth F. Swaiman et al., eds. 2006)). Additional information came from exhibit O (Pediatric Reference Intervals, (6th ed. Steven J. Soldin et al., eds. 2007)) at 172; exhibit P (Pediatric Reference Intervals, (2d ed. Steven J. Soldin et al., eds. 1997)) at 127; and exhibit Q (lab report from Dr. Wiznitzer's hospital prepared in July 2009).

line. Dr. Wiznitzer said in such circumstances, the closeness of two results (both being near the foul line) does not change the significance (both being foul). Tr. 355.

The evidence from the laboratory studies tends to favor a finding that Thomas was not experiencing inflammation. After all, the results were within the range accepted as normal. Nevertheless, in light of Dr. Steinman's concern about two borderline normal results, evidence of inflammation will be sought in other places.

- Imaging and Electrodiagnostic Studies

After Thomas experienced his first seizures, he was admitted to Hinsdale Hospital. In that facility, he was given three tests that provide some information about whether he was experiencing inflammation. Listed in chronological order, beginning with the earliest, these are an EEG, a CT scan with contrast, and an MRI without contrast. Collectively, these studies corroborate Dr. Wiznitzer's opinion that Thomas did not have inflammation and undermine the reliability of Dr. Steinman's opinion that Thomas did have inflammation following his hepatitis B vaccination. After Thomas was discharged from Hinsdale, he continued to have seizures and while being treated at other facilities, Thomas had additional MRIs. These later MRIs reinforce the finding that Dr. Steinman's theory does not describe what happened to Thomas.

The first relevant electrodiagnostic study on Thomas was the EEG, which was performed on October 15, 1997. The EEG was abnormal because of a "clinical and electrical recorded seizure." Apart from the seizure, "[a]rousal patterns were seen and wake patterns produced no change in background activity." Overall, the EEG was "consistent with a multi-focal CNS [central nervous system] disorder." Exhibit 3 at 118.

Dr. Wiznitzer stated that the finding that there was no change in the background activity was important. This finding means that when Thomas was not seizing, his brain was functioning normally. Tr. 189-91. Dr. Steinman agreed that Thomas's background rhythm was not disturbed. Tr. 297. But, according to Dr. Steinman, the normal background would not rule out inflammation. Tr. 335; see also tr. 297.

Another study at Hinsdale Hospital was a CT scan. A CT scan is like an

X-ray of the brain and presents a two dimensional picture of the brain. Contrast is a material that will show any inflammation in the meninges. Tr. 174-75 (Dr. Wiznitzer); see also tr. 330 (Dr. Steinman agreeing with Dr. Wiznitzer's explanation).

A CT scan of Thomas's brain was done on October 15, 1992. The impression was "Normal CT of the brain." Exhibit 3 at 116. According to Dr. Wiznitzer if Thomas's seizures, which began on October 13, 1992, were immune-mediated, then this CT scan would have shown inflammation. Tr. 177.

Dr. Steinman's response was not persuasive. Dr. Steinman contended that the CT scan missed the inflammation because it "may have been done too early. The inflammation should have been measurable a little later in time." Tr. 329. This explanation seems forced because Dr. Steinman's theory presupposes that the inflammation would occur before the seizures. Since Thomas started experiencing seizures on October 13, 1992, the inflammation that Dr. Steinman posits as being a step between the vaccination and the seizure must have occurred before October 13, 1992. Thus, the inflammation would have appeared on the October 15, 1992 CT scan. Dr. Wiznitzer's testimony, tr. 177, is persuasive. Dr. Steinman recognized that the CT scan would be one point showing "that there wasn't inflammation." Tr. 329.

The third study that Thomas underwent was an MRI with T1 and T2 sequences. Thomas's first MRI was done in Hinsdale Hospital on October 19, 1992, which was four days after the CT scan.

The Hinsdale Hospital MRI was given without contrast. (The significance of the doctor's decision not to order contrast is discussed in the section on views of treating doctors below.) The report stated that the MRI showed: "The sizes of the ventricles and sulci are appropriate for the patient's age. . . . [A] completely formed but diffusely thin corpus callosum for the patient's age of three months. Myelination and morphology are normal." In reference to the thin corpus callosum, the radiologist's impression was that "This finding is nonspecific, and the corpus callosum may develop a more normal appearance in several months. Otherwise, no other intracranial abnormalities are demonstrated." Exhibit 3 at 117.

Dr. Wiznitzer, again, stated that if Dr. Steinman's theory explained why Thomas developed his seizure disorder, then this MRI should have shown some abnormalities in the brain, especially in the myelin (the white matter). Tr. 177-78; 183-84. Dr. Wiznitzer explained that an MRI with T2 sequences, which is the type

of MRI Thomas had, is especially useful in detecting problems in the white matter such as edema. Tr. 252-54. Edema, which means swelling, would appear on an MRI if there were inflammation according to Dr. Steinman. However, Dr. Steinman did not see evidence of edema on the MRI. Tr. 65-66.<sup>8</sup> The MRI also did not show any damage to myelin. Exhibit 3 at 117.

Dr. Steinman's response was that the MRI did not show inflammation because the correct test, one with contrast, was not done. Tr. 281; see also tr. 284. Dr. Steinman's observation that the MRI was performed without contrast fails to account for the T2 analysis. According to Dr. Wiznitzer's explanation, the T2 sequence would show inflammation, tr. 177-78, and Dr. Steinman accepted Dr. Wiznitzer's explanation. Tr. 330. Thus, a preponderance of evidence supports a finding that the October 19, 1992 MRI could have detected inflammation but did not detect inflammation.

Although the October 19, 1992 MRI was normal for myelin, this MRI detected a thin corpus callosum. Exhibit 3 at 117. The corpus callosum connects the two hemispheres of the brain. Tr. 182. It is a form of gray matter. Tr. 53; tr. 64; tr. 75.

Dr. Steinman points to the thin corpus callosum as evidence that the hepatitis B vaccine damaged Thomas's brain because the brain was showing a sign of atrophy. Tr. 69; tr. 331. Brain atrophy, however, is the result of a process that takes a lengthy amount of time after an initial injury. Tr. 184-89. In addition, atrophy caused by an injury would appear with other changes to the white matter. Tr. 359-60. So, the thin corpus callosum does not strongly support a theory that it resulted from an inflammatory process beginning 11 days before the MRI.<sup>9</sup>

As doctors at other hospitals continued to treat Thomas's continuing seizure disorder, they ordered additional MRIs. A February 19, 1993 MRI was an

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<sup>8</sup> Although Dr. Steinman stated that the October 19, 1992 MRI could show edema, he also stated that "scarring" would be evident "weeks to a month afterwards." Tr. 66.

<sup>9</sup> The significance of the thin corpus callosum is not entirely clear. Dr. Wiznitzer suggested that the radiologist may have over-interpreted the images on the October 19, 1992 MRI because the next three MRIs do not detect a problem with Thomas's corpus callosum. Tr. 181-82.

“essentially unremarkable magnetic resonance scan.” The myelin appeared normal. The only potentially unusual finding was that the size of the third and fourth ventricles was at the “upper limits of normal to mildly prominent in size.” Exhibit 4 at 342.

This MRI further undermines Dr. Steinman’s opinion. Dr. Steinman stated that evidence of scarring would appear “weeks to a month afterwards.” Tr. 66. According to Dr. Wiznitzer, the passage of approximately four months from the onset of Thomas’s seizures would allow for any old areas of damage from a “significant meningoencephalitis” to be apparent. However, the MRI showed normal myelin. Tr. 179; see also tr. 207-08; tr. 357. Dr. Steinman did not have any persuasive response to this point.

The report from Thomas’s third MRI, which was done on September 17, 1993, was similar to the report on the previous MRI. The report from the September 17, 1993 MRI did not identify any defects in the corpus callosum. It also stated that Thomas’s myelination was normal and the ventricles remain prominent. The MRI may have shown some atrophy in a part of the brain known as the inferior vermis. Exhibit 4 at 341.

Once again, this report tends to detract from Dr. Steinman’s theory. As stated by Dr. Wiznitzer, the sequence of MRIs constitutes “a trail of imaging studies that basically show that there’s no evidence either acutely of meningoencephalitis or of the residua of the meningoencephalitis that was proposed by Dr. Steinman.” Tr. 180; accord tr. 208.

On October 11, 1994, Thomas had another MRI. The report stated that there was more prominence to the ventricles that may represent a deep form of atrophy. Exhibit 4 at 340. For Dr. Steinman, enlarged ventricles mean that Thomas’s brain has shrunk. Tr. 282. To Dr. Wiznitzer, any changes come from having intractable epilepsy for years. Tr. 358-59. Thus, this MRI, which was administered approximately two years after Thomas started having seizures, does not provide much persuasive evidence for the cause of the seizures.

The MRI that was done on October 19, 1992, which was much closer in time to the onset of Thomas’s seizures, supports Dr. Wiznitzer’s opinion that the cause of the seizures was not inflammation. The October 15, 1992 CT scan with contrast also tends to rule out inflammation as the source of Thomas’s seizures. The same point has been made for the other MRIs and the EEGs. Taken as a whole, this set

of medical reports supports Dr. Wiznitzer's opinion more than Dr. Steinman's opinion.

- Clinical Appearance

Another piece of evidence in determining whether Thomas suffered inflammation is how he appeared and acted in the hospital. Dr. Steinman said that the clinical presentation of a child with encephalitis could include seizures, behavioral disturbances, paralysis, sensory disorders, and blindness. Tr. 58. Dr. Steinman also said that an impairment of consciousness is not needed in his definition of encephalitis. Tr. 59.<sup>10</sup> For meningoencephalitis, which is the diagnosis that Dr. Steinman assigned to Thomas, symptoms in a three-month-old infant would include a fever, a bulging soft spot on the top of his head, irritability, and/or seizures. Tr. 332.

Thomas, clearly, had seizures. But, seizures are not enough to fulfill the clinical picture of encephalitis. Tr. 171. So, aside from seizures, did Thomas display any other clinical manifestations of encephalitis?

Dr. Wiznitzer testified that Thomas did not have clinical manifestations of encephalitis. Tr. 190. Although the Riccis' briefs omitted any discussion of Thomas's clinical presentation, an independent review of the records attempted to verify Dr. Wiznitzer's conclusion about Thomas's clinical picture. Various references support his opinion. For example, Thomas's fontanelle was described as "soft." Exhibit 3 at 98, *id.* at 163 (October 16, 1992), *id.* at 168 (October 17, 1992), *id.* at 173 (October 18, 1992). His temperature was consistently between 97 and 98 degrees. Exhibit 3 at 162 (October 16, 1992), *id.* at 167 (October 17, 1992). When Thomas was not having a seizure, he was described as alert, attentive, and socially interactive. Exhibit 3 at 98-99. These clinical signs and symptoms weigh against a finding that Thomas suffered inflammation.

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<sup>10</sup> Dr. Wiznitzer disagreed. He stated that according to the Brighton Group, an alteration of consciousness is needed to diagnose encephalitis. Tr. 168-70; tr. 237. In deciding this case, analyzing whether Thomas's consciousness was altered is not necessary because Thomas did not display the symptoms that Dr. Steinman associated with encephalitis or meningoencephalitis.

- Comments of Treating Doctors

In deciding whether Thomas suffered an encephalopathy, another piece of evidence to consider is the view of Thomas’s treating doctors. Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). The doctors did not use the term “meningoencephalitis.” Tr. 350 (statement of the Riccis’ attorney); tr. 361 (testimony of Dr. Wiznitzer). A search of the Hinsdale Hospital records did not show any instances of “encephalitis.” Exhibit 3, passim.<sup>11</sup>

The treating doctors considered Thomas’s cerebrospinal fluid normal. Exhibit 3 at 134 (pediatric special care unit), id. at 136 (pediatric neurologist), id. at 142 (no signature).<sup>12</sup> According to Dr. Wiznitzer, they acted in accord with a judgment that the tests of Thomas’s cerebrospinal fluid did not show inflammation. For example, the doctors did not prescribe an antibiotic, which would have been the prudent course to protect against meningitis. Tr. 353. Additionally, when the doctors ordered the MRI, they did not order contrast. The lack of contrast is also consistent with an understanding that Thomas did not have inflammation. Tr. 177-78.

- Summary

The evidence favors finding that Thomas did not suffer inflammation. Relevant evidence includes:

<b>Criteria from Hinsdale Hospital</b>	<b>Result</b>
CSF – protein	44 (normal is 15-45)
CSF – WBC	5 (normal is 0-9)
EEG	Seizure with normal background
CT scan with contrast	Normal
MRI on October 19, 1992	Normal myelin, thin corpus callosum
Clinical Appearance	No fever, fontanelles were soft (not bulging),

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<sup>11</sup> The Riccis’ counsel identified four instances of “encephalitis,” appearing in the medical records. Tr. 350. However, none of these citations reflected the opinion of Thomas’s treating doctors at the time.

<sup>12</sup> In December 1993, a specialist in genetics at Loyola University Medical Center obtained a history of Thomas’s hospitalization in Hinsdale. This doctor also stated that the spinal tap was normal. Exhibit 4 at 254.

	socially interactive, no paralysis or blindness
Treating doctors	Did not diagnose Thomas as having “encephalitis” or “meningoencephalitis”
<b>Later Tests</b>	
MRI on February 19, 1993	Normal myelin
MRI on September 17, 1993	Normal myelin
MRI on October 11, 1994	Normal myelin, prominent ventricles suggesting atrophy

When weighed against this evidence, Dr. Steinman’s “argument” that Thomas suffered inflammation (see tr. 309) is not persuasive. Preponderant evidence supports a finding that Thomas did not have inflammation.<sup>13</sup>

Inflammation is an essential part of Dr. Steinman’s theory as inflammation would be evidence that portions of the immune system were attacking tissue in Thomas’s central nervous system. Tr. 346. Without this step, the evidence offered by the Riccis ceases to be “logical,” and, consequently, it fails to establish the second prong of Althen. See Doe 11 v. Sec’y of Health & Human Servs., 87 Fed. Cl. 1, 9 (2009) (affirming special master’s determination that although petitioners had established Althen prong 1, they had not established prong 2 because the child did not experience symptoms incorporated into their medical theory), aff’d, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (noting that the special master “chose not to credit [petitioners’ expert’s] theory, because she found it unsupported by the facts of this particular case.”).

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<sup>13</sup> As discussed in the text, this finding is based upon an analysis of the data recorded about Thomas, informed by the testimony of Dr. Steinman and Dr. Wiznitzer. Dr. Wiznitzer’s opinion that Thomas did not suffer inflammation was more persuasive, primarily because his opinion is consistent with the evidence about Thomas’s condition. Thus, the Riccis’ attempt to impeach Dr. Wiznitzer’s credibility, Pet’r. Br. at 25-29, is ineffective because Thomas’s medical records corroborate Dr. Wiznitzer’s opinion. Cf. In re Cygnus Telecommunications Technology, LLP, Patent Litigation, 536 F.3d 1343, 1360 (Fed. Cir. 2008) (noting that the Federal Circuit “does not condone ad hominem attacks [such as charging the other party lied to the court]. Typically, however, such attacks do more harm than good to the party that launches them.”).

### C. Althen Prong 3

Although the finding on prong 2 means that the Riccis are not entitled to compensation, the remaining prong warrants some discussion. Even if the Riccis had established prong 1 and prong 2, to be entitled to compensation they also must establish, by a preponderance of evidence, “a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278.

The relevant dates for Thomas are October 8, 1992, the day he received the first dose of the hepatitis B vaccine, and October 13, 1992, the day his mother first noticed his arm jerking. The ensuing question is whether five days is a medically appropriate time for Dr. Steinman’s theory to take place.

To review, Dr. Steinman’s theory contains the following steps: first, the hepatitis B vaccine causes the immune system to produce antibodies; second, the antibodies cross-react with myelin causing damage to the white matter in the central nervous system; and third, the immune system continues its attack, moving from the white matter to the gray matter. For Thomas, the gray matter destruction is reflected in his thin corpus callosum, which was detected on the October 19, 1992 MRI. Dr. Steinman maintains that these steps can happen in five days. Tr. 87, tr. 312; see exhibit 34 (Dr. Steinman’s supplemental report), citing, among other articles exhibit 39 (Munir Pirmohamed and Peter Winstanley, “Hepatitis B vaccine and neurotoxicity,” 73 Postgrad Med J. 462 (1997)) and exhibit 41 (Sedat Kaygusuz et al., “Afebrile Convulsion in an Adult after Recombinant Hepatitis B Vaccination,” 34 Scand J. Infect. Dis. 314 (2001)).

This timing seems unlikely. Dr. Steinman stated that the body’s development of an antigen known as immunoglobulin M (abbreviated IgM) takes three days. Tr. 313.<sup>14</sup> This leaves three days for IgM to attack the myelin, to attack the corpus callosum, and to cause enough damage that it produced a seizure. Dr. Steinman asserted that “The whole process could certainly be happening within a week. A lot shorter than that, we could have problems making the argument. But a week, it is possible to do this.” Tr. 314; accord tr. 87.

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<sup>14</sup> Dr. Wiznitzer agreed that a couple of days would be needed to produce IgM. However, Dr. Wiznitzer stated that the antibody in the Bogdanos article was immunoglobulin G (IgG), not IgM. Tr. 372. The difference between IgG and IgM is potentially important because the body produces IgM before it produces IgG.

Dr. Wiznitzer opined that the process described by Dr. Steinman was “biologically impossible.” Dr. Wiznitzer asserted that the corpus callosum could not become thin within six days of an injury. Tr. 184-85; tr. 358-61.

Whether Dr. Wiznitzer or Dr. Steinman is more persuasive on this point need not be resolved. Much like the issue about the persuasiveness of Dr. Steinman’s theory (addressed in the section on Althen prong 1), any determination about the timing prong would not affect the outcome of the Riccis’ case. Even if Thomas’s seizures developed within a medically appropriate time, a mere temporal proximity, causation is not necessarily established. Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1147 (Fed. Cir. 1992).

## V. Conclusion

Thomas Ricci received a dose of the hepatitis B vaccine on October 8, 1992, and had a seizure within one week. When he was hospitalized, he appeared not to have any signs or symptoms of inflammation within his central nervous system. His treating doctors did not identify a cause for Thomas’s epilepsy, which has left him developmentally delayed.

In this litigation, the Riccis and Dr. Steinman claim that the hepatitis B vaccine caused the subsequent neurological problems. This claim is not persuasive because Dr. Steinman’s theory posits that the adverse reaction to the hepatitis B vaccine would cause inflammation in his central nervous system and Thomas did not have this inflammation. Consequently, the Riccis have failed to meet their burden of proof. The Clerk’s Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

IT IS SO ORDERED.

S/ Christian J. Moran

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Christian J. Moran  
Special Master