In the United States Court of Federal Claims

No. 99-533V
(Filed: January 26, 2005)

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CASEY HOCRAFFER,	*	
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Petitioner,	*	
	*	**Vaccine Act; Non-Table Injury;**
v.	*	**Causation in Fact; Hospitalization**
	*	**with Surgical Intervention**
SECRETARY OF HEALTH and	*	
HUMAN SERVICES,	*	
	*	
Respondent.	*	
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Paul S. Dannenburg, Huntington, VT, for petitioner.

Michael P. Milmoe, U.S. Department of Justice, Washington, DC, with whom was *Peter D. Keisler, Assistant Attorney General* for respondent.

OPINION

FIRESTONE, *Judge*.

This matter comes before the court on Petitioner's Motion for Review of Special Master LaVon French's dismissal of her claim for compensation under the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. § 300aa-1--34 ("Vaccine Act" or "Act"). Petitioner seeks compensation for injuries allegedly resulting from the administration of two hepatitis B vaccinations in 1996. After careful review of the record

presented, the court finds that the decision of the Special Master was arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law. Accordingly, as provided for under the Vaccine Act, the court will issue its own findings of fact and conclusions of law pursuant to 42 U.S.C. § 300aa-12(e)(2)(B).

I. FACTUAL BACKGROUND

Petitioner, Casey Hocraffer, filed a petition in 1999 alleging that, after receiving two hepatitis B vaccinations, the first on November 7, 1996, and the second on December 11, 1996, she suffered, inter alia, the following injuries: an encephalopathy,[1] Reye's Syndrome,[2] and mental and physical deficits as a result of the encephalopathy. Petitioner alleged that she met the criteria for compensation under the Vaccine Act for a "Non-Table" injury. Under § 300aa-11 of the Vaccine Act, a petitioner may establish a right to compensation upon proof that (1) the petitioner received one of the covered childhood vaccines on the "Table" of vaccines covered by the Act; (2) the petitioner suffered an injury or aggravated an injury set forth in the Table associated with the vaccine, or sustained an injury, illness, disability, or condition not set forth in the table [i.e. a Non-Table Injury] but which was "caused" by the vaccine; (3) the petitioner suffered complications from the vaccine which lasted for more than six months, died, or was hospitalized and had a surgical

[1] Encephalopathy is simply, "a disease of the brain." Merriam-Webster's Collegiate Dictionary 380 (10th ed. 1998).

[2] Reye's Syndrome is characterized by increased fattiness in the liver and encephalopathy, or brain injury, the manifestation of which can range in severity from mild lethargy and irritability to severe coma. Pet'r Ex. P (Jay M. Meythaler & Rajiv R. Varma, Reye's Syndrome in Adults, 147 Arch. Intern. Med. 61 (Jan. 1987)).

procedure resulting from the vaccination[3]; (4) the petitioner has not collected an award or settlement for such vaccine injury or death; and (5) the illness, disability, injury, condition or death described in the petition was not due to factors unrelated to the administration of the vaccine described in the petition. See 42 U.S.C. § 300aa-11(c)(1).

Petitioner alleged that she contracted Reye's Syndrome following her hepatitis B vaccinations and that this "Non-Table" injury caused her to be hospitalized and to sustain a surgical intervention. In addition, Petitioner alleged that she suffered the residual effects of the Reye's Syndrome for more than six months. She did not, however, claim that her current health condition, as of the hearing in 2003, was related to her Reye's Syndrome.

According to the medical records, Ms. Hocraffer was born on February 10, 1981. Between her birth and her receipt of the hepatitis B vaccinations in 1996, Ms. Hocraffer suffered a variety of illnesses. She was hospitalized four times for dehydration and three times for ovarian cystectomies. She had also been treated for recurrent urinary tract infections. She had a history of irritable bowel syndrome, and suffered from wrist, shoulder, and right and left knee injuries.

Although specific vaccination documentation is not available, the records indicate that Petitioner received her first dose of the hepatitis B vaccine from a Public Health nurse

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[3] The Vaccine Act was amended in 2000 to include hospitalization and surgical intervention as a compensable consequence of a vaccine injury. The amendment provided that it applied to all petitions pending on the date of its enactment. Childrens Health Act of 2000, Pub. L. No. 106-310 § 1701, 114 Stat. 1101 (Oct. 17, 2000). Petitioner filed her petition on July 29, 1999 and a decision was issued on March 12, 2004. Therefore, this petition was pending on the date of the amendment's enactment.

at her school on November 7, 1996. On November 12, 1996, five days after her initial vaccination, Petitioner went to her family physician, Dr. David Crozier, complaining of a sore throat, difficulty swallowing, and low grade fever. She was treated with fluids, phenylfenesin, and Flonase nasal spray. Pet'r Ex. A at 3. Petitioner returned to Dr. Crozier on November 15, 1996 complaining of central chest discomfort, shortness of breath, and a minor sore throat. At that time, she was diagnosed with non-strep, non-mononucleosis pharyngitis and an upper respiratory infection and was prescribed increased fluids, vitamins, Gatorade, and a Vanceril inhaler. Id. On November 23, 1996, the Petitioner returned to Dr. Crozier complaining of increasing sinus congestion, sore throat, fever, and occasional headaches. She was given the antibiotic, Septra. Id. When her symptoms persisted, she returned to Dr. Crozier, on November 26, 1996, and was given a new antibiotic, Lorabid. Id. at 4. Her medical records indicate that Tylenol caused her to vomit and thus, in November 1996, her doctor recommended that she take Advil for fever and pain. Id. at 3. On December 2, 1996, Petitioner returned to Dr. Crozier for a wrist injury. Her records indicate that she was better following use of the Lorabid. Id. at 4. On December 5, 1996, Petitioner again returned to Dr. Crozier, this time complaining of three days of nausea, weakness, and achiness. She was diagnosed with viral gastritis and was treated with Zantac. Id. On December 6, 1996, Dr. Crozier noted that a call from Petitioner's mother indicated that Petitioner was "feeling slightly better." Id.

Thereafter, on December 11, 1996, Petitioner received her second dose of the hepatitis B vaccine. On December 16, 1996, Petitioner developed pernicious vomiting

(every 7-10 minutes) and was admitted to the hospital on December 17, 1996. According to the emergency room records, Dr. Crozier had prescribed Phenergan suppositories to stop Petitioner's vomiting, but when the Phenergan did not work, her mother became concerned and the Petitioner was taken to the hospital. Pet'r Ex. C at 101. The hospital records document that Petitioner had been previously hospitalized on four prior occasions for dehydration. Id.

Laboratory tests were conducted on the day Petitioner was admitted. These tests showed a minimal increase in her serum AST (liver enzyme). Id. at 94. Petitioner had been given liver function tests on December 6, 1996 which showed normal liver functioning. While in the hospital, Petitioner was treated with intravenous fluids, Demerol, morphine, and Phenergan. Id. at 101. She complained of headaches and photophobia, as well as lethargy and irritability. Petitioner had a lumbar puncture, a surgical procedure,[4] to rule out infection. The results of the lumbar puncture were normal. Id. During her hospitalization Petitioner was given additional tests that showed a significant rise in her liver enzymes and higher than normal ammonia levels. Id. Based on these results, Petitioner was tested for a variety of viral agents that might explain her condition. She was tested for hepatitis A, B, and C. The tests showed that Petitioner was beginning to have an immune response to hepatitis B, following her vaccination, but was negative for hepatitis A and C. Id. at 108.

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[4] The court specifically requested supplemental briefs on the issue of Petitioner's claim for relief based on a hospitalization and surgical intervention. Respondent did not object to Petitioner's characterization of her lumbar puncture as a "surgical intervention." See Resp't Suppl. Br. at 2-3. The court finds that Respondent has therefore conceded this issue.

Her tests for cytomegalovirus (CMV), Epstein-Barre virus, and mononucleosis virus were negative. Id. at 109, 99; see also Tr. at 42-43. While tests showed that she had an elevated adenovirus index, later results indicated that she was not likely suffering from an adenovirus either before or during her hospitalization.[5] Id. at 109, 118. Based on these test results, Petitioner was given a presumptive diagnosis of Reye's Syndrome by the hospital physicians. Id. at 101. After improving, she was discharged on December 22, 1996, with orders to have a follow-up

visit with her primary care physician within a few days. The follow-up visit indicated that her liver function had returned to normal. Id. at 116.

After her release from the hospital in December 1996, Petitioner continued to have respiratory health problems. In April 1997, Dr. Crozier referred her to Dr. Nathaniel Ratnasamy, an infectious disease specialist, for her recurrent respiratory tract infections. Petitioner also claimed that her motor and cognitive skills have diminished following her contraction of Reye's Syndrome.

Petitioner has had additional health issues from 1997 to the present time.

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[5] As discussed later, although the Special Master found that Petitioner tested positive for adenovirus, the record plainly shows that she was not likely suffering from an adenoviral illness before or during the period of her hospitalization. As Respondent's own expert made clear, Petitioner's adenovirus titers were elevated while she was hospitalized, the test requires follow-up study and her follow-up adenovirus index on February 6, 1997 made it plain that the virus was not a likely cause of her hospitalization in the first instance. Resp't Ex. C at 4. This view was also shared by Petitioner's two experts.

Petitioner was hospitalized on multiple occasions in 1999, 2000, and 2001 for a variety of reasons, including dehydration, mononucleosis, difficulty swallowing, pain associated with migraine headaches, and acute abdominal pain. She has also been diagnosed with pelvic inflammatory disease and endometriosis.

II. THE JUNE 17, 2003 HEARING

A hearing was convened on June 17, 2003 at which oral testimony was presented by both Petitioner and Respondent. Petitioner presented the testimony of Dr. Nathaniel Ratnasamy, Petitioner's treating physician and infectious disease specialist. Dr. Ratnasamy was in practice at the McFarland Clinic in Ames, Iowa. He has considerable experience with vaccines. Petitioner also called Dr. James Heubi, a nationally recognized expert on Reye's Syndrome. Dr. Heubi is a pediatric gastroenterologist who specializes in pediatrics, gastroenterology and nutrition. He serves as an attending physician at the Children's Hospital in Cincinnati, Ohio and is program director of the General Clinical Research Center, a National Institute of Health-funded research program. Dr. Heubi is also medical director of the National Reye's Syndrome Foundation and has extensive experience with the diagnosis and treatment of Reye's Syndrome.

Petitioner endeavored to show through these two witnesses that: (1) Petitioner had Reye's Syndrome; (2) Reye's Syndrome requires a viral trigger; (3) the hepatitis B vaccine can serve as the trigger for Reye's Syndrome; (4) the hepatitis B vaccination was the only logical temporal trigger for Petitioner's Reye's Syndrome; and (5) Petitioner's Reye's Syndrome caused hospitalization and surgical intervention, i.e. the lumbar puncture, as well

as sequelae[6] for more than six months.

At the hearing, Dr. Ratnasamy testified that he believed that Petitioner's hospitalization in December 1996 and follow-on illnesses in 1997 were caused by Petitioner's hepatitis B vaccinations in November and December 1996. He explained that, initially, he was not certain of any causal relationship between Petitioner's receipt of a hepatitis B vaccination and the onset of illness; this was reflected in his initial treatment notes. However, he went on to explain that he came to believe that the antigen in the hepatitis B vaccine was the cause of her Reye's Syndrome when the vaccination became the only identifiable cause of her illnesses in December 1996. Specifically, Dr. Ratnasamy stated, "In the course of evaluation of people, both through a process of differential diagnoses[7] where we say, you know, you have a list of working diagnoses and you're shaking out things. At this point, the hepatitis B surface antigen is . . . the most likely trigger for the course of events in November and December of '96." Tr. at 25. Dr. Ratnasamy further testified that Petitioner's subsequent respiratory infections and other problems in 1997 were a result of her Reye's Syndrome.

In response to a question asking, "[i]s it fair to say that you consider it the most likely trigger because of the temporal association between the shot and the onset of

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[6] Sequelae are aftereffects of a disease or injury. Merriam-Webster's Collegiate Dictionary 1068 (10th ed. 1998).

[7] As discussed in detail infra, "differential diagnosis" is "a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 263 (4th Cir. 1999).

symptoms," Dr. Ratnasamy explained:

> [t]he temporal as well as a lot of review of literature, I think. You know, anytime we introduce an antigen into the body, there is potential for a variety of reactions, serum sickness type of reactions, and you probably saw in one of the exhibits the LFT [liver functions tests] abnormalities that have been reported with the hepatitis B. So, again, and I think based on the sequence of events as well as other case reports, I think hepatitis B is very possible.

Tr. at 25.

Finally, Dr. Ratnasamy stated that while he recognized that there was no medical literature linking Reye's Syndrome with hepatitis B he believed that the hepatitis B vaccination was still the likely cause. Dr. Ratnasamy explained, "The only report I'm aware of is the hepatitis A being associated concurrent with Reye's Syndrome, but again, t here are things that people see [as] an isolated incident that don't always make it into referred literature." Tr. at 33.

Dr. Heubi elaborated on Dr. Ratnasamy's testimony based on his extensive expertise with cases of Reye's Syndrome. Dr. Heubi explained that he believed to a medical certainty that Petitioner had Reye's Syndrome and that the Reye's Syndrome had been triggered by her second hepatitis B vaccination on December 11, 1996. Tr. at 39, 43, 48, 56. He explained that in order to develop Reye's Syndrome there must be a trigger or "prodromal illness" which is usually some type of virus and that a reaction to the trigger occurs consistently within 3-7 days, although usually within 3-5 days. Dr. Heubi explained:

> In this particular individual, she was immunized . . . on the 11th of December. On the 16th of December she started having vomiting. Vomiting, we believe, is the initial presenting complaint of these patients with Reye's Syndrome, and typically it's repetitive as it was in her case. . . . What happened with this girl was

> that she had repetitive vomiting. She was brought to the emergency room. Then , initially, she had very minimally elevated liver enzymes, but then they subsequently rose to a point where it was pretty consistent or absolutely consistent with the kind of rise you see with Reye's Syndrome, and then they declined to normal over time. . . . In addition, she had a mild elevation of serum ammonia, which is also commonly seen . . . . In her case, it was only mildly elevated, and she really experienced only some lethargy and some irritability, which makes her a very mild case of Reye's Syndrome.

Tr. at 40-42.

Dr. Heubi then went on to explain the differential diagnosis of Reye's Syndrome:

> The other thing that was done, . . . [were] studies to make sure there weren't any other viral agents that were likely to be the cause of her infection. So they tested for hepatitis A. They tested for hepatitis B. They demonstrated that she was beginning to have an immune response to hepatitis B, because she had an antibody to the surface antigens associated with hepatitis B. She had tests for hepatitis C which were negative. She had tests for cytomegalovirus, Epstein Barr virus, mono virus, all of which were negative, as well as adenovirus. Those are the agents that are commonly associated with this kind of a problem. In addition, they did a lumbar puncture to look at her spinal fluid to rule out encephalitis, and they excluded that diagnosis. So overall, she fulfilled the CDC criteria for the diagnosis of Reye's Syndrome.

Tr. at 42-43.

Dr. Heubi then further testified that he believed the Reye's Syndrome had been caused by the hepatitis B vaccination, because "the other causes[8] have been eliminated from testing." Tr. at 55. Dr. Heubi acknowledged that Petitioner did not have a liver biopsy, which is sometimes done to absolutely confirm a Reye's Syndrome diagnosis, but said that a biopsy would not be performed in a mild case like Petitioner's. Tr. at 68. Dr. Heubi also

[8] The most common causes of Reye's Syndrome are Influenza A or B, or chicken pox, although many other viruses have been associated with the onset of Reye's Syndrome. See Tr. at 43-44. It is not disputed that Petitioner did not have Influenza A or B or chicken pox.

explained why he did not find the absence of medical literature drawing a direct link between the hepatitis B vaccine and Reye's Syndrome problematic. Dr. Heubi stated that "virtually any virus you can think of has been associated with the onset of Reye's Syndrome." Tr. at 61. He explained elsewhere in his testimony as follows:

> [I]f you look at the literature in terms of epidemiological studies, a myriad of viruses have been associated with [Reye's Syndrome]. Has there been a documented case where hepatitis B vaccine has been associated with this and reported in the literature. Absolutely not. Now is it plausible that this could actually be the prodromal illness? Absolutely. . . . Hepatitis B vaccine, because it stimulates a response in the host, could be a surrogate just like any other viral agent.

Tr. at 43-44.

When asked if he could then pinpoint the component in the vaccine that causes Reye's Syndrome, Dr. Heubi explained, "it would be the antigen or the material that was in the vaccine that would be like any other virus that would precipitate a series of alterations . . . that . . . would lead to the disease. So it would be the antigenic or the protein material that was produced from the surface antigen of the normal hepatitis B virus." Tr. at 54-55. Dr. Heubi concluded that this antigen would act as any other virus would, as a prodromal, or preceding illness. Tr. at 55.[9]

Dr. Heubi emphasized that he believed the timing of the vaccination was very important to his opinion due to the unique nature of Reye's Syndrome. He stated that the timing of a viral illness and the onset of Reye's Syndrome is critical to a Reye's Syndrome

[9] Dr. Heubi also addressed the Special Master's questions regarding the relationship between bacterial infections and Reye's Syndrome. Tr. at 67. Dr. Heubi explained that Reye's Syndrome has been linked to "only viral agents." Id.

diagnosis, and that here "the time sequence was virtually dead on for that immunization being her preceding or prodromal illness." Tr. at 39. And on cross-examination, when asked, "[h]ow important is the temporal association to your opinion . . . ," Dr. Heubi responded:

> Pretty important. It probably gets into the better than 50 percent range, because I don't see any other real obvious prodromal illness that occurred just at that particular point in time. I know she had a myriad of other problems. There is no question about that. But this seems to be the focus thing that happened at that particular point in time.

Tr. at 69.

In this connection, Dr. Heubi also explained that while the precise biological mechanism that causes Reye's Syndrome is not understood, it is well-recognized that Reye's Syndrome is triggered by a viral illness and that it was only after other potential viral illnesses were ruled out that he concluded that the cause was her vaccination. He explained that he had reached this conclusion to a "reasonable degree of medical certainty" and that the use of differential diagnosis [the elimination of other potential causes] was a common medical technique. Tr. at 56.

Dr. Heubi also addressed Respondent's contention that Petitioner's vomiting on December 17, 1996 was caused by the same gastrointestinal virus she had been treated for on December 5, 1996, prior to her vaccination on December 11, 1996. Dr. Heubi stated that he did not think that Petitioner's early intestinal problem was the cause of her hospitalization because, "she never had any diarrhea" during the time she was hospitalized. Tr. at 62. He went on to explain that "because we commonly see kids that have vomiting

and diarrhea that's such very common viruses, and we generally don't pay much attention to them . . . . In contrast, with Reye's Syndrome, they typically and generally . . . have no diarrhea and that's one of the things that actually separates from gastroenteritis as a presented complaint." Tr. at 62-63. Dr. Heubi explained that the vomiting associated with Reye's Syndrome is a "consequence of [an] injury to the brain . . . there's no direct attack on the gastrointestinal tract." Tr. at 63.

Dr. Heubi also considered and rejected Respondent's theory that Petitioner's increased liver function tests during her hospitalization were caused by a toxic reaction to the Phenergan, the anti-vomiting drug Petitioner was given to stop her vomiting. Tr. at 67. Dr. Heubi explained that Petitioner's test results did not reveal the most typical toxic reaction to the drug: "her bilirubin did not rise, her alphaphosphase was normal, and she had a fairly remarkable increase in her liver enzymes. So I believe this is more consistent with Reye's Syndrome than would be with Phenergan." Tr. at 68. He later stated, "if they had Phenergan toxicity, the picture is totally different than it is with Reye's Syndrome." Tr. at 139. He also noted that Petitioner's vomiting started before she received the Phenergan and thus her Reye's Syndrome had started before she received the drug. Tr. at 140.

Finally, Dr. Heubi discussed whether any of Petitioner's other health problems following her recovery from Reye's Syndrome were sequelae of Reye's Syndrome. Dr. Heubi explained that there could be neurologic or neuropsychiatric problems but that "I don't know whether it exists or not." Tr. at 65. He testified that "with milder cases [of

Reye's Syndrome], there tends to be little problem in terms of long term sequelae. The more severe your case is in terms of coma grade, the more likely you're going to have neurologic sequelae, all the way to death." Id. Dr. Heubi stated that he had read the affidavit of Petitioner's mother regarding Petitioner's loss of cognitive and sports ability following December 1996, Pet'r Ex. D, but said that "it's hard to know whether it's directly related or not." Tr. at 75. He admitted that it was "possible." Tr. at 80. He also stated, "it is more likely than not that the level of her encephalopathy that she had with [Reye's Syndrome] did not result in any significant neurological psychiatric sequelae." Tr. at 79.

At the close of Dr. Heubi's testimony, Respondent presented the testimony of Dr. Alan I. Brenner, who is board-certified in internal medicine and rheumatology and is also an expert in drug-induced hepatotoxicity.[10] Tr. at 85. Dr. Brenner conceded that he is not an expert in the diagnosis or treatment of Reye's Syndrome. Tr. at 86. He also admitted that he is not a gastroenterologist and does not work with children. Id. Dr. Brenner nonetheless testified that he did not believe that Petitioner had experienced Reye's Syndrome. Rather, he stated that in his opinion Petitioner had experienced a hepatotoxic reaction to one or more of the drugs she had been taking or was given. "In my opinion, it's very difficult in her case to separate out Reye's Syndrome from possible drug-induced hepatotoxicity." Tr. at 87-88. Dr. Brenner conceded that Dr. Heubi had properly noted that "[Phenergan] toxicity is more commonly cholstatic and associated with a rise in serum bilirubin and jaundice and

[10] A state of toxic damage to the liver. Merriam-Webster's Collegiate Dictionary 542 (10th ed. 1998).

an elevated alcoenphosacase." Tr. at 88. However, Dr. Brenner maintained that:

> [T]he hepatitic variety of reaction to these drugs . . . can be of several different varieties, and that's been reasonably well demonstrated. I should also point out that prior to the onset of [Petitioner's] acute illness for which she was hospitalized, she was taking other drugs that are potentially hepatotoxic, including ibuprofen, naproxen, lorabid, the antibiotic. . . . I'm just pointing out that there are a whole host of possible hepatotoxic scenerios that one could make that actually occur much more commonly in this day and age than Reye's Syndrome.

Tr. at 89.

Dr. Brenner also pointed out that:

> [I]t has been advised that Phenergan not be given to children who are vomiting . . . so that its manifestation is not confused with Reye's Syndrome. At the very least, a dose of 25 milligrams every six hours, [which is what Petitioner was given in the hospital] . . . would be expected to make any of us lethargic and perhaps irritable. . . . So the association between [Petitioner's] hepatic insult and the central nervous system sequelae may have been Reye's Syndrome or may have been drug induced. . . . the only way any of us would ever have known . . . would have been to do a liver biopsy.

Tr. at 88-89.

Dr. Brenner explained that he believed Petitioner's vomiting on December 16, 1996 stemmed from the gastrointestinal illness she had complained of in early December, before she had her second hepatitis B shot. Dr. Brenner stated that this earlier virus was the likely cause of Petitioner's hospitalization. Tr. at 91. He stated that "a gastrointestinal syndrome that may have begun even 10 days earlier that culminated in severe vomiting" was a potential cause of her hospitalization. Tr. at 125. According to Dr. Brenner, "there's no way of knowing" if the viral gastroenteritis induced Reye's Syndrome. Tr. at 91-92. In his view, however, Petitioner never had Reye's Syndrome. Dr. Brenner further opined that

Petitioner more likely than not experienced drug induced hepatotoxicity rather than Reye's Syndrome. Tr. at 92. Dr. Brenner pointed to certain blood tests which revealed that she developed eosinophilia[11] as her liver tests were improving. Apparently, this response is a "common blood manifestation of some liver injuries [from] . . . drugs like Phenergan." Tr. at 92. Dr. Brenner therefore concluded that "the sudden onset of the eosinophils during her hospitalization suggested to me a drug induced hepatotoxicity." Tr. at 92.

Dr. Brenner further testified that he did not believe that Petitoner's current condition was related to her hospitalization in December 1996. Instead, he stated that in his opinion, Petitioner was suffering from "something called Central Sensitivity Syndrome." Tr. at 94. Dr. Brenner explained that "Central Sensitivity Syndrome is a complex of conditions, among which are irritable bowel syndrome, . . . irritable bladder, which is a sense of recurring urinary tract infections with steriod urine, the musculoskeletal condition fibromyalgia, migraine headache, temporo-mandibular joint dysfunction and very often, neuropsychiatric manifestations, particularly cutaneous paresthesia, numbness and tingling [of the skin] without an anatomic basis." Tr. at 94-95. Dr. Brenner concluded, "in my opinion, if I look back at [Petitioner's] history and I look forward to what I know about [Petitioner's] history, that's her story." Tr. at 95.

Dr. Brenner was then asked, "[i]s it fair to say then, that whether Dr. Heubi is right, that the hospitalization was reflective of the Reye's Syndrome, or whether you were

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[11] Eosinophilia is an increase in certain white blood cells or other granulocytes that are easily stained by eosin, a red or brown dye. Merriam-Webster's Collegiate Dictionary 388 (10th ed. 1998).

correct, that . . . those symptoms that occurred during the hospitalization were reflective of some drug induced problem, is irrelevant to the real inquiry as to the cause of [Petitioner's] current condition?" He responded, "Absolutely. Yes, sir." Tr. at 96. See also Tr. at 136.

Dr. Brenner also offered an opinion with respect the causal effect between the hepatitis B vaccine and Reye's Syndrome. Dr. Brenner confirmed that there was no evidence in the medical literature documenting any case where the hepatitis B vaccine or hepatitis B had been a trigger for Reye's Syndrome. Tr. at 100. Indeed, Dr. Brenner reiterated Dr. Heubi's statement that no one knows what causes Reye's Syndrome in the first instance. Dr. Brenner stated that in his opinion the only link between Petitoner's Reye's Syndrome, if she had Reye's Syndrome, and the hepatitis B vaccine was "temporal." Tr. at 102. Dr. Brenner conceded that there was evidence of a "medically acceptable temporal relationship between the vaccination and the onset of the injury," but stated that this did not prove that the relationship was "causal." Tr. at 106-07. Dr. Brenner explained that he did not think that the hepatitis B vaccine could cause Reye's Syndrome because the amount of viral agent in the vaccine is too small. Tr. at 100. Although he offered no medical or scientific evidence to support his point, and is not an expert in Reye's Syndrome, he stated that "it's not biologically plausible" to assume that the vaccine could trigger Reye's Syndrome. Tr. at 100.

In addition to the testimony received, the Special Master also considered the report filed by Dr. Robert Lipnick, a pediatric rheumatologist, who had been Respondent's original expert in the case. Dr. Brenner replaced Dr. Lipnick after Dr. Lipnick had to

withdraw from the case due to time constraints. See Resp't Mot. Exten. Time (October 1, 2002). In its "Prehearing Submission" filed on June 13, 2003, Respondent stated that it "will present testimony of Alan I. Brenner, M.D. Dr. Brenner will testify in person and will be the respondent's only witness." It is not disputed that Petitioner did not have notice of the Special Master's decision to consider the report filed by Dr. Lipnick until after her decision was issued.

In her opinion, the Special Master relied on Dr. Lipnick's recitation of Petitioner's medical history and on Dr. Lipnick's assessment of the possible cause of Petitioner's Reye's Syndrome. "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 titer during that hospitalization and her course of a mild Reye's-like syndrome certainly is consistent with an Adenovirus infection." Resp't Ex. A at 4. Dr. Lipnick did not address the disclaimer on the laboratory test which stated with respect to the adenovirus test results, "CLINICAL INTERPRETATION OF COMPLEMENT FIXATION TEST RESULTS REQUIRES COMPARISON OF ACUTE SERUM SAMPLE TO A CONVALESCENT SERUM SAMPLE. THE CONVALESCENT SAMPLE SHOULD BE OBTAINED 3-6 WEEKS LATER. . . . A FOUR-FOLD RISE IN TITER DURING CONVALESCENCE IS INDICATIVE OF RECENT INFECTION." Pet'r Ex. C at 109. On January 29, 1997, Petitioner had a follow-up test which showed that her adenovirus titers had fallen by half. Id. at 118. It was apparently these test results which led all of the witnesses at the hearing,

including Respondent's expert, Dr. Brenner, to conclude that Petitioner had not been suffering from an adenovirus at the time of her hospitalization. Resp't Ex. C at 3. ("A follow up adenovirus index was 16 . . . suggesting that this virus was unlikely the cause of the . . . illness with onset 12/16/96.").

III . SPECIAL MASTER'S ENTITLEMENT DECISION

The Special Master issued her entitlement decision ("Decision" or "Dec.") denying compensation on March 12, 2004. In her decision she concluded that Petitioner had failed to adequately establish that Petitioner's hepatitis B vaccination triggered her hospitalization and surgical intervention or caused any long term effects beyond six months. The Special Master found that Petitioner had suffered from Reye's Syndrome, but she was not persuaded that there was a "clear causal link [between her Reye's Syndrome and] the hepatitis B vaccine." Dec. at 17.[12] She stated, "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 sequelae." Id. She found that "Central Sensitization Syndrome and/or medication toxicity are a more likely and viable cause of petitioner's unfortunate condition." Id. The Special Master went on to find, "[Petitioner's]

[12] Although the Special Master found that the Petitioner had developed Reye's Syndrome, Dec. at 16, she determined that she had not presented sufficient evidence that she had suffered an encephalopathy. Dec. at 4. However, Petitioner had demonstrated through Dr. Heubi that the pernicious vomiting that marks the onset of Reye's Syndrome is triggered by the injury to the brain, i.e. the encephalopathy. Tr. at 63 ("[Reye's Syndrome patients] have vomiting and not diarrhea . . . [because] the disease affects the organelles, or the little portions within the cell, [in the brain]. . . . The consequence of this injury to the brain is vomiting.").

medical records reveal a litany of symptoms that preceded her hepatitis B vaccinations, including elevated Adenovirus titers." Dec. at 18. She then found that Dr. Brenner's explanation of "medication toxicity as the cause of symptoms [Petitioner] suffered after vaccinations is highly persuasive, negating petitioner's assertion of lack of alternative cause." Dec. at 18. Although she found that Petitioner had "Reye's syndrome," she did not rule out Dr. Brenner's alternative theories of causation. Dec. at 16. Specifically she found that "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." Dec. at 16. She noted that "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 [Petitioner] took were know to cause, in sensitive individuals, the symptoms [Petitioner] exhibited." Dec. at 18. The Special Master further noted that Petitioner's "medical record shows that she had, at times, suffered allergic reactions to Tylenol,[13] one of the many medications she was using at the time she was vaccinated." Id. Based on this analysis, the Special Master concluded that "respondent's medical explanation of a logical sequence of cause and effect [is] more persuasive than that of petitioner." Dec. at 19. She stated that "respondent

[13] As discussed supra, Petitioner was directed to stop taking Tylenol in November 1996 when it caused her to vomit. She was then switched to Advil, which, according to the record, did not create any similar response. See Pet'r Ex. A at 3.

persuaded the court that, more likely than not, [Petitioner] would have presented with the symptoms she did in November and December 1996 had she never received the hepatitis B vaccine." Dec. at 18. The Special Master conceded that "[i]f 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 persuaded that [Petitioner] had developed Reye's at that time because of the vaccine." Dec. at 19. She went on to state that she had to consider petitioner's entire medical history and:

> 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 [Petitioner'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.

Id.

For all of these reasons, the Special Master determined that Petitioner was not entitled to compensation.

IV. DISCUSSION

A. Background

The Vaccine Act provides two methods for establishing eligibility for compensation. Munn v. Sec'y of Dep't of Health and Human Servs., 970 F.2d 863, 865 (Fed. Cir. 1992). As noted above, a petitioner may first demonstrate that he or she sustained an injury that is both listed in the Vaccine Table and occurred within the time provided on the Vaccine Table. Id. In these "table injury" cases causation is presumed. Id. If the facts of the case

do not comport with the requirements of the Vaccine Table, the petitioner may, in the alternative, establish a right to compensation by proving by a preponderance of the evidence that the vaccine was the "actual cause" of the injury. Id.; 42 U.S.C. § 300aa-11(c)(1).

The level of proof needed to establish a non-Table injury has been discussed by the Federal Circuit in several cases. See Shyface v. Sec'y of Dep't of Health and Human Servs., 165 F.3d 1344 (Fed. Cir. 1999); Knudsen v. Sec'y of Dep't of Health and Human Servs., 35 F.3d 543 (Fed. Cir. 1994); Grant v. Sec'y of Dep't of Health and Human Servs., 956 F.2d 1144 (Fed. Cir. 1991). To establish a prima facie case, a "petitioner must show 'a medical theory causally connecting the vaccination and the injury.'" Shyface, 165 F.3d at 1353 (quoting Grant, 956 F.2d at 1148). Put another way, the evidence must show that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Grant, 956 F.2d at 1148. To meet this burden, the petitioner must present a "reputable medical or scientific explanation" to support the causation theory. Id. "A proximate temporal association alone does not suffice to show a causal link between the vaccinations and the injury." Id.

However, evidence of a strong temporal relationship combined with either reliable expert opinion or a scientific theory explaining a logical cause and effect is sufficient to establish causation in fact. Id. In this regard, the legislative history makes plain that "evidence in the form of scientific studies or expert medical testimony" may be used to establish causation in fact. H.R. Rep. No. 99-908 at 15 (1986) (emphasis added), reprinted in 1988 U.S.C.C.A.N. 6344, 6356. The Federal Circuit has stated, "causation in fact under

the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." Knudsen, 35 F.3d at 548-49. If a petitioner is able to establish causation in fact, then the burden shifts to the government to establish that a factor unrelated to the vaccine was the actual cause of the injury or illness. 42 U.S.C. § 300aa-13(a)(1)(B); Jay v. Sec'y of Dep't of Health and Human Servs., 998 F.2d 979, 984 (Fed. Cir. 1993).

Here, the Special Master decided that Petitioner had not met her burden. She also found that the government had established that a factor unrelated to the vaccine was the actual cause of her illness. Based on these conclusions, the Special Master denied compensation. This court has been asked to reverse that decision.

In deciding a motion for review of the Special Master's decision, this court may take one of several actions: (A) uphold the findings of fact and conclusions of law of the Special Master and sustain the Special Master's decision; (B) set aside any findings of fact or conclusions of law of the Special Master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and issue its own findings of fact and conclusions of law; or (C) remand the petition to the Special Master for further action in accordance with the court's direction. 42 U.S.C. § 300aa-12(e)(2).

Petitioner challenges the Special Master's finding that Petitioner had not established a causal connection between the hepatitis B vaccinations, and Petitioner's

Reye's Syndrome, her hospitalization with a surgical intervention, and sequelae for more than six months. Petitioner argues that she met her burden, and thus the Special Master's decision was arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law. She argues that the Special Master did not properly consider the differential diagnosis offered by her experts to explain the cause of her hospitalization and that she confused Petitioner's present condition, which she does not claim was caused by the vaccination, with the cause of her Reye's Syndrome and the illnesses she suffered immediately following her release from the hospital.[14] In support of her petition for review, Petitioner also charges that the Special Master erred in considering Dr. Lipnick's report in her final decision. Petitioner argues that she was impermissibly denied a right to cross-examine Dr. Lipnick or otherwise question his conclusions. She also identifies several other alleged factual errors in the Special Master's evaluation of the evidence.

In response, Respondent defends the Special Master's decision. Most importantly, Respondent charges that Petitioner's objections are largely irrelevant on the grounds that Petitioner failed to prove by a preponderance of the evidence that the hepatitis B vaccine can lead to Reye's Syndrome. Accordingly, Respondent argues that the petition must be dismissed.

B. Petitioner Established a Causal Link Between The Hepatitis B Vaccination

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[14] At the conclusion of the hearing, counsel for the petitioner stated, "Well, as far as [Petitioner's] condition, I have to say that her actual current condition, as of 2003, we're not arguing that the present condition is a direct result of the Reye's Syndrome. What we are arguing is that, at least over six months, she did have sequelae of the Reye's Syndrome." Tr. at 152.

and Her Hospitalization with Surgical Intervention due to Reye's Syndrome

At the core of Petitioner's objections to the Special Master's decision is her contention that the Special Master erred in failing to find a causal relationship between Petitioner's hospitalization with surgical intervention and her hepatitis B vaccinations in late 1996. Petitioner complains that the Special Master, without fully analyzing Petitioner's evidence, found that Petitioner's case was based solely on the temporal relationship of the vaccination and her hospitalization with Reye's Syndrome. Petitioner charges that the Special Master arbitrarily and capriciously ignored her evidence establishing a medically reliable theory of causation.

In response, Respondent states, "given the lack of literature supporting a causal connection between the vaccine and Petitioner's Reye's Syndrome, and Petitioner's expert's admission that the cause of Reye's Syndrome is not fully understood, petitioner's theory of actual causation devolved into one of mere temporal relationship." Resp't Suppl. Br. at 6. As noted above, it is well-settled that a "temporal relationship" alone is not sufficient to establish causation in fact. See Grant, 956 F.2d at 1148.

The court agrees with Respondent that Petitioner needed to show more than a temporal relationship between her hepatitis B vaccination in December 1996 and her hospitalization with surgical intervention to establish causation in fact. The court finds, however, that Petitioner did present sufficient evidence to meet her burden to show causation in fact.

To begin, the court turns to Petitioner's theory and the evidence she presented to

support her contention that the hepatitis B vaccine led directly to her Reye's Syndrome, her hospitalization, and surgical intervention. Petitioner based her case on the "differential diagnosis"[15] testimony presented by Drs. Ratnasamy and Heubi to show that Petitioner's exposure to the hepatitis B vaccine was the only likely cause of her Reye's Syndrome and thus her hospitalization and surgical intervention, i.e. her lumbar puncture. It is not disputed that both doctors were familiar with Reye's Syndrome. Indeed, Dr. Heubi was acknowledged to be one of the nation's experts on Reye's Syndrome. Both of these medical experts testified, consistent with the technique of differential diagnosis, that Petitioner had Reye's Syndrome, and that the hepatitis B vaccine was the only likely cause. Tr. 24-25, 43-44.

Importantly, both experts also testified that the hepatitis B vaccine can be a trigger for Reye's Syndrome. Dr. Heubi explained that it is well-settled in the medical community, as reflected by the medical literature, that any virus can serve as the prodromal illness or

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[15] Differential diagnosis, or differential etiology, is "a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable is isolated." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999); See also Federal Judicial Center, Reference Manual on Scientific Evidence 470 n.112 (2d ed. 2000). The technique has "widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results." Westberry, 178 F.3d at 262 (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 758 (3d Cir. 1994)). Differential diagnosis or differential etiology has been accepted as reliable under the standards set forth in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 593-94 (1993) by virtually every United States Court of Appeals to consider the issue. See Heller v. Shaw Indus., Inc., 167 F.3d 146, 154-55 (3d Cir. 1999); Baker v. Dalkon Shield Claimants Trust, 156 F.3d 248, 252-53 (1st Cir. 1998); Zuchowicz v. United States, 140 F.3d 381, 385-87 (2d Cir. 1998); Kennedy v. Collagen Corp. 161 F.3d 1226, 1228-30 (9th Cir. 1998), cert. denied, 526 U.S. 1099 (1999); Ambrosini v. Labarraque, 101 F.3d 129, 140-41 (D.C. Cir. 1996); Glaser v. Thompson Med. Co., 32 F.3d 969, 978 (6th Cir. 1994).

triggering illness for Reye's Syndrome, and thus the hepatitis B vaccine can serve that function as well. He elaborated by stating that because the hepatitis B vaccine contains a virus and creates an immune response, it could serve as the trigger for Reye's Syndrome.[16] Tr. at 43-44. As noted above, Dr. Heubi testified:

> If you look at the literature in terms of epidemiological studies, a myriad of viruses have been associated [with Reye's Syndrome]. Has there been a documented case where hepatitis B vaccine has been associated with this and reported in the literature? Absolutely not. Now is it plausible that this could actually be the prodromal illness? Absolutely. . . . Hepatitis B vaccine, because it stimulates a response in the host, could be a surrogate just like any other viral agent.

Tr. at 43-44.

As Dr. Heubi noted in his testimony, when Petitioner was tested during her hospitalization, it was shown that indeed she was having a response to the hepatitis B vaccine because she had developed antibodies. Tr. at 43; see Pet'r Ex. C at 108.

Dr. Ratnasamy offered the same analysis. See Tr. at 25. Thus, both of Petitioner's experts offered a firm medical opinion based on their experience and knowledge demonstrating how the hepatitis B vaccine, as a viral agent, could lead to Reye's Syndrome and Petitioner's hospitalization with surgical intervention.

In addition, both experts explained why the temporal relationship between the

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[16] Although neither party referenced the Lord v. Sec'y of Dep't of Health and Human Servs., No. 90-1630V, 1997 WL 588999, at *3 (Fed. Cl. Aug. 21, 1997) decision, in that vaccine case Special Master French herself quoted numerous medical treatises that confirmed this point. Indeed, in one treatise, vaccines are specifically identified as potential triggers for Reye's Syndrome. See id. at *3-4, (citing Kenneth F. Swaiman, Pediatric Neurology 1238-39 (2d ed. 1994).

vaccinations and Petitioner's illness was critical to their medical opinions. In certain cases, like this one, the temporal relationship is itself a critical part of the diagnosis. Dr. Heubi's testimony established that Reye's Syndrome occurs within 3-7 days, but usually within 3-5 days, of exposure to the triggering illness. After examining all of the potential triggering illnesses that Petitioner was tested for in the hospital, Dr. Heubi concluded that the only virus she was exposed to during the relevant time frame was the hepatitis B vaccine and thus the hepatitis B vaccine was the only logicial cause for her Reye's Syndrome. "The time sequence was virtually dead on for that immunization being her preceding or prodromal illness." Tr. at 39. See also Tr. at 69.

Where, as here, the temporal relationship between the exposure to the questioned agent and the onset of symptoms is critical to a diagnosis, the temporal relationship is highly probative. "Having demonstrated such a strong temporal relationship, petitioner must provide a reliable medical or scientific theory explaining a causal link, but under a less stringent standard than would be required if the temporal relationship was less probative of a causal link." Golub v. Sec'y of Dep't of Health and Human Servs., No. 99-5161, 2000 WL 1471643, at *3 (Fed. Cir. Oct. 3, 2000) (unpublished opinion) (emphasis added). The Fourth Circuit reached a similar conclusion in Westberry, a case involving toxic exposure to talc, in which the court stated, "Of course, the mere fact that two events correspond in time does not mean that the two are related in any causative fashion. But, depending on the circumstances, a temporal relationship between exposure to a substance

and the onset of disease or a worsening of symptoms can provide compelling evidence of causation." 178 F.3d at 265 (citation omitted). The present case is a case where the temporal relationship is highly probative of causation. Given the limited time-frame between prodromal illness and the onset of Reye's Syndrome, Dr. Heubi's explanation of a logical cause and effect between exposure to the hepatitis B vaccine and the onset of Reye's Syndrome is compelling.

Further, Dr. Heubi explained why the temporal relationship between Petitioner's vaccination on December 11, 1996 and the onset of her symptoms on December 16 and 17, 1996 virtually eliminated Dr. Brenner's alternative theory of medical toxicity based on exposure to Phenergan. First, Dr. Heubi noted that Petitioner's vomiting started before she received the Phenergan and therefore the drug could not have been the cause of her vomiting. Instead he testified that Reye's Syndrome was the cause. He also explained that there are classic responses to Phenergan exposure, such as an increase in bilirubin, which was not present in Petitioner's case. These factors confirmed in Dr. Heubi's mind that a hepatotoxic reaction to Phenergan could not explain Petitioner's illness on December 16 and 17, 1996, which was five days after she had received her second hepatitis B vaccination. See Tr. at 68, 139-40.

Similarly, the temporal relationship between the vaccination and Petitioner's illness led Dr. Heubi to conclude that Petitioner's gastrointestinal virus in early December was not the prodromol illness that triggered her Reye's Syndrome. Not only had Petitioner's gastrointestinal illness been diagnosed more than 10 days before she was hospitalized on

December 16, 1996 (i.e. outside the 3-7 day time frame identified for the onset of Reye's Syndrome), Dr. Heubi further explained that the Petitioner did not present with a gastrointestinal illness when she was admitted to the hospital. He testified that her records showed that she did not have diarrhea, but did have pernicious vomiting. The absence of diarrhea indicated to Dr. Heubi, a gastroenterolgist, that Petitioner was not suffering from a prodromol gastorintestinal virus. He thus concluded that Dr. Brenner's theory of an alternative viral illness was not supported by the medical record. See Tr. at 63.

In view of the foregoing, the absence of medical or scientific literature to show that the hepatitis B vaccine has been linked to Reye's Syndrome is not fatal to Petitioner's case. As noted above, Petitioner was not required to present medical literature to support her claim. See Grant, 956 F.2d at 1148-49 (affirming the Special Master's reliance on the petitioner's medical testimony). The Federal Circuit has recognized that a petitioner can support her case with reliable medical testimony alone. See id. at 1147-48 (quoting H.R. Rep. No. 99-908 at 15 (1986), stating that a petitioner must produce evidence in the form of scientific studies or medical testimony); Shyface, 165 F.3d at 1351 (quoting H.R. Rep. No. 99-908 at 15 (1986)). Here, Dr. Heubi, one of the nation's experts in Reye's Syndrome, explained in detail how the hepatitis B vaccine could serve as a trigger for Reye's Syndrome. He relied on established medical literature to explain how any virus can serve as a trigger for Reye's Syndrome. Tr. at 61. He also explained that the temporal relationship between the vaccine exposure and the onset of Reye's Syndrome confirmed his view, because the vaccination was the only logical trigger identified in the time period

necessary for Reye's Syndrome to develop. Tr. at 39. The fact that no one knows the precise cause of Reye's Syndrome does not alter this conclusion. There is no question in the medical community that Reye's Syndrome is triggered by a prior viral exposure. This is enough to support a reliable medical opinion. In Knudsen, the Federal Circuit expressly determined that "proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." 35 F.3d at 548.

Accordingly, the court finds that the Petitioner has demonstrated actual causation through reliable medical opinion testimony, which establishes that (1) the hepatitis B vaccine caused Petitioner's Reye's Syndrome, and (2) the Reye's Syndrome led to her hospitalization and surgical intervention.

The court notes that at the time that Petitioner filed her petition, the Vaccine Act only provided recovery for an injury with consequences extending beyond six months or for death. However, while the petition was pending, the Vaccine Act was amended to allow recovery for an injury leading to hospitalization and surgical intervention. See supra note 3. At the June 2003 hearing, Petitioner thus sought to show both that the vaccine caused her hospitalization and surgical intervention and that she suffered sequelae for more than six months. While Petitioner may not have demonstrated sequelae by a preponderance of the evidence, Petitioner did put forth sufficient evidence to support a conclusion that the vaccine more likely than not caused her to suffer from Reye's Syndrome, which caused her hospitalization and subsequent surgical intervention. It is the Special Master's failure to fully consider this aspect of causation that renders the Special Master's finding on actual

causation arbitrary and capricious.

The court does agree with Respondent and the Special Master that the record does not support a finding that Petitioner suffered any long-term effects from her illness with Reye's Syndrome. Indeed, Petitioner's own expert, Dr. Heubi, testified that children with mild cases of Reye's Syndrome, like Petitioner's, would not likely suffer any long term effects. He further testified that he did not believe that Petitioner's problems following resolution of her Reye's Syndrome were related to her Reye's Syndrome: "[i]t is more likely than not that the level of her encephalopathy that she had with this did not result in any significant neurological psychiatric sequelae." Tr. at 79. Based on Dr. Heubi's testimony, the court finds that Petitioner did not prove by a preponderance of the evidence that she had any sequelae from Reye's Syndrome after it resolved itself shortly after she was released from the hospital in late 1996.

This does not, however, mean that the court agrees with the Special Master's finding regarding Central Sensitivity Syndrome. Whether Petitioner suffers from Central Sensitivity Syndrome is irrelevant. It is enough to say that Petitioner established only that she was hospitalized and had a surgical intervention as a result of her hepatitis B vaccinations in December 1996. In this connection the court notes that the Special Master's concern that she needed to consider Petitioner's "entire medical history" when she refused to focus on the period of Petitioner's hospitalization was misguided. A Special Master should consider an entire medical history; however, a Special Master should not lose sight of the causation question presented. In this case, Petitioner focused her case on

her hospitalization and the illnesses she continued to experience for the next six months. Causation under the Vaccine Act can be established by showing that a vaccine caused a Petitioner to be hospitalized and to undergo a surgical intervention. Thus, the Special Master needed to specifically address this issue, in addition to addressing whether Petitioner's condition following resolution of her Reye's Syndrome and her current condition were sequelae of her Reye's Syndrome.

C. The Special Master's Finding of Alternative Cause Was Not Supported By the Record

Although Respondent does not contend it established alternative cause for Petitioner's Reye's Syndrome, hospitalization, and surgical intervention, the Special Master made alternative cause findings. These findings are not supported by the record. The Special Master's finding that Petitioner's Reye's Syndrome could be explained by her elevated adenovirus titer, as suggested in Dr. Lipnick's report, must be rejected. Dr. Lipnick's statement in his report is refuted by the record.[17] Drs. Ratnasamy, Heubi, and Brenner all recognized that the Petitioner's follow-on adenovirus tests indicated that an adenovirus would not be a trigger for her Reye's Syndrome. See Tr. at 22-23; Tr. at 43; Resp't Ex. C at 4.

Similarly, the Special Master's conclusion that Respondent had established an alternative cause of Petitioner's injury based on "medication toxicity" is not supported by

[17] Because the court has determined that Special Master's decision cannot stand, it is not necessary to reach Petitioner's specific objections to her consideration of Dr. Lipnick's report in her decision.

the record. To begin with, Respondent does not contend that it has met its burden of proof with regard to alternative cause. See Resp't Suppl. Br. at 10. Nowhere in its briefs to this court does it argue that Petitioner's hospitalization was caused by some other illness. Although Dr. Brenner testified that he did not believe that Petitioner had Reye's Syndrome and that he believed instead that Petitioner's vomiting was the result of gastroenteritis, he never offered a response to Dr. Heubi's testimony that Petitioner could not have had gastroenteritis when she was hospitalized because she did not present with diarrhea. Notably, Dr. Heubi is a gastroenterologist, and Dr. Brenner is not.

Moreover, while Dr. Brenner stated that he believed Petitioner's liver problems were caused by the medications she received, none of the medications identified by the Special Master were shown to cause the pernicious vomiting that led to Petitioner's hospitalization in the first instance.[18] Thus, while it may well be true that the Petitioner has had allergic reactions to medications, the record does not support a finding that Petitioner was hospitalized to treat an allergic reaction to medication. For example, Petitioner was not using Tylenol just prior to her hospitalization; the records show that she stopped using Tyenlol a month before. Pet'r Ex. A at 3. She was advised to stop taking ibuprofen on December 5, 1996. Pet'r Ex. A at 4. Similarly, the evidence showed that she was not taking any antibiotic at the time of her hospitalization on December 17, 1996. See Pet'r

[18] The medical records indicated that in November 1996 the Petitioner had vomited after taking Tylenol. However, the records also indicate that she had stopped taking the drug as of November 26, 1996. See Pet'r Ex. A at 3 (noting that Petitioner "[t]akes . . . Advil as Tylenol causes vomiting"). There was no evidence that the Petitioner was taking Tylenol at the time she was admitted to the hospital.

Ex. A at 4 (noting that Petitioner had finished a ten day course of antibiotic on December 5, 1996). Thus, the potential causes of Petitioner's vomiting put forth by Dr. Brenner are not supported by the record. Given these problems with Dr. Brenner's opinion, it cannot be said that Respondent proved an alternative cause of Petitioner's hospitalization by a preponderance of the evidence. For the Special Master to find otherwise was arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law.

V. CONCLUSION

In sum, the court finds that Petitioner established through reliable medical records and expert medical opinion testimony that it was more likely than not (greater than 50%) that the hepatitis B vaccination Petitioner received in December 1996 was the triggering cause for Petitioner's Reye's Syndrome and that this, in turn, led to Petitioner's hospitalization and surgical procedure, i.e. the lumbar puncture. Because the Petitioner established a logical sequence of cause and effect supported by reliable medical opinion, she met her burden of proof under the Vaccine Act. Respondent has not shown that an alternative cause is more likely than not to be responsible for Petitioner's hospitalization with surgical intervention. Petitioner is therefore entitled to appropriate relief under the Vaccine Act.

For these reasons, Petitioner's Motion for Review is Granted and the Decision of the Special Master is **REVERSED**. The case is hereby **REMANDED** to the Special Master for further action consistent with this decision. However, given the findings herein, the parties are encouraged to reach an amicable resolution.

IT IS SO ORDERED.

s/Nancy B. Firestone
NANCY B. FIRESTONE
Judge