OFFICE OF SPECIAL MASTERS

No. 03-2479V

Filed: April 8, 2005

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

Mr. Donald Edwards, Atlanta, Georgia, for petitioner.

Ms. Catharine Reeves, United States Department of Justice, Washington, D.C., for respondent.

DECISION[1]

GOLKIEWICZ, Chief Special Master

On October 23, 2003, Patricia Lee filed a petition for compensation under the National Vaccine Injury Compensation Program [hereinafter the Act or the Program][2] for injuries resulting from the administration of a hepatitis B vaccination. Petitioner alleges that the hepatitis B

[1]This Decision is re-issued in redacted form pursuant to Vaccine Rule 18 and the parties' request.

[2]The statutory provisions governing the Vaccine Act are found at 42 U.S.C. §§300aa-10 to 300aa-34 (2003). Hereinafter, for ease of citation, all references will be to the relevant subsection of 42 U.S.C. §300aa.

vaccine caused her fibromyalgia.[3] Fibromyalgia is not an injury listed on the Vaccine Injury Table; thus, there is no presumption of causation.[4] Therefore, petitioner is required to prove by a preponderance of the evidence that the vaccine in-fact caused her fibromyalgia. As discussed below, the court finds that petitioner *has* demonstrated by a preponderance of the evidence that the hepatitis B vaccine caused her fibromyalgia, and thus she is entitled to compensation.

Procedural Background

On July 22, 2004, the undersigned conducted a hearing in Asheville, North Carolina to address whether the petitioner's syndrome was caused by the hepatitis B vaccinations that she received on September 9, 2000 and October 27, 2000, respectively. Petition, Ex. 4 at 79. At the hearing, the court heard testimony from petitioner, several additional fact witnesses presented by petitioner, petitioner's expert witness, Dr. Kristin M. Gowin, and respondent's expert witness, Dr. Alan I. Brenner.

Subsequent to the hearing, on July 30, 2004, the undersigned issued an Order memorializing issues discussed with counsel at the hearing. In that Order, the undersigned reiterated a tentative bench finding that, based on the current state of the record, petitioner had not satisfied her burden of proof in demonstrating that the hepatitis B vaccine was causally linked to the development of her fibromyalgia. More specifically, as stated in the Order, petitioner had not "shown that [her] severe headache and sleeplessness experienced four days after her second vaccination, the potential triggering events for her [fibromyalgia] syndrome, are causally linked

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[3]Fibromyalgia is defined as:

> A syndrome of chronic pain of musculoskeletal origin but uncertain cause. The American College of Rheumatology has established diagnostic criteria that include pain on both sides of the body, both above and below the waist, as well as in an axial distribution (cervical, thoracic, or lumbar spine or anterior chest); additionally there must be point tenderness in at least 11 of 18 specified sites.

Stedman's Medical Dictionary, 27th Ed., 2000, at 671. Dr. Gowin defines fibromyalgia as

> a chronic pain disorder which basically is chronic being present for more than three months. It's diffused, being on both sides of the body and below – above and below the waist. And it's usually accompanied by fatigue and a sleep problem called nonrestorative sleep where the patient never feels rested no matter how long they sleep.

Tr. at 83.

[4]See 42 U.S.C. §300aa-14(a); see also discussion of causation-in-fact standards, *infra*.

to the vaccine." July 30, 2004 Order.[5] Thus, the court subsequently invited petitioner to "supplement the record with ***relevant*** information that could aid the court in making its final decision." Id. (emphasis in original).

On August 30, 2004, petitioner filed a "Notice of Filing of Petitioner's Supplemental Medical Expert Report" [hereinafter Pet. Supp. Rep.]. After a status conference call discussing the petitioner's supplemental expert report, respondent was ordered to file his supplemental expert report by October 8, 2004. See Order, filed Sept. 9, 2004. Respondent filed subsequently his report on October 25, 2004, and supporting literature on November 9, 2004. See Respondent's Posthearing Submissions, filed Oct. 25, 2004[6] [hereinafter Res. Supp. Rep.]; Notice of Filing Medical Literature, filed Nov. 9, 2004. Also on November 9, 2004, petitioner filed a second supplemental expert report. See Petitioner's Supplemental Expert Report, filed Nov. 9, 2004 [hereinafter Pet. Second Supp. Rep.].

On January 19, 2005, petitioner filed her closing statement. See Petitioner's Closing Argument, filed Jan. 19, 2005. Subsequently, on February 1, 2005, respondent filed a responsive closing statement. See Response to Petitioner's Closing Argument, filed Feb. 1, 2005. The case is now ripe for decision.

Statement of Facts

Petitioner, Ms. Patricia Lee, is a 42-year-old seventh and eighth grade math teacher at Scotts Creek Elementary School in Sylva, North Carolina. Petition at 1. She was required by her employer to receive a series of hepatitis B vaccinations. Id. On September 19, 2000, petitioner received her first vaccine. Id. She claims that after the vaccine she "felt very yucky, like flu-type symptoms for about a week after." Tr. at 13. However, petitioner did not seek any medical attention at that time, because it "was not enough to keep [her] from work." Id. at 32.

Thereafter, petitioner received her second vaccination on the morning of October 27, 2000. Petition at 1; Tr. at 14. Petitioner claims that before the administration of the second vaccine she "really didn't want the second vaccine, that [she] felt for about a week that [she'd] had the flu and they said that it was just a coincidence and literally just stuck my arm with the needle." Tr. at 13. October 27 was a Friday, and she "didn't have a headache that day but people were telling [her] that [she] was doing strange things." Id. at 14. For instance, the students in her

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[5]The Order dated July 30, 2004 contains an error; clearly, the records and testimony support a finding that petitioner's headache and sleeplessness began the day after the second hepatitis B vaccination. Tr. at 15; Petition, Ex. 1 at 9; *infra* at pp. 3-4.

[6]Respondent inadvertently did not label Dr. Brenner's expert report with an exhibit letter. For purposes of clarity, Dr. Brenner's supplemental expert report, a letter to the Associate Director of Programs Operation Branch for the Division of Vaccine Injury Compensation, dated October 24, 2004, but filed October 25, 2004, will be referred to as Res. Ex. M.

afternoon class stopped her from teaching claiming that she was not making any sense. Id. They told her she "was talking about things that had nothing to do with the lesson," and it just bewildered her. Id. In addition, "that afternoon when it came time to load buses and all the teachers were walking kids out to the buses, several teachers asked [her] if [she] was okay." Id. She claims they told her that her eyes were "glassed over" and that she just looked "totally bewildered." Id. She had not experienced this type of event before. Id. at 14-15.

Petitioner claims that on the next day, Saturday, she "developed a horrible headache," just "an excruciating headache and that headache, it came and went all weekend and after the excruciating headache started, by the next day [her] knees were hurting so badly" she was "putting pillows around them trying to keep anything from touching them, they hurt so badly and that was Sunday." Id. at 15. She became very concerned when her neck began hurting so badly she could not lift her head to take a sip of water. Id. at 16.

On Tuesday, October 31, 2000, petitioner's parents took her to see her primary care physician, Dr. Paul S. Gehring. See Petition, Ex. 1 at 9; Tr. at 16. Petitioner testified that Dr. Gehring gave her a shot for the pain. Tr. at 18. At that time, Dr. Gehring reported that "[t]he patient comes in with a severe headache and complaining of her legs, particularly her knees, hurting," and that she "has not been able to sleep for the past two days." Petition, Ex. 1 at 9. The pain wore off for a few hours but then, after she returned home from Dr. Gehring's office, it returned. Tr. at 18. At that point, petitioner's parents rushed her to the emergency room at Harris Regional Hospital. Id. at 19. Petitioner "arrived screaming with pain but improved after lying down." Petition, Ex. 2 at 43. Dr. Jimmy Rodden performed a lumbar puncture and noted that she had "excellent and immediate relief of headache from compazine except kept asking over and over why she couldn't sleep." Id. The record states that "[n]o organic cause found for symptoms, suspect psychogenic." Id.

After her visit to the emergency room, petitioner was referred by Dr. Gehring to a rheumatologist, Dr. Kristin Gowin. Tr. at 83. Petitioner had her first appointment with Dr. Gowin on December 6, 2000. Id.; Petitioner's Medical Records, filed Jan. 26, 2004, at 88.

Petitioner's medical history, while scribed in her records, was also elaborated on at the hearing. According to her records, petitioner has a history of hypotension and urinary tract infections. Petitioner's Medical Records, filed Jan. 26, 2004, at 88. Petitioner was in a multi-auto accident in January of 1990, and her medical records reflect that she suffered a whiplash injury from the incident. Tr. at 25; Petitioner's Medical Records, filed Jan. 26, 2004 at 97; Res. Ex. A at 1. Petitioner also had Bell's palsy or a facial stroke in June of 1990, for which she was discharged in July of 1990 after taking Prednisone and having physical therapy. Petitioner's Medical Records, filed Jan. 26, 2004 at 97-104.

A whiplash injury occurred in 1997 after a door slammed into her back. This injury, however, resolved after physical therapy. Petitioner's Medical Records, filed Jan. 26, 2004 at 88; Petitioner's Medical Records, filed Mar. 29, 2004 at 12. Two weeks prior to the hepatitis B

vaccinations, one of petitioner's students almost cut her fingers off in a snowcone machine and she reported being "very stressed out" about it. Petitioner's Medical Records, filed Jan. 26, 2004 at 88. Dr. Gowin also noted that [ ].[7] Id. Petitioner testified that she had been prescribed Zoloft and Prozac by Dr. Gehring to treat obsessive-compulsive disorder (OCD). Tr. at 23-24. Petitioner continues to take Prozac to control this disorder. Id. at 23. At the time of her diagnosis of OCD, petitioner saw a counselor, Ms. Jean Kirkland, to whom she discussed the "disappointments of [her] marriage" and "basic lifetime disappointments." Id. at 24.

With respect to petitioner's current condition, Dr. Gowin noted that petitioner has "[d]iffuse body pain with history of severe headaches following a hepatitis B vaccination." Petitioner's Medical Records, filed Jan. 26, 2004 at 91. Furthermore, "[s]he may have had an aseptic meningitis from the hepatitis B vaccine that set off a cascade which has led to what appears to be now mainly fibromyalgia." Id. Petitioner continues to be treated by Dr. Gowin for her fibromyalgia. Tr. at 87-88.

Before discussing the evidence presented to the court in this case, it is critical to understand the causation-in-fact principles that will be utilized by the court in evaluating the evidence.

Causation-in-fact – Basic Principles

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.[8]

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). Fibromyalgia is not an injury listed on the Vaccine Injury Table and thus does not benefit from the Act's presumed causation. Id. Thus, petitioner must prove that the vaccine in-fact caused the fibromyalgia, a so-called off-Table case.

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[7]Pursuant to Vaccine Rule 18 and by agreement of the parties, portions of the text have been omitted.

[8]A preponderance of the evidence standard requires a trier of fact to "believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, Civil Procedure, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

To demonstrate entitlement to compensation in an off-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 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To meet this 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 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccination 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 (Fed. Cir. 1993); Hodges v. Secretary HHS, 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, 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; Hodges, 9 F.3d at 960.[9] See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

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[9]The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability, while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that "Daubert is useful in providing a framework for evaluating the reliability of scientific evidence." Terran v. Secretary of HHS, 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert's opinion. Id. In other words, the "testimony must be supported by appropriate validation – i.e., 'good grounds,' based on what is known." Id. Factors relevant to that determination may include, but are not limited to:

> Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

However, the court also cautioned against rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication "does *not* necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." Daubert, 509 U.S. at 594. However, the

While petitioner need not show that the vaccine was the sole or even predominant cause of the injury, 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." Shyface, 165 F.3d at 1352-53. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which 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. Nor do petitioners 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 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, this proximate temporal relationship will not support a finding of causation.")); Hodges, 9 F.3d at 960. Furthermore, a petitioner does not 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.

The Court of Federal Claims has also weighed in on the evidentiary standards for causation-in-fact in Vaccine Act cases. For example, with respect to the issue of timing, although showing a proximal temporal relationship to the administration of the vaccine is not enough to satisfy a petitioner's burden, a temporal relationship can be a critical part of a diagnosis. Hocraffer v. Secretary of HHS, No. 99-533V, 2005 WL 352552 at *13 (Fed. Cl. 2005). In a case where "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." Id. When a petitioner demonstrates a strong temporal relationship between the injury and the administration of a vaccine, a petitioner must also 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.*" Id. (emphasis in original) (citing Golub v. Secretary of HHS, No. 99-5161, 2000 WL 1471643 at *3 (Fed. Cir. Oct. 3, 2000) (unpublished opinion)).

Supreme Court's only guidance to lower courts in determining the reliability of a novel proposition is that

> . . . submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Gall v. Secretary of HHS, No. 91-1642V, 1999 WL 1179611 at *8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

Additionally, the Court of Federal Claims has also found that "when a petitioner has scientific or medical evidence that demonstrates a direct causal relationship between the vaccine and the injury, then proof of causation-in-fact via *direct causation* is the preferred path." Pafford v. Secretary of HHS, No. 01-0165V, 2005 WL 318694 at *8 (Fed. Cl. 2005) (emphasis in original). Evidence of direct causation can be found from "an epidemiologic study demonstrating a relative risk greater than two . . . or dispositive clinical or pathological markers evidencing a direct causal relationship." Id. (citing Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418 at *12 (Spec. Mstr. Fed. Cl. Mar. 30, 2001)). When a petitioner is unable to present epidemiologic evidence or vaccine footprints, a petitioner must prove causation-in-fact through the use of circumstantial evidence. Pafford, 2005 WL 318694 at *9. Such circumstantial evidence may include: epidemiology (evidencing a relative risk less than two), animal studies, case reports/case series studies, anecdotal reports, manufacturing disclosures, Physician Desk Reference citations, journal articles, institutional findings (such as those reported by the Institute of Medicine), novel medical theories, treating physician testimony, and non-dispositive but inferential clinical and laboratory studies. Id.

The court in Pafford went on to explain that proving causation-in-fact in Vaccine Act cases with circumstantial evidence requires that a petitioner do much more of the "heavy lifting" than in an on-Table case or even in an off-Table case where there is direct evidence. Id. (citing Lampe v. Secretary of HHS, 219 F.3d 1357, 1360 (Fed. Cir. 2000); Hodges v. Secretary of HHS, 9 F.3d 958, 961 (Fed. Cir 1993)). Once biologic plausibility is established, a petitioner must demonstrate a nexus between the proposed mechanism and the actual injury in order to show that the vaccine more likely than not caused the injury. Pafford, 2005 WL 318694 at *9.[10] If a petitioner's proposed biologic mechanism is beyond the realm of plausibility, than other circumstantial evidence, no matter how probative, cannot overcome the petitioner's failure to establish biologic plausibility. Id.

The court also explained the relationship between a vaccination and the onset of a particular condition. At the crux of this issue is the important distinction between a "literal temporal relationship" and "scientific temporal relationship." Id. at *10. Pointing out that it is the more mechanical of the two terms, the court defined the term "literal temporal relationship" simply as the "period of time between the vaccination and the onset of symptoms." Id. The term "scientific temporal relationship" encompasses a "more analytic relationship in which the medical or scientific community recognizes a specific period of time following a vaccination within which a certain condition might materialize." Id. (citing Stevens, 2001 WL 387418 at *2 n.6.) The court found that a special master "does not act contrary to the law and commit reversible error if he determines that a plausible biologic mechanism and a literal temporal

[10] But see, Capizzano v. Secretary of HHS, No. 00-759V, 2004 WL 1399178 at *8 n.21 (Fed. Cl. Spec. Mstr. June 8, 2004) (citing Knudsen v. Secretary of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994) ("to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program").

relationship, alone, do not establish such a nexus between vaccination and condition that causation-in-fact must obtain." Pafford, 2005 WL 318694 at *11.

Finally, the court pointed out that proof that a vaccine can cause a particular injury is not per se proof that it caused the injury in petitioner's case. Id. A special master may look to other facts in the record, including potential alternative causes, that may undermine a petitioner's case. Id. Thus, a petitioner should present more proof than just biologic plausibility combined with a strong temporal relationship to buttress his argument that the vaccine in-fact caused his injury. Id. The elimination of other causes as well as the establishment of a scientifically appropriate temporal relationship weigh significantly in a special master's evaluation of the evidence. Id. The evidence is weighed in accordance with these principles.

Expert Testimony

1. Hearing Testimony

Petitioner presented Dr. Kristin M. Gowin, her treating rheumatologist, as her expert witness. Dr. Gowin graduated from the University of Cincinnati College of Medicine in 1990. Tr. at 81; Petitioner's Medical Expert Report, filed Jan. 21, 2004 [hereinafter Pet. Expert Rep.], Ex. 3. Subsequently, from 1990-93 she was a resident in Internal Medicine at The Milton S. Hershey Medical Center in Hershey, Pennsylvania. Tr. at 81; Pet. Expert Rep., Ex. 3. Dr. Gowin spent five years, from 1994-99, completing a combined fellowship in Rheumatology and earning a master's degree in Epidemiology at the University of Pennsylvania. Tr. at 81; Pet. Expert Rep., Ex. 3. From 1998-99 she was an instructor for the Division of Rheumatology at the University of Pennsylvania. Tr. at 81; Pet. Expert Rep., Ex. 3. Dr. Gowin is board certified in Internal Medicine and Rheumatology, and specializes in the area of Rheumatology in her practice in Asheville, North Carolina, where she has lived and practiced medicine for five years. Tr. at 80-82; Pet. Expert Rep., Ex. 3. At her practice, she regularly diagnoses and treats patients with fibromyalgia. Tr. at 82.

Dr. Gowin testified that, within a reasonable degree of medical probability, "the major trigger for [petitioner's] fibromyalgia was the Hepatitis B vaccination." Id. at 88. Even though petitioner "had had multiple events that may have predisposed her to get fibromyalgia, the diffused pain really didn't start until after she had – right after she had the vaccination." Id. Dr. Gowin further testified that petitioner's history of [OCD and depression][11], the other previous injuries, the motor vehicle accident, were medically accepted events that predispose a person to the development of fibromyalgia. Id. at 89.

Dr. Gowin testified that the medical community believes that anything that causes pain can potentially cause fibromyalgia. Id. at 95. More specifically, the "current thinking" is that

[11]Pursuant to Vaccine Rule 18 and by agreement of the parties, portions of the original text have been modified and replaced with the bracketed contents.

"regional pain syndromes, viral infections, trauma, anything that sets off the cascade of pain and not sleeping and all can trigger the syndrome." Id. In support of her claim, Dr. Gowin cited an article authored by Drs. Crofford and Clauw, and summarized her opinion as follows:

> I think if you read the article by Doctors Clauw and Crawfford, [sic] where they talked about fibromyalgia and the precipitating events, I think they probably explained it best that it's the sleep deprivation and psychological distress that's caused by a particular – either a traumatic event or a viral illness that really sets – seems to set off the cascade of the sleep disturbance and the fatigue and the chronic widespread pain. There's not a known specific biochemical abnormality that happens but it seems to be kind of a cascade of abnormal brain hormones and abnormal pain processing in the brain that takes place after particular triggers of which viral infections and trauma are probably two of the biggest ones.

Id. at 89-90; See Res. Ex. D.

When asked by the court whether anything that causes pain can potentially trigger fibromyalgia, Dr. Gowin testified that it is the pain and lack of sleep in combination that causes the fibromyalgia.[12] Tr. at 89. In addition, she explained that there is a potential genetic predisposition to developing fibromyalgia that may explain why a person who experiences a trauma may get the disease, but another person experiencing trauma does not. Id. at 96. More specifically, Dr. Gowin testified that

> there's probably a genetic predisposition to get a particular sleep disorder which is called alpha delta sleep or what happens is that you never get enough stage four which is the deep restorative sleep that you need for your body to feel rested and rejuvenated and there seem to be particular people who are predisposed to get that sleep disorder. It's probably mostly those people that get the required trigger, whatever it may be, viral infection, regional pain disorder, or something that triggers them to have that sleep disorder which is where you don't get enough stage four sleep.

[12]At the beginning of the hearing, Dr. Gowin testified that the cause of petitioner's fibromyalgia was the headache combined with the lack of sleep. Tr. at 91. Dr. Brenner agreed that a headache plus the sleeplessness could be a cause of fibromyalgia. Id. at 133. However, during the course of the hearing in discussing the cause of petitioner's fibromyalgia, Drs. Gowin and Brenner referenced the occurrence of the headache, without mentioning the subsequent sleeplessness. Based on a complete reading of the testimony, the court takes the view that the essential issue is the development of the headache. However, in the context of the testimony, it is clear that when a headache is discussed in relationship to the development of fibromyalgia, the resultant sleeplessness is assumed to be a part of that symptomology.

Id. Dr. Gowin, however, asserted that the scientific community does not yet know what links the "traumatic event" to the resultant fibromyalgia. Id. at 97.

Specific to petitioner's case, Dr. Gowin testified that she believes that the temporal relationship between the shot and the onset of the fibromyalgia is "a significant factor since it seems to be this reaction to the vaccine is what caused her to have that sleep disturbance where she couldn't sleep for two days and had her – and she had this severe headache that was associated with it." Id. at 90. In essence, Dr. Gowin does not directly link the hepatitis B vaccination to petitioner's fibromyalgia; rather, Dr. Gowin believes that petitioner "had a reaction [to the hepatitis B vaccine] with the pain and headache and that set off her fibromyalgia." Id. at 94. Dr. Gowin does not believe that there is a more likely cause for the development of fibromyalgia in petitioner's case than the headache and the pain. Id.

Dr. Alan I. Brenner testified on behalf of respondent. Dr. Brenner is Board Certified in Rheumatology as well as in Internal Medicine. Id. at 116. He received his undergraduate degree from Brown University in 1964 and his medical degree from the University of Cincinnati College of Medicine in 1968, and has been licensed to practice medicine since 1969. Id.; Res. Ex. B at 2. He has had several academic appointments at Boston University, and is the author of more than a half-dozen medical publications. See Res. Ex. B at 1-2. Dr. Brenner testified that his current practice focuses exclusively on clinical rheumatology, and includes patients with fibromyalgia. Tr. at 116-17.

Like Dr. Gowin, Dr. Brenner believes that fibromylagia is a functional somatic syndrome,[13] Tr. at 120, of which many overlapping symptoms are the cause. In that respect, he agrees with Dr. Gowin that petitioner has a number of symptoms pre-existing the hepatitis B vaccinations that may have predisposed petitioner for developing fibromyalgia. Id. at 121-22. Dr. Brenner also agrees with Dr. Gowin that petitioner has fibromyalgia. Id. at 132. However, based on his training and 30 years of experience as a board-certified clinical rheumatologist and immunologist, he believes that the hepatitis B vaccinations that petitioner received on September 19, 2000 and October 27, 2000, "neither caused nor contributed to the fibromyalgia syndrome that [petitioner] currently experiences." Res. Ex. A at 6. Simply put, Dr. Brenner's position is that his review of the medical literature suggests that there is no biologic plausibility to associate a hepatitis B vaccination with any of the sequela that occurred in temporal association with the receipt of the vaccine. Tr. at 117-118. Furthermore, he has not found any evidence in the medical record to show that the purported initial event – the headache – was in any way related to the hepatitis B vaccine except by a close temporal relationship. Id. at 118. In contrast to Dr.

[13]Dr. Brenner described a "functional somatic syndrome" as a group of overlapping symptoms that "are all likely interconnected and various manifestations of the same . . . neural hormonal, neural chemical process." Tr. at 120-21. Basically, it refers to several related syndromes that are characterized more by symptoms, suffering, and disability than by disease-specific, demonstrable abnormalities of structure or function. Res. Ex. F at 910.

Gowin's testimony, he believes that petitioner's prior history of "[OCD and depression][14], a history of a recurrent post traumatic regional pain syndrome, recurrent headaches as well as a history of enduring significant ongoing and recent psychological stressors," were responsible for the development of her fibromyalgia – not the vaccine. Res. Ex. A at 6.

As further support for his position, Dr. Brenner does not believe that the sequence of events occurring after the second hepatitis B vaccine support a causal relationship between the vaccine and petitioner's insomnia and headache. Dr. Brenner does not believe that the vaccine is responsible for petitioner's trauma because "the time relationship is ridiculously short." Tr. at 131. There was not enough time intervening between when petitioner received her second vaccination and the symptoms that she reported later that day. More specifically, as noted above, petitioner testified that she was "confused and glassy eyed" just hours after the vaccination. Id. Dr. Brenner believes that there was not "time for an immune response, let alone a cytokine response to have taken place in that short . . . a period of time." Id.

After hearing and considering Dr. Brenner's testimony, Dr. Gowin continued to opine that the vaccine is "still the major contributing factor" for petitioner's injuries. Id. at 148. Although she conceded that the short time period between the administration of the second vaccine and the development of the headache was "somewhat unusual," she believes it can be attributed to an accelerated immune response. Id. at 147-48.

Dr. Brenner also testified as to what he considered a plausible explanation for the development of petitioner's severe headache after the vaccine. Noting that petitioner had developed pre-menstrual migraines in the past, Dr. Brenner testified that this indicates that petitioner has a propensity for developing headaches. Id. at 139. He believes that the development of migraines is "also associated with the development of other migraine[s] at some – at some point in time." Id. More specifically, Dr. Brenner testified that "most women with pre-menstrual migraine continue to have pre-menstrual migraine until menopause but some go on and develop classic migraine, not in association with their periods." Id. Dr. Brenner, however, neither cited anything in the record indicating that petitioner had migraines in the past, nor did he provide medical literature in support of his testimony. Curiously, Dr. Brenner also testified that pre-menstrual migraine was "its own condition," not related to other types of migraines. Id.

When probed by the court as to the differences in their opinions, while Dr. Gowin opines that the severe headache and sleep deprivation triggered petitioner's fibromyalgia, Dr. Brenner sees those symptoms as the manifestation of the condition. Id. at 138. In an effort to focus the differences between the experts' opinions, the undersigned asked Dr. Brenner what his opinion would be if there was a reported connection in the medical literature between the hepatitis B vaccine and headaches and sleep deprivation. His answers, quite frankly, were confusing. At first, he responded, "[i]f I could have seen that I would have recommended handling this case

[14]Pursuant to Vaccine Rule 18 and by agreement of the parties, portions of the original text have been modified and replaced with the bracketed contents.

differently." Id. at 133. The second time the question was asked, which occurred after Dr. Brenner gave his opinion that the symptoms were a manifestation of the condition, not a trigger for the condition, Dr. Brenner stated that "[m]y opinion would probably -- well, as I said before, my opinion might – might change." Id. at 142. He then continued by offering the alternative construction that the headaches were a manifestation of the underlying condition. Id. These exchanges left the undersigned uncertain as to Dr. Brenner's position; is the vaccine unrelated to the fibromyalgia because the symptoms are a manifestation of the condition or is the vaccine unrelated because of the lack of supportive literature for a connection between the hepatitis B vaccine and the symptoms?

In an effort to address the experts' differences, the undersigned requested additional information.

2. Post-Hearing Submissions

As described *supra*, at the hearing the undersigned gave a tentative bench ruling that the petitioner had not met her burden of proof in establishing that the hepatitis B vaccine in-fact caused her fibromyalgia. In an Order dated July 30, 2004, petitioner was invited "to supplement the record with ***relevant*** information that could aid the court in making a final decision." The court found that petitioner had not demonstrated that the severe headache and sleeplessness experienced after her hepatitis B vaccinations were causally linked to the hepatitis B vaccine. July 30, 2004 Order.

In response to the court's request, petitioner filed a supplemental expert report on August 30, 2004. In that report, Dr. Gowin submitted five articles from the medical literature as well as copies of vaccine information from the Physicians Desk Reference (PDR). See Pet. Supp. Rep., filed Aug. 30, 2004. Dr. Gowin pointed out that the PDR from 2002 and 2004 lists "headache" as one of the most frequent side effects of either the Engerix-B or the Recombivax hepatitis B vaccines. Pet. Supp. Rep., Letter from Dr. Gowin to Attorney Edwards, dated Aug. 24, 2004. In addition, Dr. Gowin noted that although the onset of the headaches is not per se listed, the medical literature indicates that most symptoms resolved within 24-48 hours of the administration of the vaccine. Id. Therefore, Dr. Gowin posits that one would assume a relatively short onset from the vaccination to the onset of the headaches since the symptoms usually resolved within two days. Id. Finally, also in the PDR from 2002 and 2004, both Engerix-B vaccine and Recombivax HB vaccine listed "insomnia" as an infrequent side effect. Id. She opined that this information, "provides the link between Ms. Lee's symptoms of headache, insomnia, and the Hepatitis B vaccine." Id.[15]

[15]Dr. Gowin also testified about petitioner's sister's medical records regarding an alleged adverse reaction to a hepatitis B vaccine. Dr. Gowin added that although she "did not rely upon this to make [her] opinion for Ms. Lee," she believes that it is important and relevant that petitioner's sister had a hepatitis B vaccine-related adverse reaction because it supports a genetic predisposition for petitioner to have an adverse reaction. Pet. Supp. Rep., Letter from Dr. Gowin

Respondent subsequently filed a responsive supplemental expert report on October 25, 2004. In this report, Dr. Brenner reiterated his opinion about the biologic connection between the administration of the hepatitis B vaccine and the development of headache, that being that there is no association. Res. Ex. M at 3. He also sought to explain his statements at the hearing regarding his apparent concession that if he could have seen a link between the headache and the vaccine, he would have advised respondent to handle petitioner's case differently. Id.

In support of his opinion, Dr. Brenner cited a series of reference articles, as well as abstracts for each. See id. at 3-13. Based on several of these articles, Dr. Brenner reports that "[h]eadache has been reported as a **common adverse event** following almost all vaccinations, other drug therapies and even non-medication-associated treatments." Id. at 2 (emphasis supplied). Following vaccination, literature indicates increased reporting of headaches after vaccinia, anthrax, typhoid Vi, pneumococcal and meningococcal immunization, as well as after hepatitis B vaccination. Id. While headaches are commonly reported, Dr. Brenner contends that biologic plausibility has been demonstrated only for headache associated with smallpox, encephalomyelitis, and for aseptic meningitis after mumps vaccination. Id.

Dr. Brenner posits that the headache experienced by petitioner after her second hepatitis B vaccination could be explained by the phenomenon known as the "nocebo effect." Id. According to Dr. Brenner, the term "nocebo" originally was used to describe the distressing effects of a placebo as compared to its beneficial effects. Id. In his report, Dr. Brenner stated that

> [t]he nocebo phenomenon appears to be particularly prevalent among migraine sufferers as reported by Rogers et al[.] and by Reuter et al. In association, Spierings et al[.] have reported that "The incidence and stressfulness of daily hassles as well as the mood states: tense, irritable, annoyed, depressed and tired were significantly increased in the 2 days before a migraine headache in comparison to control days." This would suggest that the onset of severe (migraine) headache is more likely related to events and circumstances in a time frame prior to the onset of headache than related to events (i.e. vaccination) immediately preceding onset.

Id. (citations omitted). In support of this hypothesis, Dr. Brenner submitted several articles from the medical literature describing the "nocebo effect," and how and why it occurs. See Res. Exs. S, T, U, V, W. See also, Res. Exs. EE, FF, HH. Thus, Dr. Brenner argues that because headache

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to Attorney Edwards, dated Aug. 24, 2004. The undersigned has examined these records and the testimony given by Dr. Gowin regarding the records. Although considered in the analysis of the case, the undersigned believes that these records are of little evidentiary value in determining whether Ms. Lee has suffered a vaccine related injury because, as expressed at the hearing, petitioner's expert did not rely on these records for her determination that the hepatitis B vaccine caused petitioner's fibromyalgia. Tr. at 93-94.

is a common reaction to many forms of medical intervention, combined with the fact that medical literature does not report a causal relationship between the development of a headache and the hepatitis B vaccine, petitioner's development of fibromyalgia cannot be causally related to the vaccine. Res. Ex. M at 3. To a reasonable degree of medical certainty, Dr. Brenner postulates that the nocebo effect is the more likely explanation for the development of the headache that lead to petitioner's fibromyalgia. Id. This is because the onset of petitioner's migraine "appears predicated on psychophysiologic events and circumstances that predate the onset of headache and, in Ms. Lee's case, such events and circumstances are well documented in Dr. Gowin's medical record." Id.

In response to Dr. Brenner's supplemental expert report filed on October 25, 2004, on November 9, 2004, petitioner filed a second supplemental expert opinion by Dr. Gowin. Dr. Gowin believes that multiple vaccines can cause headaches based on their biologic effect – indeed, vaccines are meant to produce an immune response. Pet. Second Supp. Rep. at 1. This type of response may be similar to what occurs when a primary infection occurs. Id.

Overall, Dr. Gowin believes that Dr. Brenner does not necessarily have "the weight of the epidemiologic evidence on his side with the lack of biological plausibility." Id. at 2. Noting that there is no long-term cohort data that indicates whether specific types of headaches or other adverse events are linked to the hepatitis B vaccine, Dr. Gowin posits that "the data on the clinical trials has the most weight of the epidemiologic evidence that speaks to the fact that the vaccine can cause headaches. " Id.

Analysis

After reviewing the experts' testimony, it is apparent that the experts agree on many of the aspects of this case. In sum, both experts agree that: 1) fibromyalgia is a functional somatic syndrome of which many overlapping symptoms could be the cause; 2) there is no known biologic mechanism to explain why a person develops fibromyalgia; 3) there is no known cause for the disease, but it is thought to be triggered by viral infections, stress or trauma; 4) petitioner had multiple pre-disposing factors that led to the development of her fibromyalgia; 5) petitioner did in-fact develop a headache after the second hepatitis B vaccine; 6) the headache developed by the petitioner subsequent to the second vaccination could have been the trigger for the development of petitioner's fibromyalgia; and 7) petitioner does indeed have fibromyalgia.

Based on the experts' extensive agreement, the decision in this case devolves to, in essence, the cause of petitioner's headache. Dr. Gowin opines that the hepatitis B vaccine caused the headache, which caused petitioner's sleeplessness, which in turn precipitated the fibromyalgia. Dr. Brenner offered several explanations for the headache, all of which excluded the hepatitis B vaccine.

In summary, the undersigned finds Dr. Gowin's testimony more persuasive. Her opinions were consistent with the facts and supported fully by the proffered medical literature. Dr.

Brenner on the other hand seemed torn in this case, agreeing with Dr. Gowin on significant points but struggling and at times stretching his testimony to deny a vaccine's role in petitioner's fibromyalgia. While it is not certain that the hepatitis B vaccine caused petitioner's fibromyalgia, the undersigned finds that the evidence preponderates in favor of that conclusion.

As indicated, the primary issue in this case is what caused petitioner's headache following the vaccination? Dr. Brenner stated on multiple occasions that he was unaware of any literature supporting the proposition that the hepatitis B vaccine can cause a headache. In response to the court's July 30, 2004 Order, Dr. Gowin submitted a supplemental expert report. As support for the biologic plausibility that the vaccine can and did cause the headache in petitioner's case, Dr. Gowin presented medical literature that supports such a finding. In her expert report, Dr. Gowin highlighted several references from the 2002 and 2004 versions of the PDR. With respect to the Recombivax Vaccine as reported in the 2002 PDR, in greater than 1% of injections, with respect to the "Body as a Whole," the "most frequent systemic complaints include fatigue/weakness; headache; fever ($\geq 100^{\circ}$F); and malaise." Pet. Supp. Rep. at 2. In addition, the PDR lists under "Psychiatric/Behavioral" that insomnia/disturbed sleep occur in less than 1% of injections. Id. The 2004 version of the PDR reports the same results. Id. at 10-11.

With respect to the Engerix-B vaccine, listed in the 2002 PDR under "Adverse Reactions," with a reported incidence of 1% to 10% of injections, is "headache." Id. at 6. Also reported with an incidence in less than 1% of injections was "insomnia." Id. The 2004 PDR also reports these same results. Id. at 8.

Dr. Gowin also submitted several articles that the undersigned believes supports petitioner's contention that the hepatitis B vaccine can cause headaches. The article "Major adverse reactions to yeast-derived hepatitis B vaccines – a review," concludes that in clinical trials with recombinant hepatitis B vaccine, headaches were reported by 9% of patients. Id. at 37. In addition, the article notes that "other reported symptoms (such as gastrointestinal upset) seemed temporal and not causal." Id. This would seem to suggest that the headaches were causally and temporally linked. In addition, that same article reported that a

> [r]eview of the post-marketing surveillance literature (4.5 million doses) revealed an overall rate of one adverse effect per 15500 doses distributed. Of these, local reactions were reported to be **the only events unequivocally related to the vaccine** (at a rate of 1 in 85000 doses). These reactions included nausea, rash, **headache**, fever, malaise, injection site symptoms, fatigue, influenza like symptoms, vomiting, dizziness, pruritus, arthralgia, myalgia, diarrhea, urticaria, paraesthesia, and somnolence all of which **resolved, generally, within 24-48 [hours] of vaccine administration**.

Id. at 37 (footnotes omitted and emphasis supplied). The article goes on further to postulate that

> the link between the adverse effects described, immune-complex disease and hepatitis B vaccine can be explained in three ways. First, that it is coincidental. Second, that the patients developed a post-immunization disease, clinically indistinguishable from the natural form of the disease. Finally, that the patients had a pre-existing immunological susceptibility, which after the antigenic stimulus of hepatitis B recombinant surface vaccine, triggered the pathologic process that led to clinical disease.

Id. at 40. Dr. Gowin had testified that the third hypothesis explains how petitioner had an adverse reaction to the vaccine. Tr. at 91, 94, 147; Pet. Supp. Rep., Letter from Dr. Gowin to Attorney Edwards, dated Aug. 24, 2004.

The article goes on to discuss the potential causal relationship between the vaccine and adverse effects. It states that,

> [a]lthough a causal association between vaccination and adverse effects has not been proven, it appears to be strongly supported both by a close temporal relationship between vaccination and the onset of the symptoms, and by the immune-mediated nature of these manifestations. Furthermore, in most cases, most other etiologics associated with these phenomena other than hepatitis B, were excluded.

Pet. Supp. Rep. at 40.

In conclusion, the article states that

> the similarity between serious adverse reactions to hepatitis B vaccine and the extrahepatic manifestations of hepatitis B infection, their temporal relationship to hepatitis B vaccinination, and the possible immune complex mechanism suggest a possible etiologic link with hepatitis B vaccine. These effects are very rare, and may, in part, be immune mediated.

Id. at 40-41. Overall, this article supports the occurrence of headache/sleeplessness after administration of the vaccine as well as suggests a biologic link between the petitioner and the vaccine and the headache/sleeplessness that she developed.

Another article, "Comparison of a Triple Antigen and a Single Antigen Recombinant Vaccine for Adult Hepatitis B Vaccination," appears to be a study comparing the antibody response of two brands of hepatitis B vaccine, those being two recombinant vaccines, Recombivax and Hepacare.[16] Pet. Supp. Rep. at 23. Dr. Gowin points out that the study

[16]It should be pointed out that petitioner was administered the Engerix-B brand of hepatitis B vaccine. See Petition, Ex. 4 at 79; Pet. Supp. Rep., Letter from Dr. Gowin to Attorney Edwards, dated August 24, 2004. Engerix-B and Recombivax are single antigen

reported that "[t]he most frequently (≥10%) reported adverse events with the use of either vaccine were . . . headache (9% vs. 13% vs. 11%)," among other things. These numbers were reported for a two-dose Hepacare regimen, a three dose Hepacare regimen, and a three-dose Recombivax-HB regime, respectively. Id. at 24.

Another article, entitled "Early anti-HBs antibody response to accelerated and to conventional hepatitis B vaccination regimens in healthy persons," discusses the results obtained by a group of students that were vaccinated on different vaccination schedules with the Engerix-B brand of the hepatitis B vaccine. Id. at 42. This study reported that among those with adverse reactions, "[s]ystemic reactions consisted of headache and/or fever which lasted usually for ‹ 24 [hours]. Id. at 43. This article supports a link between the hepatitis B vaccine, as well as rapid onset of the headache. [17]

The Court finds that Dr. Gowin's testimony regarding the relationship between the development of petitioner's headache from the vaccine to be persuasive. The court finds that Dr. Gowin was a cogent, knowledgeable, and reasonable witness. Dr. Gowin's opinions were not speculative, as her opinions and findings regarding her hypothesis that a headache can be caused by the hepatitis vaccine were well documented throughout the record, as well as cogently explained at the hearing based on her expertise and the medical literature. She supported a plausible medical hypothesis regarding the development of a headache within such a short period of time by opining how and why it occurred in the petitioner, as well as proffered medical literature to substantiate the claim. Tr. at 91; Pet. Supp. Rep. at 37, 43.

As noted above, Dr. Brenner contends that there is no medical literature supporting "biologic plausibility to associat[e] a hepatitis B vaccine with any of the sequela that occurred in temporal association with her receipt of [the] Hepatitis B vaccine." Tr. at 118. He also testified that there is no medical literature that associates fibromyalgia with the hepatitis B vaccine. Id. at 123. Essentially, his view is that although the literature reports the occurrence of headaches after the vaccine, it does not support a causal relationship between the two. See Res. Ex. M at 2.

While the court finds Dr. Brenner to be a highly qualified and articulate witness, the court disagrees that the medical literature does not support a finding that the vaccine can be the cause of a headache. Over and over in his testimony, Dr. Brenner claims that there is no literature supporting such a relationship -- but does little in the way to rebut the information submitted by

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recombinant vaccines used in the United States. See Pet. Supp. Rep. at 37. Dr. Gowin also stated that the Engerix-B and Recombivax vaccines were "similarly constituted." Id.; Letter from Dr. Gowin to Attorney Edwards, dated August 24, 2004.

[17]Dr. Gowin also submitted for review several articles that related to either a combined hepatitis A and B vaccine or the administration of both vaccines simultaneously. The court does not find these articles probative inasmuch as one cannot differentiate which vaccine caused the alleged results. See Pet. Supp. Rep. at 13, 32.

Dr. Gowin. Dr. Brenner may be correct in his assertion that there have been no studies done expressly looking to find such a relationship between the vaccine and fibromyalgia; however, he has missed the point that in other studies involving the vaccine, symptoms such as headaches and insomnia that can result in the development of fibromyalgia *have* been reported. In fact, in his supplemental report, he even goes as far as to concede that headaches have been reported after receipt of vaccines, including the hepatitis B vaccine. See id. at 2. Dr. Brenner is simply looking for "certain" proof, which is not the legal standard. The submitted literature clearly supports what Dr. Gowin argues – that headaches are a recognized reaction to the hepatitis B vaccine. In the court's view, Dr. Brenner did little to rebut the evidence presented by Dr. Gowin.

Dr. Brenner, however, did raise a serious issue in testifying that he was not sure how a normal immune reaction to the hepatitis B vaccine could cause a headache to occur so quickly. Tr. at 144-45. Dr. Brenner testified that people can be over immunized. Id. at 130. He also testified that if an excessive amount of cytokines is created in response to a stimulus, a headache could occur. Id. However, because the purpose of the subunit particle of the hepatitis B vaccine is to cause a small immunologic reaction, for this kind of a reaction to take place, there would have to be multiple immunizations. Id. He does not believe, nor has it been reported, that this kind of immune response would be elicited from a second dose of recombinant hepatitis B vaccine. Id. at 130-31. In essence, he believes petitioner's reaction to the vaccine happened too quicky because there was not enough time for her body to mount an immune response, let alone a cytokine response. Id. at 131. Dr. Brenner, however, provided no support for his position.

With respect to issue of timing regarding the onset of petitioner's headache, Dr. Gowin testified that even though it would be highly unusual for an individual to experience the effects of a vaccine as quicky as petitioner did, she believes that petitioner had an allergic reaction to the vaccine which caused the headache. She believes that because petitioner received a previous vaccine, there was enough "memory" in petitioner's immune system to cause a reaction to the second vaccine, somewhat like a bee sting allergy. Tr. at 91,147. Dr. Gowin also pointed to medical literature that supports her position that the symptoms of headache could have rapid onset. See Pet. Supp. Rep. at 37, 43.

As described above, the court has reviewed the medical literature and finds that Dr. Gowin's explanation for the rapid onset of petitioner's headache is supported not only in terms of timing, but also with respect to a possible mechanism of occurrence. Petitioner cited several articles that report headaches as occurring within the first several days after administration of the hepatitis B vaccine. See, e.g., Pet. Supp. Rep. at 37, 43. One article also supported Dr. Gowin's hypothesis that the petitioner may be suffering from a pre-existing immune-complex disorder. Id. at 40-41. Although Dr. Gowin conceded that petitioner's reaction time to the vaccination was unusual, her position is nonetheless supported in the literature. Thus, on balance, the scales tilt in petitioner's favor on the issue of timing, albeit only slightly.

Additionally, the court has serious reservations regarding Dr. Brenner's effort to find an alternative explanation that the vaccine could cause a headache – that being his report regarding

the putative "nocebo effect." First, the court questions whether Dr. Brenner is qualified to make such a claim, as he is a rheumatologist and not a psychologist. Furthermore, the court believes the hypothesis is speculative. In his supplemental expert report, he pointed to nothing in petitioner's medical records to substantiate the hypothesis. Moreover, he did not bring up the "nocebo effect" as a putative cause of petitioner's headache until well after the hearing in his supplemental report, after he conceded at the hearing that the headache experienced by petitioner after her second hepatitis B vaccine could be "the" triggering event to the beginning of petitioner's fibromyalgia.

Dr. Brenner's argument regarding the nocebo effect struck the undersigned as the ultimate result-oriented argument – it cannot be the vaccine so it must be something else. However, in logical conflict with the nocebo contention, Dr. Brenner offered candid testimony recognizing that petitioner's headache and sleeplessness could have triggered the onset of her fibromyalgia, thus recognizing that if the hepatitis B vaccine could be linked to the symptoms that it followed that the hepatitis B vaccine was the legal cause of the fibromyalgia. For whatever reasons, recognizing the potential result of his candid testimony, Dr. Brenner attempted to undermine his own testimony by proffering the nocebo hypothesis. In doing so, he also successfully undermined his credibility.

In the final analysis, the disagreement between the doctors really comes down to the simple issue of whether the headache combined with sleeplessness could be a triggering event for the development of fibromyalgia. The court finds that Dr. Gowin provided more persuasive testimony as to the why and how petitioner's headache led to the development of her fibromyalgia. Dr. Gowin provided persuasive testimony regarding the accepted development of fibromyalgia and, to the extent that they are known, the accepted causes. Dr. Brenner agreed with this part of Dr. Gowin's testimony. Moreover, Dr. Gowin's hypothesis and timeline for the development of petitioner's headache is supported in the medical literature. See Pet. Supp. Rep. at 37, 43. Dr. Brenner did little in the way of rebutting her testimony on this issue.

It should be noted that the undersigned has benefitted from Dr. Brenner's quality testimony on numerous occasions. However, in this case, Dr. Brenner's testimony suffered from equivocation and speculation. For example, while at first recognizing that his "recommended handling" of this case would be different if there was a biologic connection between the hepatitis B vaccine and headaches and sleeplessness, Tr. at 133, his testimony changed to consider the symptoms as manifestations of the condition, id. at 137-38; only to see it change back to his opinion "might change" in the face of such evidence. Id. at 142. In addition, Dr. Brenner's testimony regarding the relationship of the migraine headache to petitioner's prior migraines struck the undersigned as highly speculative. The only evidence of petitioner suffering from migraines was with respect to her menstrual cycle. Dr. Brenner recognized that premenstrual migraines were different, but still maintained nonetheless that petitioner had a predisposition to developing migraines throughout her lifetime, to which he subsequently attributed petitioner's migraine after the vaccines. Id. at 138-39.

Accordingly, based upon the above discussion, petitioner is entitled to compensation.

Conclusion

The court finds petitioner's expert witness Dr. Kristin Gowin to be highly credible, and thus accepts her views on the causation of petitioner's fibromyalgia. More specifically, the court finds that petitioner has satisfied her burden of proof in showing that the hepatitis B vaccines that she received on September 19, 2000 and October 27, 2000, respectively, more likely than not caused her to develop a headache and sleeplessness which subsequently led to her fibromyalgia.[18] Petitioner's expert, Dr. Gowin, presented the stronger testimony supported by logic, the medical literature, and medical reasoning.

In summary, petitioner has proven by a preponderance of the evidence that the vaccine ultimately caused her condition circumstantially through the testimony of her treating physician, presentation of medical literature supporting her hypothesis, PDR references, a plausible biological mechanism, and the proximal temporal relationship of her injury to the receipt of the hepatitis B vaccine.

Thus, based on the foregoing analysis, petitioner's entitlement claim is *granted*. The parties shall determine damages in accordance with the undersigned's March 25, 2005 Order.

IT IS SO ORDERED.

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Gary J. Golkiewicz
Chief Special Master

[18]The undersigned acknowledges that the conclusion in this case is contrary to the undersigned's decision in Mahaffey v. Secretary of HHS, No. 01-392V, 2003 WL 22424989 (Fed. Cl. Spec. Mstr. May 30, 2003), which concluded that petitioner did not satisfy her burden of proof in demonstrating that the hepatitis B vaccine caused her headaches. That case is distinguishable from Ms. Lee's case. In Mahaffey, the undersigned found that petitioner's expert's familiarity with the facts of petitioner's condition was reliant on the "faulty factual predicate of petitioner's testimony." Id. at *11. In addition, the petitioner's expert was "minimally familiar with petitioner's record." Id. Finally, the undersigned found petitioner's expert's testimony to be unreliable. Id.