In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 05-420V
September 9, 2008
To be Published

* *
KELLY BOLEY, *
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Petitioner, *
*
v. *
*
SECRETARY OF THE DEPARTMENT OF *
HEALTH AND HUMAN SERVICES, *
*
Respondent. *
* *

Decision on remand; petitioner rejects option to reconvene hearing with same witnesses; also rejects option to have new hearing with new witnesses; selects option to file post-hearing brief; credible medical records do not support more than six months of injury; no credible proof that five years of emotional distress is causally related to transient vaccine injury; new allegation of significant aggravation of panic disorder

Ronald C. Homer, Boston, MA, for petitioner.
Katherine C. Esposito, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION ON REMAND[1]

Petitioner filed a petition dated March 30, 2005, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine caused her a

[1] Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

demyelinating[2] disorder, and an amended petition dated June 6, 2005, alleging that hepatitis B vaccine caused her a demyelinating polyneuropathy.[3] At paragraph 20, petitioner alleges she suffered the effects of her vaccine injury for more than six months. Subsequently, petitioner alleged a transient neurological illness in her prehearing brief, and, in her post-hearing brief on remand, a neuropathy, emotional distress, and significant aggravation of a pre-existing illness (presumably a pre-existing panic disorder, as petitioner claimed in her Motion for Review, p. 16, n.15)

The Omnibus Proceeding on Hepatitis B vaccine and Demyelinating Illnesses

On March 30, 2005, this case was assigned to chief special master Gary Golkiewicz. On April 6, 2005, the case was reassigned to former special master Margaret M. Sweeney. On January 11, 2006, this case was reassigned to the undersigned as part of 65 hepatitis B vaccine-demyelinating diseases cases reassigned to the undersigned in January 2006 after former special master Sweeney became a judge on the United States Court of Federal Claims.

As part of her role in determining the outcomes of these 65 cases, the undersigned issued decisions after the Omnibus hearing that former special master Sweeney held on October 13, 14, and 15, 2004 to determine whether hepatitis B vaccine can cause demyelinating diseases and,

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[2] Demyelination is "destruction, removal, or loss of the myelin sheath of a nerve or nerves." Dorland's Illustrated Medical Dictionary, 30th ed. (2003), at 488. The myelin sheath is "the cylindrical covering on the axons of some neurons; it consists of concentric layers of myelin, formed in the peripheral nervous system by the plasma membrane of Schwann cells, and in the central nervous system by oligodendrocytes. . . . Myelin is an electrical insulator that serves to speed the conduction of nerve impulses." *Id.* at 1689.

[3] Polyneuropathy is "neuropathy of several peripheral nerves simultaneously; called also *multiple* or *peripheral neuropathy*." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1482.

specifically, whether it caused the illnesses in four paradigm cases[4] in the Omnibus proceeding. The undersigned ruled in favor of petitioners in all four paradigm cases, i.e., that hepatitis B vaccine could and did cause transverse myelitis, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, and multiple sclerosis in those four cases. Petitioner's counsel in the instant action was petitioners' counsel in two of those four paradigm cases (Stevens and Peugh).

The undersigned issued an Order to Show Cause in 60 out of the 65 cases, including the four paradigm cases. The undersigned issued a 21-page Order to Show Cause in the instant action on September 5, 2006. The reason the undersigned issues orders to show cause is to assist counsel, particularly petitioners' counsel, to focus on their cases. It has been the experience of the undersigned in her 17 years as a special master that some petitioners' counsel are unfamiliar with the medical records in their cases. Counsel's unfamiliarity with their cases may stem from the fact that petitioners' counsel frequently take on many vaccine cases and rely upon staffers and expert witnesses to become familiar with their cases without spending much time themselves on the particulars of their cases.

Depending on the facts of a case, the undersigned may direct an order to show cause to respondent to show cause why the case should not proceed to damages because the evidence supports a finding of entitlement. In other cases, the undersigned may direct the order to show cause to petitioner to show cause why the case should not be dismissed and to order petitioner to

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[4] The cases were Stevens v. Secretary of HHS, No. 99-594V (transverse myelitis); Werderitsch v. Secretary of HHS, No. 99-638V (multiple sclerosis); Peugh v. Secretary of HHS, No. 99-319V (Guillain-Barre syndrome); and Gilbert v. Secretary of HHS, No. 04-455V (chronic inflammatory demyelinating polyneuropathy).

file an expert opinion in support of his or her case. Petitioner's counsel in the instant action was counsel for 18 of the 65 hepatitis B vaccine-demyelinating illness cases.

So far, 19 of the 65 cases (29%) in the demyelinating series have dismissed without a hearing after the undersigned filed an Order to Show Cause. Four of these 19 cases were dismissals on motion from the petitioner's counsel in the instant case.

So far, 11 out of the 65 cases (17%) in the demyelinating series have settled.

So far, in those cases in which the undersigned has issued decisions on the merits, in11 out of 12 of the cases in the demyelinating series, the undersigned has rule in favor of petitioners. Ten of these 12 cases went to hearing.[5] The instant action is the only case in the demyelinating series that has gone to hearing in which the undersigned ruled against petitioner.

The success rate for petitioners in the demyelinating series, considering that 11 out of 12 cases were decided for petitioners after hearing or were decided for petitioners because respondent would not present a defense, amounts to 91%. If one adds the number of settled cases (11) to the decisions in which petitioners prevailed, the success rate for petitioners in the demyelinating series amounts to 95%.

Petitioner in the instant action did not prevail in the undersigned's original decision, 2007 WL 4589766 (Fed. Cl. Spec. Mstr. Dec. 17, 2007), because her generalized vaccine reaction did not last more than six months. The Vaccine Act requires that petitioner's vaccine reaction last more than six months. The Vaccine Act, 42 U.S.C. §300aa-11(c)(1)(D)(i), states that petitioner **shall** file supporting documentation that she

[5] In two cases, respondent stated respondent would not go any further in opposing petitioners' cases. The undersigned then ruled for petitioners without a hearing.

> suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine . . . .

The Role of the Special Master

When Congress created the Vaccine Program, congressional intent was to avoid hearings and dispose of cases quickly based on the informality of the Program, with the hope that by retaining a cadre of special masters who were familiar with and capable of analyzing vaccine claims, hearings would be avoided and litigation truncated. To promote this goal, Congress expected the special masters to be vigorous, diligent, inquisitorial, in control of how much evidence they required, and in control of the format of the proceedings, if they indeed had hearings.

The Vaccine Rules of the United States Court of Federal Claims, as revised and reissued May 1, 2002, explain further the role of the special master. Rule 3(b) expounds on the duties:

> The special master shall be responsible for conducting all proceedings, **including requiring such evidence as may be appropriate,** in order to prepare a decision.... **The special master shall determine the nature of the proceedings** . . . . [Emphasis added.]

Both Vaccine Rules 3(b)(above) and 8(a) and (b)(below) incorporate congressional intent that the special masters control the proceedings:

> (a). **The special master, based on the specific circumstances of each case, shall determine the format for taking evidence and hearing argument. . . .**
> (b). **The special master will determine the format for such a hearing**. ... **The special master may question a witness** and, on request, permit questioning by opposing counsel. [Emphasis added.]

Rule 8 reflects the legislative history:

> [W]hile the **Special Master may compel any testimony** or appearance, neither party is given power to cross-examine witnesses, file interrogatories, or take depositions. In this regard, **the Committee expects the Special Master to be vigorous and diligent in investigating factual elements necessary to determine the validity of the petitioner's claim.** [Emphasis added.]

Report of the Committee on Energy and Commerce regarding the National Childhood Vaccine Injury Act of 1986, Rept. 99-908, Part 1, 99th Cong., 2d Sess., September 26, 1986, at 17.

To reflect the front-loaded aspect of Program litigation, Vaccine Rule 5 states:

> The special master shall schedule a conference to be held within 30 days after the filing of respondent's report pursuant to Vaccine Rule 4(c). At this conference, after affording the parties an opportunity to address each other's positions, **the special master will review the materials submitted, evaluate the respective positions, and orally present tentative findings and conclusions.** At the conclusion of this conference, the special master may issue a scheduling order outlining the necessary proceedings for resolving the issues presented in the case. [Emphasis added.]

This means that the special master is expected, both under legislative history and the Vaccine Rules, to know a case from its very beginning by thoroughly familiarizing herself or himself with the medical records, affidavits, and expert reports which are filed. The concept that a special master will wait until trial to see what evidence each side presents and only then mull over the weight of each side's evidence is contrary to the intent of Congress as expressed in the legislative history and the Vaccine Rules.

To reflect the informality of the Program, the Vaccine Rules provide that status conferences will be informal. Vaccine Rule 6 states:

> The special master shall conduct periodic conferences in order to expedite the processing of the case. The conferences will be informal in nature and ordinarily will be conducted by telephone conference call.

This means that status conferences between the special masters and the parties are generally not recorded. They are not viewed as formal parts of the proceedings. The purpose of the status conferences is to move the cases along, to see where the parties are in either proving, settling, or dismissing the petitions. They afford each party and the special master the opportunity to be totally honest about the merits or lack thereof of the allegations and the defenses each side has brought. If it became necessary to record each status conference, the informal give and take of the current process would be eliminated and case disposition necessarily protracted.

The distinction between traditional, formal litigation and the informal nature of the Program is also manifest by Vaccine Rule 8(c) which states that the special masters do not follow the rules of evidence:

> In receiving evidence, the special master will not be bound by common law or statutory rules of evidence. The special master will **consider all relevant and reliable evidence** . . . . [Emphasis added.]

More differences from traditional, formal litigation include the fact that the special masters do not wear robes, that all filed material is considered in evidence without the parties having to comply with the Federal Rules of Evidence, and that the parties may not conduct discovery as of right (see Vaccine Rule 7). At a conference early in the process, the special master indicates to the parties where the evidence is strong or weak so as to enable the parties to evaluate whether the case should go forward, dismiss, or settle. In order to exercise such power,

the special masters rely on congressional intent in enacting the Vaccine Act and creating the Office of Special Masters.

In the Report of the Committee on Energy and Commerce regarding the National Childhood Vaccine Injury Act of 1986, Rept. 99-908, Part 1, 99th Cong., 2d Sess., September 26, 1986, the Committee stated, at page 16: "In order to expedite the proceedings, the **power of the Special Master** is intended to replace the usual rules of discovery in civil actions in Federal courts." [Emphasis added.] Continuing at page 18, the Committee stated that the trier of fact "should, of course, **exercise its best judgment in evaluating whether the record satisfies the requirements for compensation**." [Emphasis added.]

Three years later, the Conferees were concerned because, despite congressional intent in passing the Vaccine Act, there were continued adversarial proceedings under the Vaccine Program, and stated:

> The Conferees reiterate their concern that these authorities not be used to re-create an adversarial process before the special masters. The system is intended to allow the proceedings to be **conducted in what has come to be known as an "inquisitorial" format, with the master conducting discovery (as needed), cross-examination (as needed), and investigation**. As was stated in the Report accompanying the original Act, "In order to expedite the proceedings **the power of the special master is intended to replace the usual rules of discovery in civil actions** in Federal courts." [Emphasis added.]

Omnibus Budget Reconciliation Act of 1989, Conference Report to accompany H.R. 3299, H.R. Rep. 101-386, 101st Cong., 1st Sess. (Nov. 21, 1989) at 516. The Conferees also stated that they expected "that the Special Master and the powers given to the Master will allow the proceedings to be direct and **straightforward**. The Master should be able to require from

petitioners and respondents information sufficient to evaluate the petition without resort to complex proceedings." [Emphasis added.] *Id.* at 513.

The Conferees reiterated congressional intent that the special masters be a cadre of specialists in medical and health issues:

> The Conferees would note their concern that special masters be well-advised on matters of health, medicine, and public health. No-fault vaccine compensation proceedings raise fewer legal issues than issues of medicine and masters need not be lawyers by training. Masters with health training and background should be considered for appointment and those without such training should be encouraged to seek independent experts to provide information.

Id. at 515.

The Federal Circuit has repeatedly expressed its understanding of the power Congress invested in the special masters to analyze and resolve the difficult medical issues of these cases. In Hodges v. Secretary of HHS, 9 F.3d 958, 961 (Fed. Cir.1993), the Federal Circuit stated:

> Congress assigned to a group of **specialists**, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, **based upon their accumulated expertise in the field**, judging the merits of the individual claims. The statute makes clear that, on review, **the Court of Federal Claims is not to second guess the Special Masters' fact-intensive conclusions;** the standard of review is uniquely deferential for what is essentially a judicial process. [Emphasis added.]

The Federal Circuit also stated in Whitecotton v. Secretary of HHS, 81 F.3d 1099, 1108 (Fed. Cir. 1996),

> [T]he **permissible scope of the special master's inquiry is virtually unlimited**. Congress desired the special masters to have **very wide discretion** with respect to the evidence they would consider and the weight to be assigned that evidence. [Emphasis added.]

The United States Court of Federal Claims has also recognized the unique skills, powers, and abilities of the special masters.[6]

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[6] In Sword v. Secretary of HHS, 44 Fed. Cl. 183, 188 (1999), the judge stated "this Court has recognized the unique ability of special masters to adjudge cases in the light of their **own acquired specialized knowledge and expertise**. Ultimo v. Secretary of HHS, 28 Fed. Cl. 148, 152-53 (1993); see also, Munn v. Secretary of HHS, 970 F.2d 863, 871 (Fed. Cir. 1992) (special masters accorded status as experts, entitling them to **special statutory deference** in fact-finding normally reserved for specialized agencies)." [Emphasis added.] In Sword, the judge affirmed the undersigned's ruling on behalf of petitioners for the death of their daughter Natalie, using both sides' experts' testimony, stating, at 44 Fed. Cl. 188:

> The Special Master's explanation, and only her explanation, incorporates all the facts, including the medical facts offered by the doctors, surrounding Natalie's death. The Special Master's conclusion is more than simply supported by the evidence. It is the most intellectually satisfactory explanation of the entire factual record.

In Jane Doe v. Secretary of HHS, 76 Fed. Cl. 328 (Fed. Cl. 2007), the judge affirmed the decision of former special master John F. Edwards whom petitioner's counsel accused of prejudice because of "the amount and nature of the questions posed by the Special Master during the hearing on petitioner's claims." 76 Fed. Cl. at 330. The judge affirmed the special master's dismissal of petitioner's petition. Petitioner contended that the special master conducted a "superficial review of the factual record" that deprived her of a full and fair hearing. 76 Fed. Cl. at 333. She challenged the special master's determination of her expert's credibility and argued that the special master ignored "critical evidence." *Id.* She also complained that "the Special Master assumed the role of 'zealous advocate for the government' by his extensive questioning of petitioner and her expert." *Id.*

The judge stated that, under the provisions of the Vaccine Act, the special master must consider all the relevant medical and scientific evidence contained in the records, citing 42 U.S.C. §300aa-13(a)(1)(A), (b)(1), and must evaluate the weight to be afforded to any of these sources of information. *Id.* Petitioner objected that the special master asked over 70 questions of petitioner's expert at trial compared to fewer than 60 questions from respondent's counsel, and asked petitioner 58 questions compared to just 20 from respondent's counsel at hearing. 76 Fed. Cl. at 338. Petitioner described the special master's active involvement in the hearing as "contrary to 'the traditional role of a judge in a civil matter,' stating it violated 'the explicit intent of the vaccine act as being a less adversarial forum than civil litigation.'" *Id.* The judge rejected petitioner's objection, saying that petitioner misunderstood the role of the special master:

> [I]nstead of being passive recipients of information, such as jurors, special masters are given an active role in determining the facts relevant to Vaccine Act petitioners. One reason that proceedings are more expeditious in the hands of special masters is that the

The instant action

Allegations

Petitioner in the instant action initially alleged hepatitis B vaccine caused her a demyelinating disorder. In her amended petition, she alleged hepatitis B vaccine caused her a demyelinating polyneuropathy.

On October 31, 2007, petitioner filed a pre-hearing memorandum. On page 2, petitioner alleged hepatitis B vaccine caused her a "non-specific transient neuropathy." On page 7, petitioner referred to her expert Dr. Robert Hughes as having excellent credentials and being knowledgeable regarding neurological disorders. On page 11, petitioner stated that Dr. Hughes would provide testimony at the hearing that she suffered from a poorly defined neurological disorder that hepatitis B vaccine caused.

The Hearing

> special masters have the expertise and experience to know the type of information that is most probative of a claim. Under the procedural framework erected for Vaccine Act cases, the Federal Circuit has noted that "the permissible scope of the special master's inquiry is virtually unlimited." *Whitecotton v. Sec'y of HHS*, 81 F.3d 1099, 1108 (Fed. Cir. 1996); *see also Munn*, 970 F.2d at 871 (describing Congress' designation of the special master as that of an "expert" and acknowledging that special masters are entitled to "the special statutory deference in fact-finding normally reserved for specialized agencies"). . . . Merely because the Special Master, an expert in whose care the ultimate fact determinations are entrusted, asked many questions of witnesses does not mean the Special Master crossed the line between fact-finder and prosecutor; rather, it means he did his job. Petitioner's objection to his role in the hearing is without merit.

76 Fed. Cl. at 338-39.

A hearing was held on November 14, 2007. Dr. Hughes testified that petitioner did not have CIDP and never had it. He testified she had a generalized vaccine reaction which probably lasted three to four months, although he began by stating petitioner had a generalized vaccine reaction of only two weeks, then four weeks, and then probably three to four months without explaining how he had expanded the time from two weeks. Trial tr. at 39, 40. Respondent's expert Dr. Bielawski testified petitioner did not have CIDP and her generalized vaccine reaction probably lasted two to three weeks. Trial tr. at 55.

When petitioner's counsel asked Dr. Hughes if petitioner's transient injury was possibly caused by hepatitis B vaccine, the undersigned interrupted. This interruption is consistent with the special master's role to control the format of the hearing. See discussion of legislative history of the Vaccine Act, supra. The burden of proof in vaccine litigation is by a preponderance of the evidence, i.e., that the vaccine probably, not possibly, caused a condition. 42 U.S.C. §300aa-13(a)(1) states: "Compensation shall be awarded under the Program to a petitioner if the special master ... finds on the record as a whole—(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required . . . ." Black's Law Dictionary, 7th ed. (1999), p. 1201, defines "preponderance" as "[s]uperiority in weight, importance, or influence."

Since all things are possible, it is legally irrelevant, and therefore not of assistance to the undersigned, to hear an answer from an expert that something is possible. Congress intended that the special masters receive only relevant evidence:

> The Act provides that the master may require the submission of **relevant** evidence and information . . . . [Emphasis added.]

Omnibus Budget Reconciliation Act of 1989, Conference Report to accompany H.R. 3299, H.R. Rep. 101-386, 101st Cong., 1st Sess. (Nov. 21, 1989) at 509.

Although, at the end of the hearing in this case, the undersigned and respondent's counsel remembered that Dr. Hughes had testified that petitioner's transient, generalized, non-neurologic vaccine injury lasted probably only three to four months, petitioner's counsel insisted that Dr. Hughes had testified that petitioner's vaccine injury lasted more than six months. (This conversation occurred after Dr. Hughes had finished testifying and was excused at petitioner's counsel's request in order for him to get back to seeing patients. Trial tr. at 51.) Since the court reporter was recording the testimony with a tape recorder, there was no practical way to ask the court reporter to rewind the tape to play what Dr. Hughes had said. Petitioner's counsel requested an opportunity to write a post-hearing brief. At page 66 of the transcript, the undersigned said:

> Legally, you have no case, because even assuming she had a vaccine reaction, you haven't proved that it lasted beyond four months. And the statute requires that her vaccine reaction last more than six months. So what point is there to doing a posthearing brief?

Petitioner's counsel replied: "I actually believe that Dr. Hughes gave it more than six months."

Giving petitioner the benefit of the doubt because there was always a chance the undersigned and respondent's counsel could have remembered Dr. Hughes' testimony incorrectly, the undersigned gave permission to petitioner's counsel to file a post-hearing brief.

After the hearing, the undersigned issued an Order, saying:

> A telephonic hearing was held on November 14, 2007. Petitioner shall have thirty days to read the transcript when it is filed and determine whether to file a posthearing brief. If respondent's counsel so chooses, she may file an objection to petitioner's intended filing of a posthearing brief thirty days after the transcript is filed. Respondent's objection is based on petitioner's failure to make a prima facie case since Dr. Richard Hughes testified that petitioner's vaccine injury probably lasted only three to four months. The Vaccine Act requires petitioner's vaccine injury to last more than six months.

When the transcript came in, the undersigned read it and saw that petitioner's counsel was incorrect and the undersigned and respondent's counsel were correct: Dr. Hughes had testified that petitioner's vaccine injury lasted probably only three to four months, and he would not go beyond that time. There was nothing left for petitioner's counsel to brief since petitioner had not made a prima facie case either in her credible medical records or through her expert's testimony. Had it not been for petitioner's counsel's insistence at the end of the hearing that Dr. Hughes had testified petitioner's vaccine injury lasted more than six months, the undersigned would have ruled on the record against petitioner.

On December 17, 2007, the undersigned issued a decision holding petitioner had not made a prima facie case. In the decision, the undersigned referred to the medical records that were in the Order to Show Cause, plus the medical records of Dr. Hughes dated 2006 (Ex. 20) and those of Dr. Rosenblum, her general practitioner, dated 2007 (Ex. 23), which petitioner filed only after the undersigned issued the Order to Show Cause. There were not the same medical records in both the Order to Show Cause and the decision. But even if they had been, the Vaccine Act, 42 U.S.C. §300aa-13(b)(1), requires the special master to consider all the records in the case:

> In determining whether to award compensation to a petitioner under the Program, the special master ... shall consider, in addition

> to all other relevant medical and scientific evidence contained in the record—
>
> > (A) any diagnosis, conclusion, medical judgment, ... which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition ... and
> > (B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.
>
> Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master .... In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master ... shall consider the entire record . . . .

The medical records undermine petitioner's case because they show that she did not have a vaccine injury lasting more than six months.

Petitioner appealed the decision in this case. In her Motion for Review, she alleged that hepatitis B vaccine caused her neurological injuries and emotional distress. Motion, p.1. Petitioner also states that if she had had the opportunity to file a post-hearing brief before the undersigned ruled, she would have offered another theory for recovery of damages, i.e., significant aggravation of an underlying condition (emotional distress). Motion, p.16, n.15.

On June 11, 2008 (published June 26, 2008), the judge issued an Opinion and Order vacating the decision and remanding this case to the undersigned to allow petitioner to file a post-hearing brief in order to assist the undersigned in finding medical records in evidence that would show that petitioner's expert Dr. Hughes was incorrect when he testified that her vaccine reaction probably lasted only three or four months. The judge also gave petitioner the option of reconvening the hearing with the same witnesses or of having a new hearing with new witnesses. 82 Fed. Cl. 407, 414 (2008).

On June 25, 2008, the undersigned had a status conference with each party's counsel. This status conference was recorded and the transcript filed in the record. Petitioner's counsel rejected the judge's option of reconvening the hearing with the same witnesses. He also rejected the judge's option of having a new hearing with new witnesses. He accepted the option of filing a post-hearing brief which would assist the undersigned by pointing to medical records that would show petitioner's expert Dr. Hughes was incorrect in his testimony that petitioner's vaccine injury lasted probably only three or four months.

Petitioner subsequently filed a Post-hearing Brief on July 25, 2008.

Respondent filed a Post-hearing Brief and Motion to Dismiss on August 25, 2008 after which petitioner filed a Reply to the Respondent's Post-hearing Brief on August 28, 2008.

Dr. Richard L. Hughes

The undersigned has had the opportunity to hear petitioner's expert Dr. Richard L. Hughes and make specific factual findings regarding his knowledge of the other treating doctors, the records, and petitioner. Dr. Hughes is a practicing clinical neurologist who is Chief of the Division of Neurology at the Denver Health Medical Center. He is also active at the University of Colorado School of Medicine and at the Veterans Administration Hospital. Trial tr. at 5; P. Ex. 22. He spends about 35 to 40 hours a week in direct patient care and another 20 hours in administration, teaching, and research. Trial tr. at 6. Dr. Hughes has the training, credentials, and qualifications to opine credibly on whether petitioner had CIDP, any demyelinating illness, or any neuropathy, and seemed credible in his assessment of petitioner's transient, generalized vaccine reaction lasting probably no more than three or four months..

Dr. Hughes first met petitioner four years after her vaccination, at which time he did not have her pre- and post-vaccination medical records. However, when Dr. Hughes became an expert for petitioner, her counsel sent him her medical records. When Dr. Hughes wrote an expert report in this case, filed March 29, 2007, he began the report by stating, "I have had the opportunity to review the available medical records [of petitioner]." P. Ex. 21, p. 1.

When Dr. Hughes testified at the hearing in this case, he knew petitioner's pre- and post-vaccination records, referred frequently to her medical doctors by name, and even referred to some of them by their first names because he knew them personally. Dr. Hughes testified that petitioner had seen "Judy Chen," "Jim Crosby", and "Jill Breen." He said, "I know all these folks." Trial tr. at 16, 26. Dr. Hughes was fully familiar at hearing with petitioner's pre- and post-vaccination medical records, including the four years between vaccination in 2002 and her visits to him in 2006. Dr. Hughes testified that petitioner had a mild reaction to her vaccination. Trial tr. at 24. He also testified with reference to petitioner's panic attacks: "By their nature, panic attacks tend to be transient." Trial tr. at 49. The undersigned finds that Dr. Hughes gave credible medical testimony which is consistent with the medical records and the opinions of petitioner's other treating neurologists, as well as doctors in other specialties. In choosing between Dr. Hughes' opinion of transient, generalized vaccine reaction and Dr. Andrew Campbell's contrary opinion of CIDP in the medical records, the undersigned has no hesitation in choosing Dr. Hughes's opinion over Dr. Campbell's.

Medical Records

On July 25, 2008, petitioner filed a Post-hearing Brief on remand alleging that hepatitis B vaccine caused her "neurological injuries and emotional distress." P. Br. at 1. Respondent filed

a Post-hearing Brief and Motion to Dismiss on August 25, 2008. Petitioner filed Petitioner's Reply to the Respondent's Post-hearing Brief on August 28, 2008.

According to the judge's decision, petitioner's task on remand in describing her medical records is to assist the undersigned in showing that petitioner's expert Dr. Hughes was incorrect when he testified that petitioner's vaccine injury probably lasted only three or four months. Dr. Hughes also stated that petitioner's injury was generalized, not neurological.

Pre-vaccination Records

Petitioner's Post-hearing Brief on remand omits any discussion of petitioner's pre-vaccination medical history. The symptoms about which petitioner complained post-vaccination (fatigue, dizziness, nausea, lightheadedness) are the same symptoms about which she complained before she received her two hepatitis B vaccinations. During part of the time before her vaccinations, she was pregnant. But she also complained when she was not pregnant of lethargy and dizziness lasting one to two weeks. She was diagnosed with anxiety and panic disorder before vaccination and prescribed medication for those problems. These complaints to doctors and at hospitals were for:

1. dizziness on May 9, 2000 (med. recs. at Ex. 2, p. 7);

2. dizziness, feeling faint, and lethargy on December 12, 2000 (med. recs. at Ex. 3, pp. 194, 195);

3. dizzy spells and nausea on December 13, 2000 (med. recs. at Ex. 3, pp. 190, 191);

4. lightheadedness, fast heart beat, shakiness, nervousness, headache, and grogginess on December 20, 2000; petitioner volunteered that these attacks seemed like panic attacks to her;

she was diagnosed with panic attacks and prescribed Tylenol for headache (med. recs. at Ex. 3, pp. 96, 97);

5. headaches and dizziness on December 21, 2000; question of whether she had anxiety (med. recs. at Ex. 1, p. 3);

6. in a separate record for December 21, 2000, noted to have attacks (dizziness, palpitations, shortness of breath, feeling the room closing in on her) which sounded like panic attacks; the doctor suggested biofeedback, exercise and deep breathing; she was to return in two weeks and start a serotonin reuptake inhibitor if the attacks did not improve (med. recs. at Ex. 1, p. 9); and

7. dizziness and lethargy for seven weeks, and subjective five- to 10-pound weight loss over the prior few months on March 13, 2002 (med. recs. at Ex. 5, p. 91). During that visit, petitioner was prescribed Meclizine hydrochloride.[7] Med. recs. at Ex. 5, p. 91. "Subjective" means it was petitioner's complaint without objective evidence of weight loss. Petitioner was not pregnant in 2002.

Post-Vaccination Medical Records

Petitioner received her first hepatitis B vaccination without adverse effect on May 13, 2002. Med. recs. at Ex. 5, p. 87. She received her second hepatitis B vaccination on June 12, 2002. Med. recs. at Ex. 5, p. 88. The operative date from which to start counting the more than

[7] Meclizine hydrochloride is "an antihistamine used in the management of nausea, vomiting, and dizziness associated with motion sickness and of vertigo associated with disease affecting the vestibular system." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1109. The vestibulum auris is the "vestibule of ear: an oval cavity in the middle of the bony labyrinth, communicating anteriorly with the cochlea and posteriorly with the semicircular canals, and containing perilymph surrounding the sacculus and utriculus." *Id.* at 2038.

six months of injury that the Vaccine Act requires in order for petitioner to make a prima facie case is June 15, 2002, when petitioner initially claimed she did not feel well (although later she changed that date to the day after her second vaccination, which would be June 13, 2002).

Medical Records Before Six Months Elapsed from Vaccine Injury

Petitioner's Post-hearing Brief on remand at pp. 2-5 discusses her visits to doctors before six months after her vaccine injury elapsed. Petitioner's descriptions of these records omit doctors' opinions based on their examinations of petitioner which were that she did not have a neurologic illness and that her generalized complaints could be attributed to a variety of causes including a virus, a transient vaccine reaction, or anxiety which was due to stress which petitioner herself ascribed to starting dental hygienist school and guilt over leaving her six-year-old child in order to start school. Moreover, these pre-six-month records give a context for the medical visits occurring six months after the vaccine injury onset because, similarly, petitioner voiced complaints to doctors who could find nothing physically wrong with her.

One week after vaccination, on June 19, 2002, petitioner saw her general practitioner, Dr. Phillip Rosenblum, complaining of a two- to three-day history of extreme fatigue and malaise. P. Br. on remand at 2. She felt feverish but she was not running a fever. Petitioner told Dr. Rosenblum that the onset of her symptoms was Saturday, June 15, 2002, which was three days post-vaccination. In addition to receiving the vaccination, petitioner had been bit by an insect the prior week and the bite had crusted and healed. Med. recs. at Ex. 5, p. 86. Petitioner complained to Dr. Rosenblum that she had a sore throat. Dr. Rosenblum examined her and found her throat normal. She claimed she had chills and sweats and was very tired. Dr. Rosenblum diagnosed petitioner with a viral syndrome and questioned if her symptoms were related to her vaccination

because of the temporal onset and their seeming worsening a little bit each day. *Id.* Petitioner's temperature at Dr. Rosenblum's office was 97.3º. *Id.*

Petitioner's Post-hearing Brief on remand at p. 3 then states petitioner saw Dr. Rosenblum again on June 20, 2002 and June 21, 2002, but these were actually telephone calls and not office visits. Med. recs. at Ex. 5, p. 65. Petitioner told the individual taking the calls that her symptoms were worse. The individual advised her to go to the emergency room. *Id.*

Petitioner's Post-hearing Brief on remand at p. 3 states petitioner went to the emergency room where she told the staff that her symptoms began one day after vaccination, rather than three days as she had told Dr. Rosenblum. Med. recs. at Ex. 9, p. 9. The hospital was HealthOne North Suburban Medical Center where petitioner complained of mild headache, very slight nausea, and slight neck discomfort. Petitioner's neurologic examination was normal. Her HEENT (head, ears, eyes, nose, throat) examination was completely normal. Her vital signs were normal. The diagnosis was a possible adverse reaction to hepatitis vaccine or a possible viral illness. Med. recs. at Ex. 9, p. 10. Petitioner was not acutely ill and was sent home in good condition. *Id.*

Petitioner's Post-hearing Brief on remand at p. 3 states petitioner returned to Dr. Rosenblum on July 29, 2002 complaining of dizzy spells and extreme fatigue. What petitioner omits from this summary in her Post-hearing Brief on remand is that petitioner said the reason she was stressed was because she started going to dental hygienist school. Med. recs. at Ex. 5, p.

85. She also had nasal congestion and her tympanic membranes[8] were congested. Dr. Rosenblum prescribed Rhinocourt AQ.[9] *Id.*

Petitioner's Post-hearing Brief on remand at p. 3 notes that petitioner saw Dr. Rosenblum on August 12, 2002 when he prescribed medication for dizziness and vertigo. Med. recs. at Ex. 5, p. 84. What petitioner omits from this summary in her Post-hearing Brief on remand is that Dr. Rosenblum wondered if petitioner's complaints of dizzy spells, fatigue, lightheadedness, and occasional vertiginous episodes were due to anxiety since petitioner noted that her anxiety increased when she started school. *Id.* Petitioner complained of intermittent lightheadedness and occasional vertiginous episodes as well as intermittent fatigue and some congestion. She had very sporadic symptoms. *Id.* Dr. Rosenblum prescribed Meclizine for dizziness and vertigo, which he advised petitioner might make her drowsy. He suggested she get an ear, nose, and throat evaluation. He put her on Allegra as the Rhinocort seemed not to be working. Petitioner noted that she had an increase in anxiety as she was starting school in the next week. *Id.*

Petitioner's Post-hearing Brief on remand at p. 4 notes that petitioner saw Dr. Dennis Barcz, an otolaryngologist, giving him a history of two months of dizziness which she dated to hepatitis B vaccination. This was on August 16, 2002, although petitioner omits the date in the Post-hearing Brief on remand. Dr. Barcz was not sure if she might have reacted to the vaccine with inflammatory labyrinthitis. Med. recs. at Ex. 5, p. 61. What petitioner omits from this

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[8] Also called the eardrums. Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1120.

[9] Rhinocort Aqua nasal spray is used to reduce "nasal symptoms of seasonal and perennial allergic rhinitis including runny nose, sneezing, and nasal congestion." Physicians' Desk Reference, 61st ed. (2007) at 666.

summary in her Post-hearing Brief on remand is that, on physical examination, Dr. Barcz found petitioner's ears to be normal. Neuro-otologic testing of petitioner was normal. Dr. Barcz put petitioner on Meclizine in case she had inflammatory labyrinthitis. *Id.*

Petitioner omits from petitioner's Post-hearing Brief on remand her next two medical visits. Petitioner had a brain MRI done on August 19, 2002, which was normal. Med. recs. at Ex. 6, p. 7. The results were sent to Drs. Barcz and Rosenblum. *Id.* Petitioner also omits noting that, on October 8, 2002, petitioner saw Dr. Rosenblum, saying she was told in dental hygiene school that her thyroid felt big. She still felt dizzy and almost passed out in class. Her left arm was shaking. Med. recs. at Ex. 5, p. 83.

Petitioner's Post-hearing Brief on remand at p. 4 notes that petitioner saw a neurologist Dr. Hua Judy Chen on October 30, 2002. Petitioner recounted her symptoms of two weeks of fatigue, chills, dizziness, and pain behind the eyes, followed by mild fatigue and episodic dizziness, resulting in a diagnosis from Dr. Chen of likely transient neurologic symptoms after viral or virus immunization which would eventually resolve. However, petitioner omits the findings of Dr. Chen after she did a physical examination of petitioner. Petitioner's examination was normal except for subtle decreased pinprick in the right hypothenar[10] area, leading Dr. Chen to diagnose a possible right ulnar nerve mononeuropathy across the elbow. Dr. Chen advised petitioner to avoid pressure on her elbows. Med. recs. at Ex. 5, pp. 59-60.

Petitioner's Post-hearing Brief on remand omits any discussion of her next nine medical visits and events. The first omission is petitioner's visit, on November 2, 2002, to HealthOne

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[10] Hypothenar is "the fleshy eminence on the palm along the ulnar margin...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 899. The ulna is "the inner and larger bone of the forearm, on the side opposite that of the thumb...." *Id.* at 1981.

North Suburban Medical Center Emergency Department, complaining of hand and foot numbness. Med. recs. at Ex. 9, p. 34. She said she developed hand, leg, and foot numbness, then facial numbness and carpopedal spasms lasting 10 minutes occurring about one half-hour before. She had no chest pain or shortness of breath. She had some tingling at the tips of her fingers. She had no leg swelling or pain. She felt she might pass out when this happened, but felt better. Complete review of her systems was negative, in other words, normal. The medical impression was petitioner had hyperventilated. Med. recs. at Ex. 9, p. 35. The doctor advised her to use a brown bag if needed and to follow up her ER visit with Dr. Rosenblum. *Id.*

The second medical visit which petitioner omits from her Post-hearing Brief on remand is petitioner's having an ultrasound on November 7, 2002 because of her concern that she had an enlarged thyroid. Med. recs. at Ex. 9, p. 41. The impression was that she had no significant enlargement of her gland. *Id.*

The third medical visit which petitioner omits from her Post-hearing Brief on remand is petitioner's return to the HealthOne North Suburban Medical Center Emergency Department on November 10, 2002 just eight days after her prior visit there for hyperventilation. Petitioner complained of substernal uncomfortable aching pain. She said her arms began to ache the day before. She was on Klonopin[11] until the prior week for anxiety. Med. recs. at Ex. 9, p. 45. She

[11] "Klonopin is indicated for the treatment of panic disorder.... Panic disorder ... is characterized by recurrent panic attacks, i.e., a discrete period of intense fear or discomfort in which four (or more) of the following symptoms develop abruptly and reach a peak within 10 minutes: (1) palpitations, pounding heart or accelerated heart rate; (2) sweating; (3) trembling or shaking; (4) sensations of shortness of breath or smothering; (5) feeling of choking; (6) chest pain or discomfort; (7) nausea or abdominal distress; (8) feeling dizzy, unsteady, lightheaded or faint; (9) derealization (feelings of unreality) or depersonalization (being detached from oneself); (10) fear of losing control; (11) fear of dying; (12) paresthesias (numbness or tingling sensations); (13) chills or hot flushes." Physicians' Desk Reference, 61st ed. (2007) at 2778,

had an anxiety disorder. Med. recs. at Ex. 9, p. 55. Her EKG was normal. Med. recs. at Ex. 9, p. 56. Her pain could be musculoskeletal or a reaction to stopping Klonopin or related to anxiety. Med. recs. at Ex. 9, p. 57. A chest x-ray on November 10, 2002 was negative. Med. recs. at Ex. 9, p. 59.

The fourth medical visit that petitioner omits from her Post-hearing Brief on remand is her visit on November 11, 2002 to Dr. Rosenblum as a follow-up to her ER visit for chest pain. Her tests were normal although she complained of mid-sternal/epigastric pain. Petitioner was still complaining of pain but now it felt like indigestion to her. Petitioner was still having panic attacks on and off and had had two panic attacks that day. Dr. Rosenblum gave her Pamelor[12] which gave her an anxious feeling. She wanted to try something else. Dr. Rosenblum regarded petitioner's atypical chest pain as likely related to gastroesophageal reflux disease and dyspepsia. Dr. Rosenblum reviewed all of petitioner's ER records which showed all tests were normal. He diagnosed petitioner with anxiety and panic attacks. He put her on a trial of Zoloft[13] for one week and discussed its side effects with her. Med. recs. at Ex. 5, p. 81.

The fifth and sixth medical records that petitioner omits from her Post-hearing Brief on remand are petitioner's two telephone calls to Dr. Rosenblum's office on November 12, 2002. In

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2780.

[12] Pamelor is nortriptyline hydrochloride. Physicians' Desk Reference, 61st ed. (2007) at 1859. Nortriptyline hydrochloride is "a tricyclic antidepressant of the dibenzocycloheptadiene class, also used to treat panic disorder . . . ." Dorland's Illustrated Medical Dictionary, 31st ed. (2003) at 1280.

[13] Zoloft is a selective serotonin reuptake inhibitor. It is an antidepressive and also used to treat panic disorder. In clinical trials, 25% of adverse events were headache; 12% were dizziness. Physicians' Desk Reference, 61st ed. (2007) at 2586, 2587, 2588, 2592.

the first call, petitioner said she had received a prescription for Zoloft and had recently taken Klonopin. Petitioner felt very nauseated and trembly. She had panic attacks, with her heart beating fast, and wanted to know if this was normal. The answer was yes; this was a classic panic attack. Med. recs. at Ex. 5, p. 80. In the second call, petitioner said her panic attacks were worse on Zoloft. Her nausea was better, but she could not calm herself. Petitioner complained of chest pain, muscle twitching, and loss of appetite. She went to the ER and they said her symptoms were due to anxiety. The doctors at the ER gave petitioner Xanax.[14] She took one pill and it was working. Med. recs. at Ex. 5, p. 78.

The seventh medical visit that petitioner omits from her Post-hearing Brief on remand is her visit, on November 14, 2002, to HealthOne North Suburban Medical Center Emergency Department for anxiety. She had shortness of breath, left-sided chest pain, and dizziness. She had chest pain on Sunday (November 10, 2002). She had no chronic illness except for anxiety. She was eating regularly. Med. recs. at Ex. 9, p. 63. She had been on Zoloft since Monday (November 11, 2002). *Id.* She was having repeated anxiety attacks which had been occurring over the prior several weeks. She had no other chronic medical problems. Med. recs. at Ex. 9, p. 68. She said she had some emotional distress because she was leaving her six-year-old child for the first time by going back for more schooling to learn to become a dental hygienist. She also had dizzy spells. *Id.* Petitioner had numerous symptoms of anxiety attack earlier in the day, including palpitations, a sense of anxiety, and chest pain which was her main complaint at the

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[14] Xanax is a "trademark for a preparation of alprazolam." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 2068. Alprazolam is "a benzodiazepine used as an antianxiety agent in the treatment of anxiety disorders and panic disorders and for short-term relief of anxiety symptoms...." *Id.* at 54.

time. She had hyperventilated earlier although she said she was able to bring this under control. She did not have any neurologic symptoms or weakness in the extremities. Med. recs. at Ex. 9, p. 69. The general state of petitioner's health appeared excellent. She had no tenderness or muscle weakness. She had no swelling or tenderness of the extremities. She was alert without any deficit of cognitive or motor function. There was no ataxia, tremor, or gait disturbance. Petitioner "actually was feeling quite well while in the emergency room. Any chest pain subsided and she had no further episodes of anxiety disorder-type of symptoms and she was feeling well and stable prior to her discharge." *Id.* Dr. Joseph B. Friedman concluded petitioner had an identified anxiety disorder. *Id.* He told petitioner she did not need any medical tests repeated since had had numerous normal test results. He also recommended that she continue on Zoloft although he prescribed Xanax for her to take only as needed for "breakthrough anxiety attacks that are not being well-managed with her usual methods of conscious control and her taking medication." Med. recs. at Ex. 9, p. 70. Dr. Friedman stated, "I certainly see no sign of other illness occurring at this time." *Id.*

The eighth medical record that petitioner omits from her Post-hearing Brief on remand is petitioner's visit to Dr. Rosenblum's nurse practitioner on Saturday, November 16, 2002, complaining of a reaction to medicine including difficulty swallowing, muscle spasms, and trembling inside, which was getting worse, and which started Monday (November 11, 2002). The nurse practitioner diagnosed petitioner with anxiety and panic attacks. Zoloft seemed to be

making petitioner's symptoms worse. The nurse practitioner prescribed Effexor.[15] Med. recs. at Ex. 5, p. 79.

The ninth record that petitioner omits from her Post-hearing Brief on remand is a telephone call to Dr. Rosenblum's office on November 20, 2002, to say she saw the nurse practitioner on Saturday, November 16, 2002, for Zoloft and was told to discontinue it and switch to Effexor which made her extremely tired and so dizzy that she could not even drive. She wanted to know what to do. Med. recs. at Ex. 5, p. 76.

Petitioner resumes recounting her medical history in her Post-hearing Brief on remand at p. 4 with a description of her second visit to the neurologist Dr. Chen on November 26, 2002. Petitioner quotes her giving Dr. Chen a history of continuing symptoms of dizziness, shaking, and numbness, but petitioner omits from her Post-hearing Brief on remand the results of Dr. Chen's physical examination of petitioner. Her physical examination was normal. Dr. Chen concluded petitioner's symptoms were "unexplained" and likely related either to a virus or a viral immunization. Med. recs. at Ex. 5, p. 58. Dr. Chen noted that the drugs petitioner had been taking, Nortriptyline and Clonazepam, caused side effects. *Id.* Petitioner omits mention of the side effects of her drugs in her Post-hearing Brief on remand as well. Petitioner complained to Dr. Chen of intermittent dizzy spells with mild headache. Dr. Chen decided to start petitioner on Neurontin.[16] *Id.*

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[15] Effexor is an antidepressant. Physicians' Desk Reference, 61st ed. (2007) at 3411. It is a treatment for major depressive disorder. *Id.* at 3412. Adverse reactions include anxiety, nervousness, and insomnia. *Id.* at 3413.

[16] Neurontin is gabapentin and prescribed as an analgesic. Physicians' Desk Reference, 61st ed. (2007) at 2487. Side effects may include dizziness, somnolence, and other signs of central nervous system depression. *Id.* at 2489.

Petitioner omits the next four medical visits or events in her Post-hearing Brief on remand. The first record petitioner omits is her visit on December 4, 2002 to Dr. Rosenblum with questions about her anxiety medications. She had been having chest aches for three days and fatigue and lightheadedness. Med. recs. at Ex. 5, p. 77. Her symptoms waxed and waned related to what position her body was in. For anxiety, she had tried Pamelor but had fatigue. She had tried Zoloft but had a manic response. She had tried Effexor but had fatigue. *Id.* Petitioner slept well, but was tired all the time. Dr. Rosenblum diagnosed petitioner with costochondritis (rib inflammation) and prescribed Naprosyn.[17]

The second record in this series that petitioner omits from her Post-hearing Brief on remand is her visit to Dr. Rosenblum on December 6, 2002 for a follow up for chest discomfort and pain. She had been taking Ibuprofen without much relief. She felt she had a wheezing inside. She had a non-productive cough in the mornings for two days. She could not get enough air. Dr. Rosenblum diagnosed her with atypical chest pain with subjective wheezing. Petitioner did note improvement of her symptoms after therapy with Xopenex.[18] Petitioner made a poor effort on spirometry[19] the first time. Dr. Rosenblum noted that there was still an unclear etiology for all of petitioner's recent reported symptoms which crossed over multiple systems of her body. Med. recs. at Ex. 5, p. 74.

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[17] Naprosyn is an anti-inflammatory with analgesic properties. Physicians' Desk Reference, 61st ed. (2007) at 2761.

[18] Xopenex is levalbuterol and used for mild to moderate asthma. Physicians' Desk Reference, 61st ed. (2007) at 3146-47. Side effects can include anxiety, nausea, dizziness, nervousness, chest pain, and tremor. *Id.* at 3149.

[19] Spirometry is "the measurement of the breathing capacity of the lungs, such as in pulmonary function tests." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1739.

The third record petitioner omits in this series in her Post-hearing Brief on remand is her taking a blood test on December 6, 2002 which showed she had a negative antinuclear antibody (ANA)[20] and a negative rheumatoid factor. "Negative" means normal. Med. recs. at Ex. 5, p. 6.

The fourth record petitioner omits in this series in her Post-hearing Brief on remand is the echocardiogram[21] she took on December 10, 2002 which was abnormal, showing a mild degree of anterior mitral leaflet prolapse[22] with a minor degree of leaflet thickening, but without mitral regurgitation, as interpreted by Dr. Peter P. Steele. Petitioner's clinical symptom prompting the echocardiogram was her shortness of breath. Med. recs. at Ex. 5, pp. 51-52.

Medical Records After Six Months Elapsed from Vaccine Injury

Petitioner picks up the narrative thread in her Post-hearing Brief on remand at p. 5 with the first medical visit that occurred one day after six months after the onset of her injury. This would be the time to examine whether petitioner's transient, generalized, non-neurologic vaccine reaction lasted the statutorily-required more than six months.

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[20] Antinuclear antibodies (ANA) are "antibodies directed against nuclear antigens; ones against a variety of different antigens are almost invariably found in systemic lupus erythematosus and are frequently found in rheumatoid arthritis, scleroderma (systemic sclerosis), Sjogren's syndrome, and mixed connective tissue disease. Antinuclear antibodies may be detected by immunofluorescent staining. Serologic tests are also used to determine antibody titers against specific antigens." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 100.

[21] Echocardiogram is the record produced by echocardiography which is "a method of graphically recording the position and motion of the heart walls or the internal structures of the heart and neighboring tissue by the echo obtained from beams of ultrasonic waves directed through the chest wall." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 585.

[22] Mitral valve prolapse is "redundancy or hooding of mitral valve leaflets so that they prolapse into the left atrium, often causing mitral regurgitation...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1517. In mitral valve syndrome, palpitations and chest discomfort may occur. *Id.* at 1825.

On December 16, 2002, petitioner saw her neurologist Dr. Chen. What petitioner states in her Post-hearing Brief on remand is that she saw Dr. Chen for dizziness, shaking, and numbness. P. Br. at 5. Petitioner omits mentioning anything else from this medical record. However, petitioner did not complain to Dr. Chen about all three of these symptoms on December 16, 2002, as if she still had them. Dr. Chen states in her record of December 16, 2002 that this visit was a follow up for petitioner's past visits when she complained of numbness, dizziness, and shaking. Med. recs. at Ex. 5, p. 57. A follow up means seeing if the symptoms about which petitioner complained in the past still exist. In this visit, petitioner did not complain about numbness. She did complain about dizziness and shaking. Petitioner omits the rest of this record in her Post-hearing Brief on remand.

For instance, petitioner told Dr. Chen that she had finished her school semester and her shaking episodes disappeared. Med. recs. at Ex. 5, p. 57. (This reinforces petitioner's connecting her symptoms with her anxiety toward attending school and her guilt feelings about leaving her six-year-old child to attend school.) Petitioner told Dr. Chen she had one week of eye pain with intermittent black spots and blurring, and occasional nausea. She had an ophthalmological test which was normal and petitioner gave the printout to Dr. Chen. Dr. Chen's impression was petitioner had "Unexplained dizzy and shaking symptoms possibly related to anxiety." *Id.* Petitioner omits from her Post-hearing Brief on remand Dr. Chen's diagnostic impression. Dr. Chen thought petitioner's current eye pain, visual disturbance, and nausea might be due to migraine. *Id.*

Petitioner omits from her Post-hearing Brief on remand the visit petitioner made also on December 16, 2002 to Dr. Matthew C. Sanderson for a visual field test which was basically

normal. Med. recs. at Ex. 10, p. 2. This was the visit about which petitioner told Dr. Chen on the same day.

Petitioner continues on p. 5 of her Pre-hearing Brief on remand with her visit on January 6, 2003 to Dr. Jill R. Breen, her second neurologist after Dr. Chen. Petitioner describes in her Post-hearing Brief on remand her history to Dr. Breen, including petitioner's claim that she had no significant improvement over six months, but omits from her Post-hearing Brief on remand the results of Dr. Breen's examination of her and Dr. Breen's conclusions.

Petitioner's chief complaint to Dr. Breen was chronic dizziness. Med. recs. at Ex. 5, p. 53. For her symptoms, petitioner had tried Pamelor, Effexor, and Zoloft, all of which increased her anxiety. She also tried Clonazepam[23] which caused her to be dysfunctional. Dr. Breen did a review of ten of petitioner's physical systems ("ten-system review") which was negative except for the history petitioner gave of waxing and waning grogginess, lightheadedness, sensitivity to light, pain when focusing her eyes, a dull ache behind her eyes, and some nausea. Med. recs. at Ex. 5, pp. 53, 54. On motor examination, petitioner had normal tone, bulk, and strength in all four extremities. Med. recs. at Ex. 5, p. 55. Her deep tendon reflexes were 2+ and symmetric. *Id.* Petitioner's August 19, 2002 brain MRI was normal. Her thyroid was normal. Her chemistry panel was normal. All other tests were normal or negative. Dr. Breen stated that despite extensive evaluation and multiple medication trials, petitioner continued to complain of fatigue, eyestrain pain, and some lightheadedness. Dr. Breen concluded, "On her examination, history and with a normal MRI, I do not find any evidence of primary neurologic disease. I do not find

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[23] Clonazepam is a benzodiazepine used as an anti-panic agent to treat panic disorders. Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 377. Klonopin is clonazepam. Physicians' Desk Reference, 61st ed. (2007) at 196.

any evidence for multiple sclerosis, CNS [central nervous system] vasculitis, etc." *Id.* Dr. Breen thought petitioner's complaints were consistent with chronic fatigue syndrome which she explained to petitioner could be due to a virus, or nondefined immune-mediated abnormality, or depression or anxiety. Med. recs. at Ex. 5, p. 56. Dr. Breen recommended that petitioner have no further neurological evaluation. She discussed with petitioner the use of Paxil[24] since Zoloft caused her to be manic. Dr. Breen did not schedule a follow-up visit for petitioner. *Id.*

Petitioner omits the next four medical visits from her Post-hearing Brief on remand. The first omitted record is petitioner's visit, on January 24, 2003, to Dr. Steele, her cardiologist. He found petitioner had reasonably consistent mitral prolapse symptoms, non-predictable effort-induced chest pain, and dyspnea. She had a perception of arrhythmia. Dr. Steele talked with petitioner about prolapse and told her it was best thought of as being normal. He suggested intermittent use of a beta blocker. The issue was sympathetic nervous system dysfunction rather than cardiac response. Petitioner felt that she may have had a little benefit from an initial week of Propranolol.[25] They discussed dose increase and duration of therapy. Med. recs. at Ex. 5, p. 50.

The second record in this series that petitioner omitted from her Post-Hearing Brief on remand is petitioner's visit, on January 30, 2003, to Dr. Rosenblum. Petitioner states in her Post-

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[24] Paxil is a psychotropic drug known as paroxetine hydrochloride used for the treatment of major depressive disorder, social anxiety disorder, obsessive compulsive disorder, panic disorder, generalized anxiety disorder, and posttraumatic stress disorder. Physicians' Desk Reference, 61st ed. (2007) at 1530.

[25] Propranolol is "a non-selective beta-adrenergic blocking agent that lacks intrinsic sympathomimetic activity, decreases cardiac rate and output, reduces blood pressure, and is effective in the prophylaxis of migraine." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1519.

hearing Brief on remand at p. 5 that her "symptoms continued." But petitioner completely omits Dr. Rosenblum's analysis of her symptoms and his relating them to mitral valve prolapse. Dr. Rosenblum records that petitioner had mitral valve prolapse and had been getting dizzy, but did not have vertigo. She complained of episodic dizziness and lightheadedness, not associated with palpitations or chest pain which she got occasionally. She complained of anxiety and wondered if her symptoms were related to anxiety. Dr. Rosenblum diagnosed petitioner with mitral valve prolapse and stated that she should restart Propranolol. Petitioner was to follow up in one month. If she did not have relief, she was to consider therapy for anxiety. Med. recs. at Ex. 5, p. 72.

The third record in this series that petitioner omitted from her Post-hearing Brief on remand is her visit on February 7, 2003 to Dr. Steele, her cardiologist, to complain of a continuation of a kind of vertigo. Petitioner in her Post-hearing Brief on remand at p. 5 refers to this visit by medical record and page number (but no specificity) as showing that petitioner's "symptoms continued," but totally ignores Dr. Steele's identification of the cause of her symptoms (a kind of vertigo) as being a side effect of Xanax. Dr. Steele records in his notes that petitioner said if she bent forward, she had the kind of vertigo, but if she stood up, it was relieved. (This is what is meant by "positional.") He did not think it was related to prolapse. Petitioner had been taking Propranolol three times a day and it had a substantial beneficial effect on her perception of arrhythmia. He thought she should continue with it. He spoke to her about the potential for Xanax to cause inner dizziness. Dr. Steele stated, "I really think that is what it is." Med. recs. at Ex. 8, p. 2.

The fourth record in this series that petitioner omitted from her Post-hearing Brief on remand is her visit on February 21, 2003 to Dr. Rosenblum. She complained of a rapid heart beat

for four days. She had worse chest pain and shortness of breath which got worse after she drank hot chocolate the day before. She had a history of mitral valve prolapse diagnosed in December 2002. She had been on Propranolol and was doing well. Dr. Rosenblum diagnosed petitioner with mitral valve prolapse, palpitations, and anxiety. She was to continue with Propranolol. Med. recs. at Ex. 5, p. 71.

Petitioner resumes narrating her medical visits in her Post-hearing Brief on remand at p. 5 with her visit to Dr. Michael A. Volz, a specialist in allergy, asthma, and immunological disorders on March 15, 2003. Petitioner states in her Post-hearing Brief on remand at p. 5 that petitioner complained to Dr. Volz of dizziness and fatigue. Again, petitioner omits portions of the medical records. Dr. Volz diagnosed petitioner with three conditions:

> 1. Dizziness and Fatigue–The basis of the symptoms remain[s] uncertain. To date, there reportedly have been **no objective findings** but interestingly the onset of this problem was within 24 hours after receiving the HBV vaccination–the second dose in a series of 3. She previously had received two doses 10 years earlier without incident. The complex of symptoms comes and goes and has not changed in frequency or severity over the past several months.
> 2. History of Mitral Valve Prolapse
> 3. Minimal Cervical Lymphadenopathy–This is suggestive of some persistent upper respiratory tract inflammation, but may not be related to problem #1 since there was no other identifiable lymphadenopathy. [Emphasis added.]

Med. recs. at Ex. 12, p. 19. Dr. Volz also noted that petitioner had seen her primary doctor, one otolaryngologist, one cardiologist, an ophthalmologist, and two neurologists with no abnormal objective findings. *Id.* Dr. Volz conducted a physical examination of petitioner, including a neurological examination. She was normal. Med. recs. at Ex. 12, p. 20. He concluded: "Objective findings demonstrate the presence of rhinitis and non-tender anterior cervical

lymphadenopathy...." Med. recs. at Ex. 12, p. 21. He found no other palpable lymph node groups and found this and the absence of objective or subjective fever notable. *Id.*

Petitioner omits from her Post-Hearing Brief on remand the 14-page questionnaire she filled out on May 24, 2003 for Dr. Andrew W. Campbell, who is not an immunologist or a neurologist, titled "Immune Dysfunction Questionnaire," at the end of which, she states:

> I began to have anxiety issues when I started [dental hygienist] school in August 2002, but the medicines that my dr. tried made me feel worse so I have been able to manage on my own. My doctor said they [sic] thought it is all linked to anxiety. I think anxiety can aggravate it, but this underlying dizziness, fatigue, eye pain seems to be some other problem. I am 99% sure that it is linked to the Hep B shot. I've lived in my body for 29 yrs. & I know what it feels like to be me, and I have not felt like myself since that shot. I've been to 7 doctors seeking help and no one can give me an answer and all but one said it was not the shot. [Emphasis included]

Med. recs. at Ex. 14, p. 36. She also states on the questionnaire that she was currently exposed to chemicals and radiation. Med. recs. at Ex. 14, p. 31. She states on the questionnaire that her symptoms get better on weekends. Med. recs. at Ex. 14, p. 32.

Petitioner continues her recitation of histories she gave to doctors without also giving the results of the doctors' physical examinations of her or the doctors' analyses of petitioner's condition in her Post-hearing Brief on remand at p. 6 when she recounts her return visit to the second neurologist Dr. Breen on May 28, 2003 for chronic dizziness. And that is all petitioner says in her Post-hearing Brief on remand about this visit to Dr. Breen. But the visit resulted in a lengthy record. Petitioner did not have dizziness at night. Occasionally, she had pain behind both eyes. Her ophthalmologist told her she was normal and she did not have optic neuritis. Photosensitivity could last one to two days but was not associated with her dizziness. She did

not have nausea, vomiting, headache, or blurred or double vision associated with light sensitivity or eye pain. She slept well and woke feeling rested. She had muscle twitching during a one- to two-week period when she sat in chairs or lay in bed. Med. recs. at Ex. 11, p. 5. Petitioner stated she initially had a lot of anxiety about the possibility that she had multiple sclerosis. She stated she no longer had this anxiety and was no longer taking Zoloft or any other SSRI. She would occasionally have poor sleep when she had increased stress due to her school work. *Id.* (This is petitioner's further attribution of her stress to attending school.)

Petitioner reported to Dr. Breen that she had a negative Holter test for irregular heart beat. Dr. Breen tested petitioner's cranial nerves, motor abilities, sensation, coordination, reflexes, and gait. All were normal. As for petitioner's complaint of chronic dizziness, Dr. Breen wrote that petitioner was not describing symptoms of vertigo. Med. recs. at Ex. 11, p. 6. Petitioner agreed to a trial of Lexapro[26] to see if this would help with possible anxiety surrounding her dizzy symptoms. Med. recs. at Ex. 11, p. 6.

Petitioner continues in her Post-hearing Brief on remand at p. 6 with a description of an electronystagmography (ENG) test for balance. A clinical audiologist (not a medical doctor) named Karen Schroer found that petitioner had a 25% left ear unilateral weakness with no significant directional preponderance. Petitioner had normal results on ocular-motor testing, static positional tests, and positioning tests. (Petitioner omits this information from her Post-hearing Brief on remand.) Clinical audiologist Schroer thought the results of the test were

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[26] Lexapro is escitalopram oxalate, "a selective serotonin reuptake inhibitor (SSRI) ... used as an antidepressant." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 642, 1025. It is used to treat major depressive disorder. Physicians' Desk Reference, 61st ed. (2007) at 1190. It is also used to treat generalized anxiety disorder. *Id.* at 1191.

abnormal, suggesting a peripheral pathology. Med. recs. at Ex. 14, p. 115. Since clinical audiologist Schroer is not a medical doctor, the undersigned does not take her suggestion of a peripheral pathology as relevant evidence. See Domeny v. Secretary of HHS, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999) (proffer of dentist's testimony for diagnosis of a neuropathy rejected), aff'd in unpublished opinion (Fed. Cl. May 25, 1999), aff'd, 232 F.3d 912 (Fed. Cir. 2000) (per curiam) (unpublished). Diagnosis of a medical condition from someone who is not trained as a medical doctor is irrelevant as an evidentiary matter. Clinical audiologist Schroer's suggestion that petitioner might have peripheral pathology may indicate that her left ear has some inner ear pathology, which other doctors surmised may have been the source of her dizziness.

Petitioner omits discussion of the next two medical visits in her Post-hearing Brief on remand. The first record petitioner omits is her taking an EEG[27] on June 4, 2003, the results of which were normal. Med. recs. at Ex. 7, p. 3. The second record petitioner omits is her visit on July 7, 2003 to her ophthalmologist, complaining of sharp shooting pain in her right eye for two days and of headache. The doctor stated the eye pain was of an unknown nature. Med. recs. at Ex. 10, p. 1.

Petitioner continues her narration in her Post-hearing Brief on remand at p. 6, noting the visit she paid to Dr. Rosenblum on July 25, 2003 and stating he recorded she "still had problems

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[27] An EEG is an electroencephalogram, "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain. The dominant frequency of these potentials is about 8 to 10 cycles per second and the amplitude about 10 to 100 microvolts. Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 596.

from Hep B vaccine." That was not Dr. Rosenblum's conclusion. That was petitioner's history to him. Petitioner omits all the rest of Dr. Rosenblum's notes for that visit. He noted that petitioner was on Propranolol and that she was seeing him for a physical examination and to fill out paperwork for her second year of dental hygienist school. Med. recs. at Ex. 5, p. 69. Petitioner told Dr. Rosenblum that she had contacted an "immunologist" in Texas and would see him the following week for a consultation. This is a reference to Dr. Andrew Campbell who runs what he calls the Medical Center for Immune and Toxic Disorders, but he is not an immunologist or a toxicologist. Dr. Rosenblum's assessment of petitioner after his examination of petitioner on July 25, 2003 was that she was well. He put a question mark next to the impression that she had had a reaction to hepatitis B vaccine. Petitioner had seen seven doctors, all resulting in a negative working diagnosis. *Id.*

Petitioner then proceeds in her Post-hearing Brief on remand at p. 6 to her visit with Dr. Andrew Campbell on August 1, 2003 for dizziness and lightheadedness. She briefly summarizes her time with Dr. Campbell in one sentence: "Dr. Campbell treated Kelly for these symptoms [dizziness and lightheadedness] for the next 34 months." *Id.* Petitioner omits any discussion of the medical visits petitioner made in 2003 and 2004, with not only Dr. Campbell but other doctors, in order to speed ahead to her first visit with Dr. Richard Hughes, a neurologist, in 2006. By these omissions, petitioner skips relevant medical data.

The first record petitioner omits is her visit on August 12, 2003 with Dr. Patricia J. Burcar to have a somatosensory evoked potential (SEP)[28] of her posterior tibial nerve. The result was normal. Med. recs. at Ex. 5, p. 1. It was Dr. Breen who sent her for this test. *Id.*

The second record petitioner omits is her visit on August 12, 2003 to Dr. John B. Woodward to test her auditory evoked responses, again at Dr. Breen's request. This test evaluated her reception of sound waves to see if there were a physical correlate to her complaint of vertigo. The results were normal. Med. recs. at Ex. 13, p. 5.

The third record petitioner omits is her visit on August 12, 2003 to Dr. Woodward to test her visual evoked responses, at Dr. Breen's request. This test evaluated her reception of visual stimuli to see if there were a physical correlate to her complaint of vertigo and headache. The results were normal. Med. recs. at Ex. 13, p. 6.

The fourth record petitioner omits is her visit on August 12, 2003 to Dr. Burcar for somatosensory evoked potentials of her median nerves, at the request of Dr. Breen. The results were normal. Med. recs. at Ex. 13, p. 7.

The fifth record petitioner omits is her visit on August 29, 2003 with Dr. Breen, the neurologist, to have nerve conduction studies performed. Dr. Breen states that she was requested to do the nerve conduction study to evaluate petitioner to see if she had demyelination following hepatitis B vaccination. Med. recs. at Ex. 11, p. 8. The examination of petitioner showed normal strength in all extremities. Petitioner had normal sensation to light touch, temperature, and

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[28] Somatosensory evoked potentials (SEP) "are waves recorded from the spinal cord or cerebral hemisphere after electrical stimulation or physiological activation of peripheral sensory fibers; analysis of deviations in latency or amplitude can detect or characterize lesions of the peripheral or sensory conduction pathways." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1496.

vibratory modalities. Her reflexes were 2+ throughout. Her toes were downgoing on plantar[29] stimulation, which means petitioner was normal. The nerve conduction studies showed slowing of the peroneal nerve impulses across the fibular head. Most commonly, this slowing resulted from focal compression of the nerve. Petitioner was asymptomatic and without neurological signs from this slowing. The remainder of the nerve conduction study, including H-reflexes,[30] was normal in both lower extremities. There was no evidence for a demyelinating process. *Id.* Dr. Breen faxed a copy of this nerve conduction study to Dr. Andrew Campbell and to Dr. Rosenblum. Med. recs. at Ex. 11, p. 9.

The sixth record petitioner omits is her visit to Dr. James A. Crosby on September 9, 2003 for electromyography or EMG.[31] Dr. Crosby noted that petitioner was being evaluated for an autoimmune disorder and petitioner told him that he should look for a demyelinating neuropathy. She had a recent study less than two weeks previously, but Dr. Crosby did not have the results. Med. recs. at Ex. 7, p. 1. Since petitioner's right side was almost completely normal, Dr. Crosby did not evaluate her left side. *Id.* Petitioner had a slight latency delay across the right median motor nerve distally which might signify carpal tunnel syndrome. Otherwise, the EMG

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[29] Plantar means "pertaining to the sole of the foot." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1445.

[30] The H-reflex is "a monosynaptic reflex elicited by stimulating a nerve, particularly the tibial nerve, with an electric shock." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1601.

[31] Electromyography or EMG is "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any of a variety of surface electrodes, needle electrodes, and devices for amplifying, transmitting, and recording the signals." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 598.

of the right upper and lower extremities was normal. Med. recs. at Ex. 7, p. 2. Dr. Crosby wrote a letter to Dr. Andrew Campbell, summarizing his findings. Med. recs. at Ex. 7, p. 1.

Just three days after the date of Dr. Crosby's letter to Dr. Campbell stating that petitioner's EMG did not show a demyelinating neuropathy and one week after Dr. Breen's fax to Dr. Campbell that petitioner's nerve conduction study was normal and did not show demyelination, Dr. Campbell wrote a letter, dated September 12, 2003, headed "To Whom It May Concern," stating that petitioner had been diagnosed with a demyelinating polyneuropathy with immune suppression. Med. recs. at Ex. 12, p. 4. He states that petitioner had an abnormal neurological examination with low reflexes in all four extremities, an abnormal nerve conduction study, and an abnormal brainstem auditory evoked response potential. Petitioner omits any mention of Dr. Campbell's letter in her Post-hearing Brief on remand.

The reason for Dr. Campbell's diagnosis is evident in the second line of his letter: "It is medically necessary that she begin the recommended intravenous immunoglobulin infusion therapy as ordered on September 2, 2003." Med. recs. at Ex. 12, p. 4. Intravenous immunoglobulin[32] or IVIG is administered to people with autoimmune diseases, such as demyelinating neuropathy. It is not administered to people, such as petitioner,[33] who do not have an autoimmune disease or demyelinating neuropathy. It makes normal people sick and it made

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[32] Immunoglobulin is "any of the structurally related glycoproteins that function as antibodies, divided into five classes (IgM, IgG, IgA, IgD, and IgE) on the basis of structure and biologic activity." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 912.

[33] "IVIG is replacement therapy for antibody deficiency disorders: immune thrombocytopenic purpura (ITP); hypogammaglobulinemia in chronic lymphocytic leukemia; Kawasaki disease." Harrison's Principles of Internal Medicine, 13th ed., Vol. 1 (1994) ed. Isselbacher, et al., at chap. 82, p. 507.

petitioner sick. IVIG therapy costs thousands of dollars. On October 24, 2003, one of Dr. Campbell's employees wrote a note that neither petitioner's primary care physician nor her neurologist wanted to write an order for petitioner to receive intravenous immunoglobulin. Med. recs. at Ex. 17, p. 275. There is a note in Dr. Campbell's records of a return phone call on December 11, 2003. Petitioner stated that the infusion company informed her that her local physician never signed the IVIG order. Petitioner called Dr. Volz, her immune specialist, and his nurse advised petitioner that he would not sign off on that order for IVIG therapy either. Med. recs. at Ex. 17, p. 11. Petitioner was infused anyway. Med. recs. at Ex. 274. Petitioner got lightheadedness and chills. *Id.* On December 8, 2003, petitioner complained of an increase in fatigue, dizziness, and weakness. Med. recs. at Ex. 17, p. 270. As Dr. Hughes testified at hearing, Dr. Campbell is the type of doctor who takes healthy patients, convinces them they are sick, and makes them sicker:

> A. It seemed that he [Dr. Campbell] ran a practice like some doctors do in this area [Denver], a brain injury and then chronic fatigue and then fibromyalgia, where the goal of the practice seems to be to encourage people to have more symptoms and to encourage them to believe that they're victims and hurt and not to do a whole lot to encourage them to be better.
> Q. And so you don't agree with Dr. Campbell's diagnosis of CIDP on [sic] Ms. Boley?
> A. No, she doesn't have CIDP.

Trial tr. at 32.

In December 2003, petitioner was still receiving IVIG infusions. There is a note saying her IVIG treatment was completed November 13, 2004. Med. recs. at Ex. 17, p. 79.

Petitioner also omits from her Post-hearing Brief on remand her visit on May 7, 2004 to Dr. Steele, her cardiologist, because of dizziness. Med. recs. at Ex. 18, p. 1. Dr. Steele

diagnosed her dizziness as quite typically inner ear. *Id.* He wanted to reinstitute her use of Xanax. *Id.*

Petitioner omits from her Post-hearing Brief on remand her visit on October 15, 2004 to physician's assistant Gina Bollinger, complaining of dizziness. Med. recs. at Ex. 23, p. 75. PA Bollinger diagnosed petitioner with Eustachian tube dysfunction from the upper respiratory infection petitioner had had a few days earlier. Med. recs. at Ex. 23, p. 77.

Petitioner omits from her Post-hearing Brief on remand her visit on November 19, 2004 to Dr. Everton A. Edmonson for another nerve conduction test. Dr. Edmonson found her normal although there may have been some technical artifact. He tested petitioner's bilateral upper and lower extremity nerve conductions involving median, ulnar, common peroneal, superficial peroneal, and tibial nerves. Med. recs. at Ex. 17, p. 150.

Petitioner omits from her Post-hearing Brief on remand her taking a balance test on November 19, 2004 called an NTI Postural Sway (Balance) Test, which she passed. Med. recs. at Ex. 17, p. 148. She also took an NTI Reaction Time Test, which she passed. Med. recs. at Ex. 17, p. 147.

Petitioner omits from her Post-hearing Brief on remand having her blood drawn on November 19, 2004 for autoimmune testing. Med. recs. at Ex. 14, p. 135. Her ANA was normal at 1:20. *Id.*

Petitioner omits from her Post-hearing Brief on remand her visit on November 30, 2004 to Dr. Richard Foa for another brainstem evoked response test, which was normal. Med. recs. at Ex. 17, p. 142.

Petitioner omits from her Post-hearing Brief on remand her undergoing another brain MRI on December 2, 2004. Her study was normal and unchanged from her prior brain MRI of August 19, 2002 which was normal. Med. recs. at Ex. 17, p. 140.

Petitioner omits from her Post-hearing Brief on remand her visit on January 27, 2005 to Dr. Rosenblum for allergic rhinitis and acquired hypothyroidism. Med. recs. at Ex. 23, pp. 59, 60.

Petitioner omits from her Post-hearing Brief on remand her visit on March 10, 2005 to Dr. Rosenblum for dizziness, migraine without headache, anxiety, hypothyroidism, and mitral valve prolapse. He counseled petitioner that there was a very common association between mitral valve prolapse and anxiety as well as between hypothyroidism and anxiety. Petitioner agreed to try Lexapro, an SSRI (selective serotonin reuptake inhibitor). Med. recs. at Ex. 23, pp. 50, 51.

Petitioner omits from her Post-hearing Brief on remand her visit on March 31, 2005 to Dr. Rosenblum, who stated her anxiety had improved and assessed that she had a migraine variant with anxiety interaction. Med. recs. at Ex. 23, pp. 43, 44.

Petitioner picks up the narrative thread in her Post-hearing Brief on remand at p. 6 with her first visit to the neurologist Dr. Richard L. Hughes. Med. recs. at Ex. 23, p. 24. Petitioner states absolutely nothing about this visit in her Post-hearing Brief on remand other than that it occurred. What petitioner omits from her Post-hearing Brief on remand is that Dr. Hughes examined petitioner and found her neurologically normal. Although she gave him a history of CIDP, Dr. Hughes found it "difficult to completely substantiate." Med. recs. at Ex. 23, p. 26.

Dr. Hughes suggested petitioner increase her sleep, exercise, fluid, and salt intake, as well as eat correctly and lose weight to deal with her fatigue and dysequilibrium. *Id.*

Petitioner omits from her Post-hearing Brief on remand her visit on May 30, 2006 to Dr. John B. Woodward for auditory evoked responses in both ears as a follow-up to two previous auditory evoked responses (which were normal) because of residual dizziness. Dr. Woodward interpreted petitioner's auditory evoked responses as normal. *Id.*

Petitioner discusses in her Post-hearing Brief on remand at p. 6 petitioner's second visit to Dr. Hughes on November 13, 2006. Dr. Hughes records that petitioner had "a significant reaction to the hepatitis B vaccine because of the temporal relationship." Med. recs. at Ex. 23, p. 17. However, petitioner does not quote Dr. Hughes also saying that petitioner's symptoms could be due to something completely unrelated to hepatitis B vaccine:[34]

> It is certainly plausible that a second, completely unrelated diagnosis could have been made at that time, unrelated to the hepatitis B vaccine.

Id. Petitioner then omits Dr. Hughes' discussion of his review of studies on petitioner's brain, including the quantitative EEG. Med. recs. at Ex. 23, p. 18. Dr. Hughes states, "I do not believe these demonstrate any specific brain injury and I believe that her brain is fine...." *Id.* He attributes petitioner's dysequilibrium to a vestibular mechanism (which means her ear). He recommended that she continue on Lexapro. *Id.*

In his expert report prior to the hearing, Dr. Hughes does not state how long petitioner's vaccine injury lasted. P. Ex. 21, filed March 29, 2007. He believed petitioner was normal when

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[34] Petitioner does quote this part of Dr. Hughes' record on p. 9 of her Post-hearing Brief on remand in a separate section devoted to her Motion for Reconsideration following the undersigned's Order to Show Cause.

he saw her. He states that petitioner "took my advice to clean up her general health, declare 'normalcy', and re-capture her life." P. Ex. 21, p. 2.

In Dr. Hughes' November 13, 2006 record (med. recs. at Ex. 23, p. 17), when Dr. Hughes states petitioner had a year or two of symptoms, it is hard to know if he is quoting petitioner's history or making an independent statement. He notes that he received many of her medical records, but it is unclear whether he received them all. When Dr. Hughes became an expert for petitioner before he wrote his expert report, he states at the beginning of his expert report that he reviewed the available records (P. Ex. 21, p. 1). When he testified at the hearing, his opinion was that her transient, generalized vaccine reaction lasted two weeks, then one month, then probably three to four months and he would not go beyond that time. There is no reason for the undersigned to credit Dr. Hughes' statement of one to two years of symptoms in 2006 when he had not read petitioner's records over his testimony in 2007 after he had read her records and stated that petitioner's vaccine injury lasted probably only three to four months.

Analysis

Petitioner's histories alone to various doctors post-vaccination do not satisfy her burden of proving by preponderant evidence that she had a vaccine injury lasting more than six months. The Vaccine Act prohibits the undersigned from ruling for petitioner based solely upon her claims "alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. §300aa-13(a)(1). The only medical records and medical opinion in support of petitioner's claim that she had a vaccine injury lasting more than six months belong to Dr. Andrew Campbell whose diagnosis is not credible. Dr. Hughes' testimony is consistent with the credible medical records and the medical opinions of petitioner's other treating physicians. The Federal Circuit in

Capizzano v. Secretary of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006), stressed the importance of the opinions of treating doctors. Once petitioner provided Dr. Hughes with all of her medical records, he formed his expert opinion that her adverse reaction to hepatitis B vaccine lasted probably no longer than three or four months. Respondent's expert Dr. Bielawski testified that petitioner's vaccine reaction lasted two or three weeks. It really does not matter whether petitioner's vaccine reaction lasted two weeks or four months. She does not meet the Vaccine Act's requirement that it last more than six months.

Petitioner closes her Post-hearing Brief on remand at p. 26 with a reiteration that hepatitis B vaccine caused her to experience a neuropathy, citing the records of Drs. Hughes, Rosenblum, Barcz, Chen, Breen, Volz, and Campbell. Only Dr. Campbell diagnosed petitioner with a neuropathy and his opinion is not credible.

In petitioner's Reply to the Respondent's Post-hearing Brief, petitioner reiterates her recitation of the medical records that she used in her Post-hearing Brief on remand. In essence, she repeats the histories she gave to various doctors of continuing symptoms past the six-month mark while omitting the doctors' physical examinations of her and their conclusions that she was normal physically. There is nothing new in petitioner's Reply brief. Although petitioner insists that these medical records of her complaints satisfy the proof required to show she had a vaccine injury lasting more than six months, they do not. Dr. Hughes knew that when he testified.

Dr. Andrew Campbell

No doctor has ever diagnosed petitioner with a vaccine injury lasting more than six months except for Dr. Andrew Campbell who first saw petitioner in August 2003, 13 months after she received hepatitis B vaccine. Dr. Campbell's diagnosis is not credible for several

reasons. First and most importantly, his diagnosis conflicts with the diagnoses from other doctors. Before petitioner saw Dr. Campbell, she saw Drs. Chen and Breen, both neurologists, as well as other neurologists, all of whom physically examined her, tested her nerve conductivity, and found her neurologically normal. Dr. Campbell is neither a neurologist nor an immunologist. Thus, his opinion about petitioner's having a neurological disease is less persuasive than petitioners' treating neurologists such as Drs. Chen and Breen who opined that she did not have one. His records have been filed in scores of vaccine cases in the Vaccine Program as petitioners sought his services. Dr. Campbell always diagnoses petitioners as having chronic inflammatory demyelinating polyneuropathy or CIDP. Even though the results of the tests Dr. Campbell gave petitioner in the instant action were normal, Dr. Campbell diagnosed her as having CIDP and proceeded to treat her with intravenous immunoglobulin (IVIG), which made her ill.

Secondly, Dr. Campbell's diagnosis of CIDP lacks persuasive value because his medical judgment is questionable. Special Master Christian J. Moran considered the credibility of Dr. Andrew Campbell in Perrodin v. Secretary of HHS, No. 99-573V, 2007 WL 1467297 (Fed. Cl. Spec. Mstr. May 1, 2007). In that case, petitioner alleged that hepatitis B vaccine caused him an adverse reaction. Petitioner in Perrodin saw Dr. Campbell who opined that petitioner had an adverse reaction to hepatitis B vaccine. Counsel in the case took Dr. Campbell's deposition. Dr. Campbell admitted he has diagnosed patients as having a vaccine reaction more than 100 times. 2007 WL 1467297, at *2. Dr. Campbell stated he did not need the results of the tests he ordered for petitioner in order to make a diagnosis of a vaccine reaction. *Id.* Dr. Campbell recommended that petitioner receive IVIG which is used to treat primary immunodeficiency disorders and constitutes six weeks of therapy. *Id.* Dr. Campbell wrote a letter stating that petitioner had

CIDP. *Id.* But Dr. Campbell's understanding of CIDP is quite different from that of neurologists:

> Dr. Campbell attempted to explain during his deposition that he was using each of these four terms [chronic inflammatory demyelinating polyneuropathy] singularly. He was not diagnosing Mr. Perrodin with the condition called "chronic inflammatory demyelinating polyradiculopathy" or CIDP, which is a diagnosis sometimes made by neurologists.

Id.

After Dr. Campbell's deposition in Perrodin, petitioner "determined that he did not wish to proceed with his case" and asked for a ruling on the record. 2007 WL 1467297, at *4. Special Master Moran stated that Dr. Campbell diagnosed Mr. Perrodin as suffering a neuropathy in which he had both too much feeling and too little feeling. 2007 WL 1467297, at *5. Special Master Moran found Dr. Campbell's statement that petitioner has CIDP "problematic." 2007 WL 1467297, at *6. Moreover, Dr. Campbell's diagnosis of Mr. Perrodin with CIDP was contradicted by Mr. Perrodin's own neurologist. 2007 WL 1467297, at *7. Dr. Campbell did not provide a medical theory and could not reasonably explain how he could diagnose Mr. Perrodin with CIDP without waiting for the results of tests. *Id.* The subsequent repetition of Dr. Campbell's diagnosis of Mr. Perrodin with CIDP in another doctor's records as part of petitioner's history "did not increase its persuasiveness." 2007 WL 1467297, at *9. Special Master Moran found Dr. Campbell's statement that Mr. Perrodin suffered an adverse reaction to hepatitis B vaccine not reliable and dismissed the petition. *Id.*

Thirdly, at trial in the instant action, petitioner's expert Dr. Richard Hughes shared his concern about Dr. Campbell's medical judgment. With reference to Dr. Andrew Campbell and

his diagnosing petitioner with CIDP, Dr. Hughes testified that there are doctors in Colorado like Dr. Campbell in Texas who specialize in telling well people they are sick and making them believe it: "[T]he goal of the practice seems to be to encourage people to have more symptoms and to encourage them to believe that they're victims and hurt and not to do a whole lot to encourage them to be better." Trial tr. at 32. Asked if Dr. Hughes agreed with Dr. Campbell's diagnosis that petitioner had CIDP, he said, "No, she doesn't have CIDP." *Id.* Dr. Hughes said it was better to look at the records after the vaccination and "ignore completely" the records from Dr. Campbell in Texas. *Id.* Only Dr. Campbell, whom both Dr. Hughes and Dr. Bielawski (respondent's expert) disparaged, diagnosed petitioner with a vaccine injury (CIDP) more than six months after vaccination, in contradiction to petitioners' treating neurologists' medical opinions as well as Dr. Campbell's own test results of petitioner which were normal. Dr. Campbell's opinion is not credible. Credible evidence is evidence "that is worthy of belief; trustworthy evidence." Black's Law Dictionary, 7th ed. (1999), p. 577. One need not see someone testify to know, on reading a diagnosis that flies in the face of the doctor's own medical tests as well as the diagnoses of every other physician, including treating neurologists, that Dr. Campbell's diagnosis is not credible. When Dr. Campbell attempted to have petitioner's treating physician, treating neurologist, and treating immunologist approve his prescription for IVIG therapy for petitioner, they declined to do so.

Fourthly, Dr. Campbell has been roundly criticized in other fora.[35] In Gaudette v. Conn Appliances, Inc., 2007 WL 2493437 (Tex. App. 2007), a Court of Appeals in Texas affirmed the trial court's exclusion of Dr. Andrew Campbell's testimony and the awarding of summary judgment to defendant in a case in which plaintiffs alleged that defendant negligently installed a refrigerator, causing them exposure to toxic mold and fungi, and causing, according to Dr. Campbell, CIDP. Initially he diagnosed all five plaintiffs with CIDP, but he later changed his mind to diagnosing mother and daughter with CIDP and stating the three others just had immune systems that were "off." 2007 WL 2493437, at *1. Defendant asserted that Dr. Campbell's diagnoses were junk science. *Id.* The trial court concluded that Dr. Campbell's theories were not sufficiently tested, his diagnoses were subjective, and his causation conclusion not supported by sufficient peer review. 2007 WL 2493437, at *2. The court stated that "Campbell chose to use his own methods instead of established diagnosing criteria. . . . He also admitted that although there is a published standard for diagnosing CIDP, he 'use[s] basically [his] clinical judgment from the information [he is] able to obtain.'" 2007 WL 2493437, at *5.

All of these reasons support a finding that Dr. Campbell's diagnosis that petitioner had CIDP and a vaccine injury lasting more than six months is not correct.

Emotional Distress

Petitioner also raises in her Post-hearing Brief on remand that hepatitis B vaccine not only caused her a neuropathy, but also emotional distress. To satisfy her burden of proving

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[35] Harper v. Grand Casino Coushatta, 940 So.2d 911, 915 (La. App. 3 Cir. 2006) (Dr Campbell's opinion was questionable at best and lacked medical evidence); Barrow v. Bristol-Myers Squibb, 1998 WL 812318 (MD FL 1998), at *13, aff'd without op., 190 F.3d 541 (11th Cir. 1999) (Table, No. 98-3637) (Dr. Campbell's tests were excessive and unusually expensive).

causation in fact, petitioner must prove by preponderant evidence "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

Mere temporal association is not sufficient to prove causation in fact. Grant, 956 F.2d at 1148.

Petitioner never addresses the pre-vaccination medical records which show she had emotional distress that sent her to doctors and emergency rooms where she received a diagnosis of anxiety and panic attacks. Petitioner never addresses her post-vaccination explanations to her doctors that her anxiety was due to her beginning dental hygienist school and to her guilt feelings about leaving her six-year-old child for the first time in order to attend dental hygienist school. Petitioner never addresses her post-vaccination account to her doctors that when the school semester ended, her anxiety symptoms went away. Petitioner never addresses her writing in her questionnaire answer for Dr. Campbell that she felt better on weekends.

Besides having consistent symptoms both before and after vaccination of dizziness,[36] lightheadedness, palpitations, and anxiety, doctors have offered other reasons for her symptoms than the ones petitioner gave (school, guilt about leaving her child). Besides the inner ear problem, Dr. Steele told petitioner he thought she might be having a side effect from taking Xanax which itself can cause inner ear problems. Dr. Rosenblum ascribed her palpitations and anxiety to her mitral valve prolapse and migraine. All her treaters have warned her about the side effects of the numerous anti-anxiety medications she was taking.

There is no credible medical proof in petitioner's records that her post-vaccination anxiety is related to her vaccination. Dr. Hughes testified that he would not be surprised to find an emotional component to a physical vaccine injury, but he went out only to three or four months for petitioner having a probable vaccine injury.

Without any credible medical evidence to support her allegation of emotional distress as a vaccine injury due to a two-week or even four-month vaccine reaction, and a biologically plausible reason why a transient, generalized reaction would cause five years of emotional distress, petitioner is relying solely on her allegations as if they offered sufficient proof. Again, 42 U.S.C. §300aa-13(a)(1)(A) prohibits the special master from ruling in favor of petitioner based solely upon her allegations unsupported by medical records or medical opinion.

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[36] Respondent discusses in respondent's Post-hearing Brief and Motion to Dismiss at pp. 24-25 the alternative cause of petitioner's dizziness and other symptoms of vertigo, which is inner ear dysfunction in petitioner's left ear. Med. recs. at Ex. 14, p. 115; tr. at 59. Respondent's expert Dr. Bielawski testified that petitioner's left inner ear unilateral weakness could account for her vertigo and dysequilibrium. Tr. at 59-60. Petitioner's audiologist noted her left ear abnormality might explain her vertigo. Med. recs. at Ex. 14, p. 115.

Petitioner had the options of reconvening the hearing to have the same witnesses or a new hearing to have new witnesses testify and she rejected those options. There is no expert testimony in this case to support her allegation that a transient, generalized vaccine injury that lasted two or three weeks (Dr. Bielawski) or three or four months (Dr. Hughes) was causally related to her emotional distress that lasted to at least July 31, 2007, which is the last record petitioner filed in this case. Med. recs. at Ex. 23, p. 1.

Petitioner has not provided any medical support, either from the records or expert evidence, that her emotional distress lasted longer than her physical injuries and was due to them. Her expert testified that her vaccine injury lasted probably three or four months. She attributed her anxiety to attending dental hygienist school and guilt over leaving her six-year-old child to attend school. She admitted her symptoms went away when the school semester ended. She wrote she felt better on weekends. She had an inner ear disorder, mitral valve prolapse, hypothyroidism, migraine, and multiple anti-anxiety drugs, all of which could cause dizziness, headache, palpitations, and lightheadedness. She experienced all these symptoms before she was vaccinated. Petitioner has failed to provide sufficient evidence to exclude all the causes for these symptoms that the doctors gave and has refused to acknowledge that no doctor, except Dr. Campbell, found her to have vaccine-related emotional distress more than six months after vaccination, as the Vaccine Act requires.

New Allegation of Significant Aggravation of Anxiety and Emotional Distress

Petitioner raises in her Post-hearing Brief on remand at pp. 26-29 and in her Reply brief at pp. 8-9 that the undersigned may find that petitioner suffered significant aggravation of her underlying condition. The undersigned is aware of only one underlying condition petitioner had

before vaccination which is anxiety and panic disorder. The allegation of significant aggravation is new. She never raised this allegation in the case before petitioner's appeal. In the original petition, petitioner alleged hepatitis B vaccine caused her a demyelinating illness. In her amended petition, petitioner alleged that hepatitis B vaccine caused her demyelinating polyneuropathy. In her prehearing brief, she alleged a transient neurologic injury.

Vaccine Rule 8(f) states:

> Any fact or argument not raised specifically in the record before the special master shall be considered waived and cannot be raised by either party in proceedings on review of a special master's decision.

Petitioner waived the allegation of significant aggravation of pre-existing anxiety and panic disorder by not raising it specifically in the record before the undersigned and cannot raise it on appeal or on remand. See Weddel v. Secretary of HHS, 23 F.3d 388, 390 n.2 (Fed. Cir. 1994) (noting that "Congress has expressly forbidden" the Federal Circuit from considering two arguments that petitioners did not raise before the special master); Jay v. Secretary of HHS, 998 F.2d 979, 983 & n.4 (Fed. Cir. 1993) (holding that petitioners had abandoned an argument that they "did not pursue or defend ... either in their case in chief or on motions for summary judgment" and that it would not consider an alternative argument first raised on appeal); Nussman v. Secretary of HHS, No. 99-500V, 2008 WL 331971, at *14, _____ Fed. Cl. _____ (Fed. Cl. 2008) (petitioner raised new arguments based on special master's decision; but since he did not raise these arguments before the special master, he waived them). The judge in Sword faced a similar attempt to inject new material into the case on appeal, this time by respondent, which the judge denied, stating at 44 Fed. Cl. at 190:

> [B]ecause of the deference accorded fact-finders, this Court will not aid a party who seeks to present additional evidence after his initial effort proves unpersuasive. . . . On a more fundamental level, judicial officers conducting evidentiary hearings–trials–are afforded great latitude on how they administer the proceedings in their forum. *See* Vaccine Rules 3 and 8.

The judge stated on the same page, "[C]ounsel must live with their witnesses' testimony; they do not usually get a chance to do it better a second time." Regarding respondent's claim of surprise by the undersigned's holding in Sword, the judge rejected the claim, stating, at 44 Fed. Cl. at 191: "Litigants under the Vaccine Act are not faced with an extraordinarily long list of possible evidentiary issues or grounds for compensation."

For the sake of completeness, however, the undersigned will discuss petitioner's new allegation of significant aggravation of her pre-existing panic disorder. The Vaccine Act defines, at 42 U.S.C. §300aa-33(4), "significant aggravation" as follows:

> The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

As the undersigned discussed earlier, petitioner's pre-vaccination symptoms of dizziness, lightheadedness, palpitations, anxiety, and panic attacks are identical to her post-vaccination symptoms. Petitioner has not provided evidence that there was a markedly greater disability, pain, or illness accompanied by substantial deterioration of her health after vaccination. Her expert witness, Dr. Hughes, testified that petitioner had a mild reaction to hepatitis B vaccination. He also testified that this reaction probably lasted only three or four months. There is no evidence therefore that petitioner experienced the statutory definition of significant aggravation.

But assuming arguendo that petitioner has proved a markedly greater disability, pain, or illness accompanied by substantial deterioration of her health after vaccination, she has failed to prove that the vaccine and/or her generalized transient physical reaction to the vaccine caused in fact her substantially worsened panic disorder.

Petitioner has failed to provide evidence of significant aggravation of a pre-existing panic disorder even though she could have opted to reconvene the hearing in this case and had a psychiatrist testify that her panic disorder post-vaccination was markedly worse than her panic disorder pre-vaccination, giving a biologically plausible medical theory connecting hepatitis B vaccine and/or a transient, generalized physical reaction to a substantial worsening of her panic disorder, showing a logical sequence of cause and effect from the vaccination and/or her transient reaction and the substantial worsening of her panic disorder, and a medically appropriate time frame. See Althen, 418 F. 3d at 1278. Since petitioner was still taking medication for her emotional problems through 2007, this medical expert testimony would have to explain how a transient vaccine reaction is causally connected to five years of panic disorder. But petitioner never presented this evidence even though given the option of doing so. The undersigned cannot rule in petitioner's favor on this new allegation even if, under the rules, petitioner is not deemed to have waived this new allegation by not presenting it before appeal.

Injury Lasting More than Six Months

Petitioner states in her Post-hearing Brief on remand at p. 30 that whether her injury lasted more than six months was never an issue. Satisfying the requirements of the Vaccine Act is always an issue in every case and it is petitioner's burden to satisfy these requirements by a preponderance of the evidence. Noticeable in Dr. Hughes' expert report, filed before the hearing,

was his failure to state how long petitioner's general reaction lasted. The special masters are not required to give petitioners notice of the defects in their cases. In Saunders v. Secretary of HHS, 26 Cl. Ct. 1221, 1226 (1992), aff'd, 25 F.3d 1031 (Fed. Cir.. 1994), the judge, in denying petitioner's claim for costs for which petitioner's counsel had provided no evidentiary support, stated:

> Petitioner's claim was disallowed because the proof was lacking. The suggestion that the special master had an obligation to cure this defect by calling upon counsel to supply the missing information misconstrues the relationship between court and counsel. Even under the less adversarial mode of proceeding that characterizes litigation before the special masters, it remains counsel's responsibility to submit proof sufficient to support the point in issue.

Summary

Petitioner has failed to make a prima facie case because the Vaccine Act requires her to prove that she have a vaccine reaction lasting more than six months. 42 U.S.C. § 300aa-11(c)(1)(D)(i):

> "A petition for compensation under the Program for a vaccine-related injury ... **shall** contain ... supporting documentation ... demonstrating that the person who suffered such injury ... [shall have] suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine...." [Emphasis added.]

Merely claiming she was sick does not satisfy the Vaccine Act's requirements that she provide confirmation of her claim from credible medical opinion and/or medical records. 42 U.S.C. §300aa-13(a)(1).

Petitioner has failed to prove that she had a neuropathy, much less a demyelinating illness or a demyelinating polyneuropathy as she initially alleged in her petition and amended petition respectively. Dr. Campbell's diagnosis of CIDP is not credible.

Petitioner has failed to prove that the vaccine caused in fact emotional distress or that her transient, generalized vaccine injury led to emotional distress that has lasted five or more years.

Petitioner waived her theory that hepatitis B vaccine significantly aggravated her pre-existing anxiety and panic disorder by not raising it before appeal. But, assuming arguendo that she had not waived this new allegation, she failed to prove significant aggravation because of the absence of proof that her panic disorder post-vaccination was markedly worse than her panic disorder pre-vaccination. Even assuming arguendo that petitioner proved that her panic disorder was markedly worse post-vaccination, petitioner failed to prove that the vaccine or her transient generalized physical reaction was the cause in fact of the worsening of her panic disorder.

CONCLUSION

The petition is dismissed. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk of the court is directed to enter judgment accordingly.[37]

IT IS SO ORDERED.

September 9, 2008
DATE

s/Laura D. Millman
Laura D. Millman
Special Master

[37] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.