OFFICE OF SPECIAL MASTERS
99-533V

Filed: March 12, 2004

CASEY HOCRAFFER,	*	
Petitioner,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Attorney Michael P. Milmoe, US. Department of Justice, Washington, D.C.
Attorney Paul S. Dannenburg, Esquire, Huntington, Vermont.

ERRATA[1]
ENTITLEMENT DECISION

FRENCH, Special Master

I. PROCEDURAL BACKGROUND

On July 2, 1999, petitioner Casey Hocraffer filed a petition pursuant to the National Vaccine Injury Compensation Program[2] (hereinafter referred to as "the Program") alleging that, after receiving two Hepatitis B vaccinations, the first on November 7, 1996, and the second on December 11, 1996, she suffered from the following injuries: sore throat, upper chest pain, difficulty in breathing and swallowing, encephalopathy, and Reye's Syndrome. Petitioner specifically alleged

[1] The changes herein reflect corrections of spelling and mechanical errors only. The content remains the same as that of the original decision filed March 11, 2004.

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 990660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-1 et seq. (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act"). Hereinafter, individual section reference will be to 42 U.S.C.A. §300aa of the Vaccine Act.

a "non-table" injury, but reserved the right to claim a "'table' injury as future facts may indicate." She claims that several symptoms developed within days of her first Hepatitis B vaccination, and that she suffered more severe symptoms following the second vaccination. Petition for Compensation Under the National Childhood Vaccine Act ("Petition," or "Pet."). The case was originally assigned on August 2, 1999 to Chief Special Master, Gary Golkiewicz, and was reassigned to the undersigned Special Master on July 23, 2002.

On April 30, 2002, respondent filed a Rule 4 Report recommending compensation be denied. Respondent's Report ("R. Report"). In his Rule 4 Report, respondent took the position that compensation in this case is not appropriate under the terms of the Program because petitioner has not established that the Hepatitis B vaccine is capable of causing her symptoms and has not established the requisite proof that the vaccine caused, in fact, her present condition. Petitioner disputed respondent's ultimate conclusion.

A hearing was postponed due to difficulties in acquiring the complete medical history, although petitioner's attorney of record made diligent efforts to produce the records relating to Casey Hocraffer's early medical history. Records were filed from the McFarland Clinic in Ames, Iowa and from the Mayo Clinic in Rochester, Minnesota. On December 11, 2002, respondent notified the court that he was satisfied with the medical records and that there was no challenge to the apparent facts. To elicit medical expert testimony, a hearing was held on June 17, 2003, in Washington, D.C.

The record is now closed and the case is ripe for decision. After reviewing the entire record, and for the reasons set forth below, the court finds petitioner has not carried the burden of proof required under the Act, and thus, is not entitled to compensation. A full discussion follows.

In providing an analysis of the case, the court will first discuss the statutory provisions and methods of proof as they apply here. Secondly, the court will lay out the undisputed facts. Next, the court will examine the testimony of the medical experts for the parties, focusing on petitioner's medical history and the chronology of events. Finally, the court will explain why the court finds testimony establishing alternative causation persuasive given the overall medical history, and how the chronology of events provides just cause for denying entitlement in this case.

II. STATUTORY PROVISIONS and METHODS OF PROOF

To prevail in a vaccine-related case, petitioner must establish that she is entitled to compensation, and can do so by one of two methods. First, if petitioner can establish that she sustained an injury or condition set forth in the Vaccine Injury Table, and if the injury was observed or manifested within a prescribed time following the immunization alleged to have caused the injury, the statute presumes causation, and petitioner is entitled to compensation. This method of proof is designated as a "Table"case. If petitioner is unable to meet the Table case criteria, the statute provides that petitioner may pursue a second method of proof, establishing that the vaccine actually caused the injury, including any sequellae. This method is commonly described as "actual causation" or "causation-in-fact." The actual causation method of proof has been the most common

method pursued by petitioners in recent years, although it presents indeed, a very heavy burden. As noted in the initial filing in this case, petitioner has identified this case as one of causation-in-fact, but reserved the right to pursue it as a Table case, should the evidence support such pursuit. Upon review of the entire record, the court agrees with the parties that this is an non-Table case and the court will analyze it as such.

To demonstrate entitlement to compensation in a non-Table case, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See, e.g., Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Secretary of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Secretary of HHS, 956 F2d 1144, 1146, 1148 (Fed.Cir. 1992). See also, §§11(c)(1)(C)(ii)(I) and (II). While the Act relaxes proof of causation standards for on-Table injuries, it does not relax the standards for non-Table injuries. See, e.g., Whitecotton v. Secretary of HHS, 81 F3d 1099, 1102 (Fed. Cir. 1996); Grant 956 F2d at 1148. To prevail under an actual causation theory, petitioner must establish entitlement to an award through traditional tort standards to prove legal causation-in-fact. See, e.g., Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

To meet the traditional preponderance of the evidence standard, "[a petitioner must] show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Secretary of HHS, 165 F.3d at 1353. A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury." Hines 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Secretary of HHS, 998 F.2d 979, 984; Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994). The logical sequence of cause and effect must be supported by "[a] reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." Grant, 956 F. 2d at 1148; Jay, 998 F.2d at 984; See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

The Federal Circuit has held that for a petitioner to establish a prima facie case of compensation based upon actual causation, petitioner must prove by a preponderance of the evidence that the vaccine was not only a "but-for cause of the injury, but also a substantial factor in bringing about the injury." Shyface 165 F.3d at 1352-1353. Petitioner does not meet her affirmative obligation to show actual causation by simply demonstrating an injury that bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also, H.R. Rep. No. 99-908, Pt. 1, at 15 (1986, reprinted in 1986 U.S.C.C.A.N. 6344. Moreover, a petitioner does not satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 718 F.2d 202, 205 (6th Cir. 1983), cert. denied 469 U.S. 817 (1984) (stating "inoculation is not the cause of every event that occurs within the ten-day period [following it]. . . . Without more, a proximate temporal relationship will not support a finding of causation")); Hodges v. Secretary of HHS, 0 F. 3d 958, 960. Nor does a petitioner demonstrate actual causation by solely eliminating other potential causes of the injury. See, e.g., Grant, 956 F.2d at 1149-1150; Hodges, 9 F.3d at 960.

In this case, petitioner alleges that she "suffered an encephalopathy and Reye Syndrome with repeated infections, and that these illnesses were actually caused by her vaccinations." Petition. She invokes both methods of proof "as the evidence may indicate," and contends that she suffered several vaccine injuries that continued to worsen. Id. An initial issue, therefore, is whether petitioner suffered an encephalopathy. A thorough review of the record reveals that petitioner failed to present testimonial evidence that persuaded the court that she did suffer an encephalopathy. Petitioner's copious medical records document many illnesses and injuries starting in early childhood, long before administration of the hepatitis B vaccine. The central remaining issue, then, is whether the vaccine did in fact cause or exacerbate petitioner's many symptoms. Accordingly, the court relies heavily on the experts' interpretation of the medical records as explained through their reports and oral testimony. The discussion begins with a summary, albeit a lengthy one, of the uncontested facts of this case.

III. FACTUAL BACKGROUND

Because most of the requisite medical records concerning petitioner's early medical history were delayed, the following facts represent a report by Robert N. Lipnick, at the request of Dr. Robert Weibel of the Division of Vaccine Injury, Rockville, Maryland. Dr. Lipnick agreed to summarize the available information to enable the parties to go forward in this case. The court agreed that a summary would be expedient. After a cautious review of Dr. Lipnick's report, the court finds it to be consistent with the complete medical record. Moreover, petitioner did not challenge the facts as reported in Dr. Lipnick's report. The parties are in apparent agreement as to the facts in this case.

The Lipnick Report

Dr. Lipnick is well qualified to review Casey Hocraffer's medical history. He is certified in pediatrics and rheumatology and has published an impressive number of peer reviewed articles and textbook materials in his field. Resp. Ex. B. Dr. Lipnick's full report provides a summary of the facts, based on the available medical records including medical documents, medical reports, hospital records, treatment records, and a review of medications. Resp. Ex. A.

To better understand Dr. Lipnick's report, the court now presents a list of symptoms as delineated by petitioner in her initial filing. Petition. It should be noted that the list was not included in Dr. Lipnick's report. The hepatitis B vaccine first administered on November 7, 1996 and again on December 11, 1996, allegedly caused these symptoms. The list is presented here as comity:

Upper respiratory infection: respiratory infection; pharyngitis
Acute sinusitis
Allergic rhinitis
encephalopathy
Reye's syndrome
Maxillary sinusitis

Severe headache
Photophobia
Nausea and vomiting
Loss or degradation of mental capabilities
Loss or degradation of coordination
Fatigue/malaise
Acute rhinitis
Mild dehydration
Numbness in hands and skin rash[3]

Relevant Facts

Dr. Lipnick's report of petitioner's medical history was filed on April 5, 2002. As noted above, the factual matters in this case were unusually lengthy and difficult to organize. Dr. Lipnick's description is fully consistent with petitioner's claim and the parties have agreed to these facts.

Casey Hocraffer was born on February 10, 1981. The delivery was without complications. At the present time, Casey is approximately 23-years-old and suffers with migraine headaches, abdominal pain, and mild endometriosis along with other symptoms claimed as sequellae of her alleged vaccine-related injury.

In October 1996, her intermittent abdominal pain led to a diagnosis of cystitis and was treated with Bactrim for ten days. At that time, she had a five-year history of abdominal symptoms, having been hospitalized in 1991 for abdominal pain and treated with intravenous fluids for dehydration and gastroeneteritis. During that five-year period, Casey was hospitalized four times for dehydration, three times for ovarian cystectomies and she had treated for recurrent urinary tract infections ("URI"). From 1993-1995, she had intermittent knee and ankle pain and was diagnosed with chondomalacia as well as patellofemoral syndrome and was treated with conservative measures including physical therapy.

Approximately 10 days after her October 1996 diagnosis of cystitis, she was again seen by Dr. Crozier, her primary care physician. Casey's mom wanted to discuss an offer by the public health nurse at school to administer the hepatitis B vaccine. Dr. Crozier discussed the pros and cons of the vaccination with Casey and her mother, commenting that Casey was not at high risk for hepatitis B. Casey's mother, however, decided that her daughter should receive the vaccine. The first dose was administered on November 7, 1996. Petitioner alleges that the onset of her vaccine-related symptoms first occurred approximately five days later. At that time she presented with a sore throat, upper chest pain, and difficulty breathing and swallowing, accompanied by a low-grade fever. These symptoms, it is claimed, got progressively worse. Rapid strep and mono-spot tests were administered, with negative results. She was treated with Phenylfenesin and Advil. Three days

[3] The skin rash and numbness would thereafter resolve.

later, she was still not feeling well. She had a normal CBC[4] at that time. The diagnosis was a non-strep, non-mono pharyngitis and URI. Eight days later, she returned to Dr. Crozier, complaining of increased sinus congestion, low-grade fever, sore throat and cough, and was diagnosed with acute sinusitis. She was placed on Septra, Claritin, and Tylenol. Three days later, she returned to Dr. Crozier's office and was diagnosed with persistent sinusitis; the Septra was discontinued and Flonase was added.

In December, exact date unknown, Casey was seen again by Dr. Crozier, who felt her sinusitis was improving, but noted that she had sustained trauma to her left wrist. Casey attributed the injury to her wrist having been pinched by the headboard of her water bed. No fracture was found. It was recommended she use an Ace bandage and take ibuprofen. Two days later, she was seen for nausea and weakness. She was diagnosed with viral gastritis and Zantac was recommended.

Although not documented in the medical reports, Casey received a second hepatitis B vaccination, administered at her school, on December 11, 1996. Five days later, she was admitted to the ER at Community Memorial Hospital in Clarion, Iowa with a one-day history of vomiting. On admission to the hospital, it was noted that her past medical history included a tonsillectomy, an adenoidectomy, an appendectomy, the removal of three ovarian cysts, in addition to having been hospitalized four times for dehydration. She had a history of irritable bowel syndrome as well.

Tests conducted on the day she was admitted, December 16, 1996, revealed an SGOT[5] of 175, SGPT[6] of 170, total protein at 5.9 and albumin at 3.7. The SGOT increased to 442 and the SGPT to 1190. Total protein was 4.8, albumin 3.4, hemoglobin 13, hematocrit 39, and WBC[7] 5.4. During that hospitalization she was noted to have mild nuchal rigidity.[8] A spinal tap was done, yielding no source of infection. Although Casey was noted to be slightly irritable during the hospitalization, there were no focal neurological findings. A presumed diagnosis of mild Reye's syndrome was made and she was primarily treated with IV fluids providing hydration, Demerol, morphine, and Phenagren. She was discharged on December 22, 1996, with orders for a follow-up visit with her primary care physician within a few days for a hepatitis panel, EBV[9] and CMV[10]. All

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[4] Complete blood count. Dorland's Illustrated Medical Dictionary at 287 (27th ed. 1988).

[5] Serum glutamic-oxaloacetic transaminase. Id. at 1513.

[6] Serum glutamate pyruvate transaminase. Id.

[7] White blood cell. Id. at 1852.

[8] Rigidity of the neck, or back of the neck. Id. at 1152.

[9] Id. at 525.

[10] Cytomegalovirus.

were found to be within normal limits. Adenovirus titers, however, were found to be elevated at 32 (0-8). Dr. Lipnick noted that the Reye's-like symptoms were found to be consistent with an adenovirus infection and that the elevated adenovirus titers support this conclusion.

On April 14, 1997, Casey was evaluated by Dr. Nathaniel Ratnasamy, an infectious disease specialist, for recurrent upper respiratory tract infections. Dr. Ratnasamy is also certified in internal medicine and respiratory illness.[11] Casey had follow-up visits with Dr. Ratnasamy on April 21, 1997 and June 16, 1997. During the April visit he noted that after starting Zyrec, petitioner developed a rash that became generalized, with diffuse numbness of her hands, all of which soon cleared. He noted that many of Casey's symptoms could be attributed to allergic reaction to the many medications she had been using. Casey's initial laboratory review included a normal CBC, ESR 23, normal chemistry profile, normal thyroid function, negative ANA[12], normal IgG, IgA and IgM. A throat culture was negative and chest x-ray normal. His notes include a review of her vital signs, general appearance, and a thorough exam on the first follow-up visit. Dr. Ratnasamy felt Casey was improving from her sinusitis and recommended that she continue with the treatment already prescribed and to complete a 2-week course of Ceftin, a nasal decongestant, as well. He remarked that there did not seem to be any underlying immune deficiency and that her condition appeared to be consistent with Reye's syndrome. He noticed that the onset of her upper respiratory tract and sinus infections seemed to be temporally related to her hepatitis B vaccinations. He believed, however, that they were not necessarily causally related. Resp. Ex. A at 18, Tr. at 24.

Because she was having headaches at that time, and seemed to be improving from her sinusitis, he raised the possibility that her headaches might be related to birth control pills, and recommended that she discontinue them. There is no information as to whether she followed through with Dr. Ratnasamy's recommendation.

On March 10, 1999, she was admitted to Community Hospital for IV hydration to treat her dehydration. During that time, she was diagnosed with mononucleosis and associated dysphagia[13] from her pharyngitis. Her liver enzymes were elevated including a SGOT of 79(0-35) and SGPT of 135(30-65) that increased on March 12, 1999, to a SGOT of 93 and SGPT of 149. An ammonia test on March 12, 1999, provided a normal result at 18(9-33). She was treated with Prednisone and Ultram. On June 10, 1999, petitioner had a motor vehicle accident that caused a hip contusion.

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[11] At the time of Casey's evaluation, Dr. Ratnasamy was in practice at the McFarland Clinic in Ames, Iowa. He currently practices in Findlay, Ohio. He provides preventive treatment to many patients traveling abroad, administering vaccination protection against yellow fever, Japanese encephalitis, and other less common diseases. In short, Dr. Ratnasamy has considerable experience with vaccines. Tr. at 19.

[12] Antinuclear antibodies. Dorland's at 69.

[13] Difficulty swallowing. Id. at 519.

On October 10, 1999, she was hospitalized for uncontrolled pain secondary to long-standing migraine headaches. She was on Amtriptyline and treated with magnesium citrate, Naprosyn, Inderal, and Prilosec.

She was admitted to Mercy Hospital in Mason City, Iowa, on August 29, 2000, for acute abdominal pain and underwent a diagnostic laparoscopy.[14] Diagnosed with mild endometriosis, she was treated with birth control pills.

Casey was again admitted to Mercy Hospital on March 22, 2001, for abdominal pain and possible pelvic inflammatory disease. She was admitted to Community Memorial Hospital a week later, on March 29, 2001 and diagnosed with pelvic inflammatory disease ("PID") and endometriosis.

From time to time, Casey would be re-admitted to Community Hospital for IV hydration. She had frequent office visits with Dr. Crozier. Recurrent URI's prompted Dr. Crozier to request another consultation with Dr. Ratnasamy.

IV. EXPERTS' TESTIMONY

For Petitioner: Dr. Nathaniel Ratnasamy, M.D., Findlay, Ohio by report and telephonic oral testimony
Dr. James Heubi, M.D., Cincinnati, Ohio by report and in person

For Respondent: Dr. Robert Lipnick, M.D., Charlottesville, Virginia by report
Dr. Alan I. Brenner, M.D., Cincinnati Ohio, by report and in person

Dr. Nathaniel Ratnasamy for Petitioner

Dr. Ratnasamy's initial impression of Casey's condition, on April 14, 1997, was that her respiratory tract infections were persistent and were consistent with recent findings of sinusitis. Because of her previous allergic history, he opined that despite the temporal relationship of the recurrent infections with administration of the vaccine, he doubted any causal relationship. He opined that her overall symptoms were consistent with Reye's syndrome. He did consider the fact that some people develop "post-infectious fatigue" and that this fatigue is sometimes associated with mild immune dysfunction. Tr. at 22. He reviewed possible etiological agents, including Epstein-Barr virus and human herpes 6, and suspected connective tissue disease caused by the viruses. Id. He

[14] Laparoscopy is an examination of the interior of the abdomen by means of a laparoscope. Id. at 896.

considered the possibility of abdominal CT[15] to rule out lymphoma. Test results showed no evidence of lymphoma and that possibility was no longer considered.

In a follow-up visit with petitioner, Dr. Ratnasamy observed development of a rash that became generalized with diffuse numbness of the hands, that worsened. There followed an onset of vomiting. A later visit, in late April 1997, showed that the rash had cleared. Dr. Ratnasamy's notes indicate that a neurologic evaluation was normal. In a continued attempt to explain petitioner's condition, he considered the possibility of allergic reaction to the many medications she had been using, but a review of all lab results available to him indicated no evidence of immune dysfunction or ongoing infection. By June 1997, Dr. Ratnasamy concluded that the persistent headaches, fatigue, and general malaise were probably all part of "post-viral fatigue."

Dr. Ratnasamy continued to follow Casey's condition until October 2001, when, after a consultation with Dr. Crozier, at Dr. Crozier's request, Dr. Ratnasamy slowly came to change his conclusions about the cause of Casey's medical problems. Following that consultation, Dr. Ratnasamy opined that a post-vaccinal reaction to her two hepatitis B vaccinations most likely caused her condition. He based his opinion on three factors. First, the medical record demonstrated no alternative cause. Second, her symptoms were remarkably temporally related to her hepatitis B vaccinations. Third, her symptoms significantly worsened after the second hepatitis B vaccination of December 11, 1996, an observation that will be addressed below.

Dr. Ratnasamy came to believe that Casey's general malaise was probably due to an antigen. He suggested that the vaccine was the trigger that started the cascading events. Tr. at 23. At first, he believed that Reye's syndrome was the most likely illness. He was not able to identify any other antigen, and all subsequent test results were within normal limits. Upon cross-examination at the June 17, 2002 hearing, Dr. Ratnasamy acknowledged that he was not able to identify any antigen per se, but that the hepatitis B vaccinations were administered close to the time Casey had these symptoms. He commented, "that factor stands out to me more than anything else. In the process of differential diagnoses, the hepatitis B surface antigens are likely the antigen in the picture." Tr. at 24, 25. Respondent then asked the doctor, "Would it be fair to say that you consider [the vaccine] the most likely trigger because of the temporal association between the [shot] and the onset of symptoms?" Tr. at 25. Dr. Ratnasamy replied,

> The temporal association, as well as a lot of review of literature, I think. You know, any time we introduce an antigen into the body there is potential for a variety of reactions, serum sickness type of reaction, and you probably saw in one of the exhibits the LFT[16] abnormalities that have been reported with the hepatitis B. . . . and I think based on the sequence

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[15] Computerized tomography. Tomography is the recording of internal body images at a predetermined plane by means of the tomograph. Id. at 1729.

[16] Liver function tests.

of events as well as other case reports, I think hepatitis B [as the trigger] is very possible. Id.

Dr. James E. Heubi for Petitioner

Dr. Heubi is a pediatric gastroenterologist, a medical doctor specializing in, and board-certified in the fields of pediatrics, gastroenterology and nutrition. He is currently serving as an attending physician in hepatology[17] and gastroenterology at the Children's Hospital in Cincinnati, Ohio. He is licenced in Ohio, Indiana, and Kentucky. He is program director of the General Clinical Research Center, an NIH- funded research program at the Children's Hospital, and medical director for the National Reye's Syndrome Foundation. He has extensive experience with the diagnosis and treatment of Reye's syndrome and conditions presenting with Reye's-like symptoms. Dr. Heubi has often served as an expert witness regarding Reye's syndrome and other liver diseases. He has reviewed the materials relating to Casey Hocraffer, including the notes of her various treating physicians. He has corresponded with Smith Kline Beecham Pharmaceuticals regarding her condition and adverse reactions associated with the hepatitis B vaccine the company manufactures. In short, Dr. Heubi is a nationally recognized expert on Reye's syndrome.

Based on his acknowledged expertise, Dr. Heubi is convinced that Casey's vaccinations caused the onset of Reye's syndrome. Dr. Heubi is of the opinion, to a reasonable degree of medical certainty, based on his experience with the hepatitis B vaccine, that the development of repetitive emesis heralding the onset of Reye's syndrome in this case, is convincing evidence of a causal relationship to the hepatitis B vaccine for several reasons. Casey was immunized twice with Engerix hepatitis B vaccine. The first such immunization, administered on November 7, 1996, resulted in a series of symptoms described in the early portions of this decision, some of which had not manifested prior to the vaccination. According to petitioner's experts, the second dose of hepatitis B vaccine, administered on December 11, 1996, prompted significantly more severe and more damaging symptoms.

The presumptive diagnosis of Reye's syndrome was made during hospitalization. Dr. Heubi is of the opinion that the pernicious vomiting, which prompted Casey's hospitalization following her December vaccination, was in fact Reye's syndrome and was related to the second hepatitis B vaccination. He explained, "Vomiting, we believe to be the initial presenting complaint of those patients with Reye's syndrome, and typically it's repetitive, as it was in her case." Tr. at 40, 41.

Linking the illness to the vaccine, he relies upon the temporal association of the onset of symptoms, five days after the second vaccination. "[T]he time sequence was virtually dead on for that immunization being her preceding or prodromal illness." Tr. at 39. When asked by the court why symptoms of Reye's typically occur several days after a preceding illness, Dr. Heubi stated there is no known answer to that question. He offered a theory that "there were events occurring and [Reye's] may relate to the release of circulating protein, things called cytokines or other particular

[17] Study of the liver. Id. at 754.

factors that then led to the cascade of events that precipitated with vomiting and the mitochondrial injury or the organelle injury in the liver and brain and the other organs that we saw associate with the disease." Tr. at 40. Dr. Heubi explained that to date, we don't know what causes Reye's syndrome, nor do we understand the pathogenesis to disease. Id. He attested to the rarity of the illness, and to the decline in the number of cases.[18] Tr. at 38, 40.

Dr. Heubi concedes that there is no literature directly linking the hepatitis B vaccine to Reye's syndrome, but adds that the type of adverse reactions associated with the vaccine represent a large variety of viruses associated with Reye's. Tr. at 58. He explains that he thinks the vaccine could have triggered Reye's because "the antigen is present, it does stimulate an immune reaction, most likely cytokine production and other materials that may be very similar to what occurs from influenza A and B and varicella." Tr. at 60. He notes a case series in which the children with JRA[19] were found to have Reye's syndrome without a prodromal illness, suggesting that systemic disease, or, as in this particular case, the reaction to a vaccine, could be a surrogate prodromal illness. He maintains that the onset of Reye'syndrome is convincing evidence of a causal relationship, yet states that the CDC[20] criterion for Reye's "doesn't include hepatitis B because it's clearly not an agent that it's commonly associated with." Tr. at 43.

As to Dr. Heubi's understanding of Casey's current condition, he stated that he cannot tell if the symptoms she is currently experiencing are due to Reye's syndrome. Tr. at 60. On cross-examination, he explained that although an article published in 1974[21], lists URI and chicken pox as the most common prodromal viral illnesses to trigger Reye's, there is a "myriad of other viruses . . . associated with the onset of Reye's syndrome." Tr. at 61. Dr. Heubi concludes that the temporal relationship between vaccination and development of a Reye's-like syndrome, evidenced in the pernicious repetitive emesis that occurred shortly after vaccination, is, in his opinion, indicative of a causal relationship.

The court will explore the issue of Reye's syndrome in more detail below.

Dr. Alan I. Brenner for Respondent.

Dr. Brenner is board-certified in internal medicine and rheumatology, and is an expert also

[18] Dr. Heubi explains that the reason for the decreased occurrence has not been completely considered but opines that "[p]art of it probably is related to reduction in aspirin usage. Some are [reasons] that we don't understand very well." Tr.at 39.

[19] Juvenile Rheumatoid Arthritis.

[20] Centers for Disease Control.

[21] Sullivan, et al. American Journal of Epidemiology (1974).

in evaluation of drug-induced hepatoxicity[22]. Dr. Brenner was the sole expert witness to testify in person for respondent at the June hearing. His report provides the core of respondent's position in this case. See, Resp. Exs. C and D.

Dr. Brenner's opinion is based on his training and experience, his review of Casey Hocraffer's medical record, and his own extensive review of the relevant medical literature. He argues, to a reasonable degree of medical certainty, there is no reason to consider that the hepatitis B vaccinations played any causal role in the medical problems alleged by petitioner. In his opinion, the problems documented in her medical records, were "a natural outgrowth" of problems developed prior to the vaccinations. Dr. Brenner believes that symptoms existing prior to vaccination, including those conditions that may have resulted from medication toxicity, are more likely related to a condition called Central Sensitization Syndrome than to the vaccine. Dr. Brenner explains that medication toxicity is a real possibility here, and includes among the suspect medications, Promethazine and other medications, including analgesics and Tylenol. Casey has been known to suffer adverse allergic reactions to NSAIDS,[23] such as Tylenol, since birth.

Dr. Brenner observed that,

> Casey's past medical history is unfortunately interesting. Her past medical history is replete with episodes of respiratory and gastrointestinal illness acknowledged by her treating physicians long before she received the hepatitis B vaccine. It is replete with musculoskeletal injuries slow to heal or at least slow to be accepted to have healed by Casey. It is replete with other gastrointestinal problems, particular [sic] irritable bowel syndrome, the diagnosis made and accepted by her treating physicians long before she was administered hepatitis B. Tr. at 93, 94.

Dr. Brenner explains that the gastrointestinal ("GI") symptomology is called irritable bowel syndrome, and is an initial manifestation and extremely common element of a condition called Central Sensitization Syndrome. "This has only been actually recognized for the last several years."[24] Tr. at 97.

The syndrome encompasses "a complex of conditions, among which are irritable bowel syndrome; a condition called irritable bladder, which is a sense of recurring urinary tract infections with steroid urine; the musculoskeletal condition of fibromyalgia; migraine headache; temporo-mandibular joint dysfunction and, very often, neuropsychiatric manifestations, particularly cutaneous paresthesia, numbness and tingling without an anatomic basis." Tr. 95, 96.

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[22] The quality or property of exerting a destructive or poisonous effect upon liver cells. Dorland's at 755.

[23] Non-steroidal anti-inflammatory drug.

[24] Dr. Heubi also addresses this condition. See, Tr. at 63, 633.

These conditions, he claims, all seem to be part of central nervous system imbalance. Patients like Casey Hocraffer,

> . . . who appear to be hypersensitive to noxious stimuli, feel things the rest of us don't feel. They hurt when the rest of us don't hurt. All of these manifestations probably are of a single origin. Looking back at Casey Hocraffer's history, and looking forward to what I know about her history, that's her story. It's unfortunately typical. There is a long literature of these conditions also beginning in childhood and progressing through to adulthood, and they don't go away. They're difficult to manage under the best of circumstances. . . . I spend much of my day trying to manage those people with a hormonal or chemical imbalance that causes certain people, and there are many, who appear to be hypersensitive to noxious stimuli. Tr. at 94 - 97.

The gastroenterology pathology is neurochemical. " I mean, you can find evidence of changes, but they are not anatomic, they are neurologic, they are neurohormonal, so that all of these things have a common ideology, and I think that's this girl's long- term problem." Tr. at 98. According to Dr. Brenner, a high percentage of children with irritable bowel syndrome and/or children with otherwise undiagnosed, but non-recurrent abdominal pain, continue to have irritable bowel syndrome. Tr. 93, 94, 95. "As soon as I saw that this young girl had a diagnosis as a child of irritable bowel syndrome, I thought to myself, I know where this case history is going. I know where it's going, because it's predictable." Tr. at 96.

The symptoms associated with Central Sensitization Syndrome are representative of much of petitioner's long symptomology history. Dr. Brenner opines that her symptoms during hospitalization may, at times, have been caused by problems due to the many medications she took. Nevertheless, he insists, her symptoms are clearly consistent with those observed in Central Sensitization Syndrome. He lists some of the manifestations observed in Casey's case as irritable bowel and bladder syndrome; recurrent upper respiratory and urinary tract infections; fibromyalgia; migraine headaches; neuromicropsychiatric manifestations, particularly cutaneous paresthesia, numbness and tingling without an anatomic basis; and probable atopy[25] as manifested by peripheral blood eosiniphilia. In addition, "she experienced dysfunctional menses as well as adverse reactions to over-the-counter NSAID analgesics [e.g., Tylenol], and had numerous evaluations for musculoskeletal injuries including a left knee injury in 1995 that took over one year to

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[25]Atopy is a genetic predisposition toward the development of hypersensitivity reactions against common environmental antigens (atopic allergy) occurring in 10 % of the general population, 50% of those with one affected parent, and 75% of those with two affected parents. The most common clinical manifestation is allergic rhinitis; bronchial asthma, atopic dermatitis, and food allergy occur less frequently. The form exhibited may vary over time and may differ from that exhibited by the parents. Dorland's at 163.

symptomatically resolve despite negative physical and arthroscopic examinations and intra-articular corticosteroid administration." Resp. Ex. C at 6. That Casey's clinical history mirrors the symptoms Dr. Brenner ascribes to Central Sensitization Syndrome and the explication of his expert opinion statement causes the court to take close notice.

Dr. Brenner maintains that Casey Hocraffer's overall picture is consistent with the features of Central Sensitization Syndrome in that her pre-vaccination history and post-vaccination course are consistent with that condition. The respiratory infections that Casey Hocraffer manifested after her first hepatitis B vaccination were eventually associated with a thickening of the mucoperiosteum of the right maxillary antrum, as evidenced by x-rays taken on November 26, 1996. Dr. Brenner maintains that from a medical view, this suggests underlying chronic sinus inflammation, and argues that it would be unlikely to have begun less than three weeks earlier, and therefore would have been developing prior to her first hepatitis B vaccination, administered on November 7, 1996. Dr. Brenner comments that petitioner's experts rely too strongly on the issue of temporal association with the vaccination. After petitioner received the hepatitis B vaccinations, her doctors were well aware of the unusually close association with certain symptoms. Still, they were baffled as to the cause of those symptoms. Dr. Brenner maintains that Casey had developed these problems prior to vaccination.

As for the diagnosis of Reye's syndrome, Dr. Brenner challenges the opinions of petitioner's experts. Dr. Brenner notes that the circumstances surrounding the development of elevated transaminase and her slightly elevated ammonia level found shortly after Casey's second vaccination could actually suggest that the condition causing these results may actually have originated before that second vaccination. He explains that the elevations noted in her test results have been associated with hepatotoxicity and eosinophilia[26] and as such are more likely, the result of the administration of Phenergan (promethazine) than of the hepatitis B vaccine. Dr. Brenner adds that medical literature documents that a high percentage of children and adolescents who develop hepatic dysfunction in association with gastrointestinal illnesses, do so in reaction to antiemetics administered to stay vomiting. Casey was treated with antiemetics when hospitalized for pernicious vomiting in December 1996. Thus, he argues that the symptoms attributed to Reye's syndrome are more likely a reaction to medication. Furthermore, he continues, another percentage of patients previously diagnosed with Reye's syndrome, are now known to have hepatic dysfunction including hyper-ammonemia, based on defects in mitochondrial metabolic pathways. Resp. Ex. C at 7.

Dr. Robert Lipnick for Respondent

Having provided the summary of facts as requested by respondent, Dr. Lipnick is of the opinion that Casey Hocraffer most likely had a viral infection that resolved rather quickly. He proposes several reasons for rejecting petitioner's arguments, maintaining that although this viral infection appears to be temporally related to the vaccinations, it is not likely causally associated. He

[26] The formation and accumulation of an abnormally large number of eosinophils in the blood. Id. at 564.

bases his position on several factors.

Six days after receiving a second hepatitis B vaccine, Casey was hospitalized with a 24-hour history of vomiting. She was ultimately diagnosed with mild Reye's syndrome. Dr. Lipnick opines that any viral infection found is significant, but he finds it more so in this case because some of her symptoms preceded her hepatitis B vaccinations. According to Dr. Lipnick, nothing in the medical records, nor any arguments from petitioner's experts convincingly demonstrate that Casey's condition was caused, or in any way aggravated, by the vaccine. He argues that Dr. Ratnasamy's theory of causation is based strictly on two factors, temporal association and what Dr. Ratnasamy regards as a lack of any alternative cause. These factors, Dr. Lipnick states, are mere speculation. The legal implications of these factors will be discussed often in the analysis below.

Dr. Lipnick challenges this expert's position, finding no sound reason for Dr. Ratnasamy's change of opinion. Dr. Lipnick considers that change to be an unsupported departure from Dr. Ratnasamy's earlier statement in which he determined that Casey's symptoms were temporally related to the vaccine but not necessarily causally related. Dr. Lipnick finds it significant that during Casey's December 1996 hospitalization, the presence of Adenovirus was evidenced by the virus' elevated titers. He opines that this evidence strongly suggests other causes, more likely than the vaccine, are responsible for Casey's condition. Dr. Lipnick finds it unlikely that "mild Reye's syndrome," was caused by the vaccine.

In short, Dr. Lipnick dismisses Dr. Ratnasamy's position, insisting that it fails to establish the causal relationship required by statute. Mere evidence that a viral syndrome appears to be temporally related to a vaccination does not establish that it is causally related. In addition, he speculates that Casey's severe migraine headaches might be related to the birth control pills she took. Contrary to petitioner's assertion that there is no alternative to the vaccine as the cause of Casey's condition, Dr. Lipnick presents several alternatives. He questions the likelihood of any causal link to the vaccine, noting that after her discharge on December 22, a hepatitis panel performed several days later, showed EBV titers and CMV titers to be within normal limits. Ultimately, it is Dr. Lipnick's opinion that Petitioner suffered from a viral infection unrelated to the administration of hepatitis B vaccine.

The Issue of Reye's Syndrome

Whether Casey Hocraffer had Reye's syndrome is not the primary issue in this case. Dr. Heubi maintains that petitioner demonstrated the classic symptoms of Reye's syndrome, but the main issue is not whether Casey's condition following the second vaccination was indeed Reye's syndrome. The main issue is whether it was the hepatitis B vaccine that caused the symptoms of Reye's syndrome and whether petitioner's current condition is sequellae related to the hepatitis B vaccine. Respondent demurs, arguing that petitioner's condition immediately after the second vaccination was not Reye's syndrome.

Although the issue of Reye's syndrome is only tangentially relevant, the court has carefully reviewed Dr. Heubi's opinion testimony and the articles he filed, including one article titled Reye's

Syndrome Diagnostic Considerations. Pet. Ex. P. The court finds Dr. Heubi to be a most credible witness. Dr. Heubi convinced the court that Casey's symptoms fit the medical criteria for a diagnosis of Reye's syndrome, but that factor is irrelevant to the issue of causation. On the contrary, Dr. Heubi does not provide any reliable mechanism whereby the vaccine could cause Reye's syndrome. The court concurs with Dr. Lipnick's opinion that there is no credible evidence that the Reye's syndrome was caused by the vaccine. It appears likely, however, that Reye's syndrome did cause Casey's pernicious vomiting.

The court finds that the testimony of Dr. Brenner was also highly credible and proposes a more likely cause of petitioner's long-standing condition. He acknowledged Dr. Heubi's expertise concerning Reye's syndrome and never professed to share the same. Tr. at 106, 109. Instead, he presented an alternative diagnosis, based upon his area of expertise, hepatoxology. For Reye's syndrome, the medical community has no definitive test upon which to rely, and relies instead on the interpretation of symptoms. That Drs. Ratnasamy, Heubi, and Lipnick agree on a diagnosis of Reye's, or Reye's-like condition, cannot be ignored. As previously stated, however, the diagnosis of Reye's syndrome does not provide the necessary causal link between Casey's condition and the hepatitis B vaccine. On the contrary, both Drs. Lipnick and Brenner provide well-reasoned alternatives to a vaccine-related causation.

Dr. Lipnick testified that he believed it most likely that Casey had a viral infection that resolved within a short period of time. He explained that Reye's syndrome

> certainly may follow any viral infection and again; though temporally related to the second hepatitis-B vaccine injection, it is not likely causally related. She did have elevation of Adenovirus titers during that hospitalization and her course of a mild Reye's-like syndrome certainly is consistent with an Adenovirus infection.

Apparently, Dr. Ratnasamy's initial conclusion that there was no causal relation between the hepatitis B vaccine and Reye's syndrome was in keeping with that of Dr. Lipnick. In fact, several years passed before Dr. Ratnasamy departed from that conclusion to concur with petitioner's position that the injury was vaccine-related.

After careful analysis of not only the expert testimony, but of the entire record, the court finds that in December 1996, petitioner, more likely than not, developed Reye's syndrome. This finding does not rule out Dr. Brenner's alternative theories of causation. It is probable that at least some of the symptoms following the second vaccination, were a reaction to any one of several medications administered. Furthermore, nothing in the record indicates that Reye's syndrome and Central Sensitization Syndrome are mutually exclusive.

Dr. Heubi provided persuasive evidence that the persistent emesis following the second vaccination is symptomatic of Reye's. Yet, as stated earlier, that diagnosis does not explain years of illness and injury prior to the vaccine. Dr. Brenner provides compelling explanation with his diagnosis of Central Sensitization Syndrome. This finding is an important factor in settling the most

important issue, whether the hepatitis B vaccine had a role in causing petitioner's present condition. The court is of the opinion that, in fact, it did not.

V. ANALYSIS AND CONCLUSIONS

As noted earlier, petitioner sustained an injury not set forth in the Vaccine Injury Table. Therefore, the court will analyze the record as a non-Table case. To prevail, petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See supra, Bunting v. Secretary of HHS, 931 F.2d 867, Hines v. Secretary of HHS, 940 F.2d 1518, Grant v. Secretary of HHS, 956 F2d 1144. Petitioner bears the burden of establishing "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." See, Shyface 165 F.3d at 1352, supra. In the matter before this court, petitioner does not qualify for a Table presumption and has not presented credible substantive evidence that would support an argument for actual causation. The court finds that a clear causal link to the hepatitis B vaccine has not been persuasively presented. Petitioner has not established a likely mechanism of causation, no logical sequence of cause and effect showing that the vaccination was the reason for the injuries and their sequellae. On the contrary, a preponderance of the evidence leads to causes unrelated to the vaccine. Respondent has persuaded the court that Central Sensitization Syndrome and/or medication toxicity are a more likely and viable cause of petitioner's unfortunate condition. Therefore, petitioner has failed to satisfy the requirements for compensation under the Program.

This case presents intriguing medical issues. Central to the court's discussion, is the comparison between the parties' interpretation of petitioner's extensive medical history, a history that documents almost a lifetime of illness and injury starting many years before administration of the hepatitis B vaccine. The interpretations were well-reasoned, demonstrating the high level of professionalism of these experts. The ultimate outcome of this case depends upon the court's evaluation of the expert testimony. Both parties' experts linked their assertions to two compelling issues, temporal association and alternate causes. While petitioner's experts relied heavily on the temporal association to establish causality between administration of the hepatitis B vaccine and Casey's injury, respondent's experts consistently explained why the undisputed temporal association carries little weight, medically. Petitioner does not meet her affirmative obligation to show actual causation by merely showing a proximate temporal association between the vaccine and the injury. Grant, 956 F.2d at 1148 (quoting Hasler, 718 F.2d 202, supra, (stating inoculation is not the cause of every event that occurs within the ten-day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation")); Hodges, 9 F.3d at 960. Nor does petitioner demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

In Shyface, the Federal Circuit has held that,

> establishment of prima facie entitlement to compensation according to the non-Table method would require the petitioner to prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury

> but also a substantial factor in bringing about the injury. As discussed in Grant, in order to show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show "a medical theory causally connecting the vaccination and the injury." There must be a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Id. Shyface, 165 F.3d at 1352, 1353.

The court takes notice of the professional manner in which the medical experts presented their opinions and recognizes petitioner's attempts to bolster her arguments with copious medical literature discussing Reye's syndrome. These articles bear mention here in that they provided the court with a fine understanding of the diagnostic markers for the condition, along with its implications. Drs. Ratnasamy and Heubi provided well-articulated medical opinions, but the court does not agree with their conclusions, at least not in this particular case. They have simply not persuaded the court that even if Casey did develop Reye's, that the vaccine was the cause.

In fact, the literature informed the court that Reye's is most usually related to prior illness. That Casey was ill goes without question. That the illness was attributable to hepatitis B vaccine is, however, not only questionable, but legally untenable. Casey's medical records reveal a litany of symptoms that preceded her hepatitis B vaccinations, including elevated Adenovirus titers. Moreover, nothing in those records or the testimony of any expert establishes that her condition was in any way exacerbated by the vaccine.

Dr. Brenner's explanation of medication toxicity as the cause of symptoms Casey suffered after her vaccinations is highly persuasive, negating petitioner's assertion of lack of alternative cause. Even Dr. Ratnasamy initially attributed Casey's symptoms to medication toxicity, acknowledging a temporal association between vaccination and onset, but asserting that the temporal association was not a causal one. Resp. Ex. A at 18, Tr. at 24. The court acknowledges that while Dr. Ratnasamy noted that Casey's symptoms suggested an adverse reaction to medication, he also suggested that her condition seemed consistent with Reye's syndrome. Petitioner admits to a dearth of literature attributing the onset of Reye's syndrome to the hepatitis B vaccine. Respondent furnished the court with literature supporting his theory that specific medications Casey took were known to cause, in sensitive individuals, the symptoms Casey exhibited. Significantly, Casey's medical record shows that she had, at times, suffered allergic reactions to Tylenol, one of the many medications she was using at the time she was vaccinated. Dr.Brenner is an expert in the field of evaluating drug-induced hepatoxicity. Relying upon his expertise, the court finds it probable that some of Casey's medications spawned several of her persistent symptoms.

Petitioner has not established that the vaccine was a substantial factor in causing her injury nor that it was a but-for cause. Simply put, respondent persuaded the court that, more likely than not, Casey would have presented with the symptoms she did in November and December of 1996 had she never received the hepatitis B vaccine. The court is held to the substantial factor and but-for standard set forth in Shyface. Admittedly, petitioner is not allowed much flexibility in persuading the court that she is entitled to compensation. "The bar set for petitioner to provide evidence that the vaccine was the actual cause of injury is a high one. The Act relaxes proof of causation in fact for injuries

satisfying the Table in § 300aa-14, but does not relax proof of causation in fact for non-Table injuries." Grant, 956 F.2d at 1148. Petitioner's burden of proof in non-Table cases is a heavy one. Whitecotton v. Sec'y HHS, 81 F.3d 1099, 1102 (Fed. Cir. 1996); reh'g denied (1996). Repeated review of the record as a whole convinces the court that respondent's theories of causation are more plausible than petitioner's.

The court is not looking for medical certainty in determining causation, acknowledging that "identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." Knudsen v. Secretary HHS, 35 F. 3d 543, 549 (Fed. Cir. 1994). The court is looking for a well-reasoned medical explanation of a logical sequence of cause and effect (Grant, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, 35 F.3d at 548-549). As applied to this matter, the court, having been presented with medical explanations of causation from both parties, is left to determine which of those explanations is more probable than not. After careful consideration, the court finds respondent's medical explanation of a logical sequence of cause and effect more persuasive than that of petitioner.

Not only did respondent present a compelling argument for medication toxicity having caused Casey's condition, but he furnished a persuasive argument for causation in his discussion of Central Sensitization Syndrome. Given her expansive medical history, Casey Hocraffer's condition is markedly similar to the description of patients who demonstrate symptoms of a central nervous system imbalance. The symptoms these patients present, the constellation of which comprise what Dr. Brenner identifies as Central Sensitization Syndrome, read like an excerpt from Casey's medical records. The symptoms amply documented in her medical history present support for Dr. Brenner's theory of causation. At the same time, the court acknowledges that, for the most part, Casey's symptoms in 1996 are similar to those outlined in the Reye's syndrome literature.

If the court were to, as petitioner would have it, consider the events of late 1996 as an isolated series of incidents, it would possibly be more easily persuaded that Casey had developed Reye's at that time because of the vaccine. The court is charged, however, with considering the injured's entire medical history. Petitioner fails to address the unfortunate occurrence of a multitude of conditions that pre-date exposure to the hepatitis B vaccine. A diagnosis of Reye's does not explain the unusually high incidence of illnesses and injuries that Casey suffered from her earliest years. A diagnosis of Central Sensitization Syndrome provides such explanation. The court is not at all convinced that Casey's condition is anything but a natural progression of a pattern of illness established years before her exposure to the hepatitis B vaccine; a pattern that, sadly, has continued into adulthood.

VI. CONCLUSION

This case has required an unusual amount of testimony extended over many months due to

apparently unavoidable delays in submission of medical records and reports. Additional delay resulted from difficulty in scheduling a hearing date that accommodated the schedules of experts and counsel. Following the hearing held on June 17, 2003, the court expended great time and effort in reviewing the record as a whole. The court's decision, therefore, is based on a most fundamental consideration – which of the parties provided the more persuasive theory of causation? Respondent provided a more probable theory of causation, and it is upon that theory that the court relied in reaching its conclusion that petitioner failed in carrying her burden of proof. Casey Hocraffer's condition is, more likely than not, caused by factors unrelated to the hepatitis B vaccine.

Based on the above, the court finds, after considering the entire record in this case, that petitioner is not entitled to compensation under the Vaccine Act. The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

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E. LaVon French