

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-420V

December 17, 2007

To be Published

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KELLY BOLEY,

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Petitioner,

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v.

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Hepatitis B vaccines; panic

attacks two years before;

suspension of Dr. Andrew

SECRETARY OF THE DEPARTMENT OF

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HEALTH AND HUMAN SERVICES,

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Campbell's medical license;

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petitioner's expert testifies

Respondent.

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vaccine reaction lasted

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probably 3-4 months

Ronald C. Homer, Thao Ho, Boston, MA, for petitioner.

Katherine C. Esposito, Washington, DC, for respondent.

**MILLMAN, Special Master**

## DECISION<sup>1</sup>

Petitioner filed a petition dated March 30, 2005, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., and an amended petition dated June 6, 2005, alleging

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<sup>1</sup> 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.

that hepatitis B vaccine administered to her on June 12, 2002 caused her to suffer a demyelinating polyneuropathy.

On January 11, 2006, this case was reassigned to the undersigned. All of the other hepatitis B vaccine-demyelinating diseases were also reassigned to the undersigned at this time, including resolution of the Omnibus proceeding concerning hepatitis B vaccine and demyelinating diseases. On October 13, 14, and 15, 2004, former Special Master Sweeney held a hearing to determine whether hepatitis B vaccine can cause demyelinating diseases and, specifically, whether it caused the illnesses in four paradigm cases<sup>2</sup> in the Hepatitis B - Neurological Demyelinating Omnibus Proceeding.

The undersigned ruled in the four paradigm cases that hepatitis B vaccine can and did cause the demyelinating illnesses upon which the testimony focused: Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006); Gilbert v. Secretary of HHS, No. 04-455V, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006); Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. May 26, 2006); and Peugh v. Secretary of HHS, No. 99-638V, 2007 WL 1531666 (Fed. Cl. Spec. Mstr. May 8 2007) (the undersigned held that hepatitis B vaccine caused his GBS; Mr. Peugh died and the undersigned held a hearing to determine if his vaccine injury caused his death, ruling in a decision that it did).

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<sup>2</sup> The cases were Stevens v. Secretary of HHS, No. 99-594V (transverse myelitis or TM); Werderitsch v. Secretary of HHS, No. 99-638V (multiple sclerosis or MS); Peugh v. Secretary of HHS, No. 99-319V (Guillain-Barre syndrome or GBS); and Gilbert v. Secretary of HHS, No. 04-455V (chronic inflammatory demyelinating polyneuropathy or CIDP). Initially, Cramer v. Secretary of HHS, No. 99-128V, was to be the CIDP case, but petitioner died. On July 19, 2004, petitioner's counsel informed former Special Master Sweeney that Gilbert would substitute as the paradigm case for CIDP.

In the instant action, petitioner does not have a neurological condition and has no objective illness other than mitral prolapse, possible elbow compression, and possible carpal tunnel syndrome. She is prone to anxiety and panic attacks. Although she told doctors after her May 13, 2002 and June 12, 2002 hepatitis B vaccinations that she had been fine before the vaccinations, her medical records reveal that she had dizziness, lightheadedness, and headaches (plus a diagnosis of anxiety and panic attacks) two years before she received her 2002 hepatitis B vaccinations.

Moreover, all the seven medical doctors (two of whom were neurologists) petitioner saw after her 2002 hepatitis B vaccinations found her clinically normal except for the possibility of elbow nerve compression, carpal tunnel syndrome, and mitral valve prolapse.

Petitioner discovered Dr. Andrew W. Campbell, a Texas practitioner who holds himself out as a toxicologist. He is not a neurologist or immunologist. Despite testing showing petitioner to be neurologically normal, Dr. Campbell diagnosed her with chronic inflammatory demyelinating polyneuropathy (CIDP) and prescribed intravenous immunoglobulin (IVIG), a therapy petitioner's treating doctors refused to authorize.

After getting a CIDP diagnosis from Dr. Campbell, petitioner told all her other doctors, including her new neurologist Dr. Richard Hughes, that she had CIDP. Meanwhile, the Texas Medical Board suspended Dr. Campbell's medical license for unprofessional and fraudulent activities concerning his patients.

On September 5, 2006, the undersigned issued a 21-page Order to Show Cause, requiring petitioner to show cause why this case should not be dismissed by October 13, 2006.

On October 13, 2006, petitioner orally moved for an extension of time until December 1, 2006 to respond to the undersigned's Order to Show Cause, which the undersigned granted.

On December 4, 2006, petitioner filed a Status Report stating that petitioner had filed Dr. Richard Hughes' medical records and would file a Motion for Reconsideration of the undersigned's September 5, 2006 Order to Show Cause on or before December 30, 2006.

On January 4, 2006, petitioner filed a Motion for Reconsideration. Petitioner repeated Dr. Hughes' history which he took from petitioner on May 22, 2006 that she had a diagnosis of CIDP. This diagnosis came from Dr. Andrew Campbell whose records were available to petitioner's counsel, although apparently not to Dr. Hughes. Dr. Hughes believed petitioner had had a significant reaction to hepatitis B vaccine because of the temporal relationship, i.e., she complained of symptoms after she received the vaccines. Dr. Hughes was also not in possession of petitioner's pre-vaccination records which showed her making the same complaints, but petitioner's counsel did have those records. Petitioner's counsel stated in the Motion for Reconsideration that Dr. Hughes' opinion is totally unrelated to Dr. Campbell's opinion.

On January 8, 2007, the undersigned issued an Order stating that Dr. Hughes' record of March 22, 2006 did not substantiate that petitioner had CIDP although he thought she had a vaccine reaction. In the Order, the undersigned described in detail the Texas State Office of Administrative Hearings proposal for decision whose administrative law judges had issued a 138-page Proposal for Decision on October 10, 2006 concerning Dr. Campbell's failure to practice medicine in an acceptable manner, including unprofessional or dishonorable conduct that was likely to deceive or defraud the public or injure the public, and prescribing or

administering a drug that was nontherapeutic in the manner in which he prescribed or administered it.

In the Order, the undersigned called to the parties' attention that when Dr. Hughes examined petitioner, she was essentially normal (Ex. 20, p. 2). The next time petitioner saw Dr. Hughes, after she took Dr. Hughes' advice to get more sleep, exercise, fluid intake and salt, and to eat right and lose weight, she had dramatically improved (Ex. 20, p. 4). Dr. Hughes' opinion that petitioner had had a vaccine reaction was based solely on the temporal relationship. The undersigned denied petitioner's Motion for Reconsideration, ordering petitioner to file an expert report by February 9, 2007 or the case would be dismissed.

On February 20, 2007, petitioner orally moved for an extension of time to March 30, 2007 within which to file an expert report, which the undersigned granted.

On March 29, 2007, petitioner filed Dr. Hughes' report and CV. P. Exs. 21, and 22. Dr. Hughes states petitioner had a variety of symptoms beginning the day after her second hepatitis B vaccination. Her neurologic testing showed non-specific slowing in a few nerves without clear clinical explanation. When petitioner took his advice to "clean up her general health," she did "great." Dr. Hughes believed petitioner had a "poorly defined immunological reaction to the Hepatitis B vaccine." Ex. 21, p. 2. He was "underwhelmed" by the evidence for her having CIDP. *Id.* He thought she had a generalized hyperimmune state. *Id.*

On November 1, 2007, the undersigned held a prehearing telephonic status conference and reviewed the evidence in this case with the parties. The undersigned asked petitioner's counsel whether it was reasonable to go forward to hearing. Petitioner's counsel insisted on having a hearing. The undersigned expressed her doubts that having a hearing was reasonable.

On November 2, 2007, the undersigned issued an Order requiring Dr. Hughes to file a supplemental report in response to respondent's expert Dr. Bielawski's report stating that there is nothing wrong with petitioner, and also to state if Dr. Hughes is aware that Dr. Campbell's medical license was suspended and that petitioner complained two years before she received her 2002 hepatitis B vaccinations of the symptoms of lightheadedness, weakness, and dizziness (and was diagnosed with panic attacks). In addition, the undersigned asked if Dr. Hughes was aware that none of petitioner's medical doctors diagnosed her with any immunologic or general neurologic problem before she saw Dr. Campbell.

On November 13, 2007, petitioner responded to the undersigned's November 2, 2007 Order by saying that Dr. Hughes was too busy to respond to the undersigned's Order but would respond to the undersigned's questions at the hearing.

On November 14, 2007, the undersigned held a telephonic hearing in this case with Dr. Hughes testifying for petitioner and Dr. Bielawski testifying for respondent. Petitioner was not present at the hearing. The hearing began at 10:04 a.m. and ended at 11:34 a.m., for a total of one hour and 30 minutes, during which Dr. Hughes testified that petitioner's vaccine reaction probably lasted three to four months, but after that time, he believed it was only possible that petitioner still had a vaccine reaction. He did not specify what that transient reaction was. Respondent's expert Dr. Bielawski agreed that petitioner had had a transient reaction which lasted only a few weeks.

Petitioner has failed to make a prima facie case because the Vaccine Act requires that if petitioner has a vaccine reaction, it or its sequela must last 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....”

At the end of the testimony, petitioner’s counsel Ms. Ho requested filing a posthearing brief 30 days after the transcript was filed. The undersigned asked her why she thought filing a posthearing brief was necessary considering that petitioner had failed to make a prima facie case since petitioner’s expert Dr. Hughes stated petitioner had had a probable vaccine injury for only three to four months. Petitioner’s counsel stated that, at the end of his testimony, Dr. Hughes changed his mind and said the vaccine injury lasted more than six months. The undersigned said this was not what she heard and respondent’s counsel confirmed that. However, to satisfy petitioner’s counsel’s request, the undersigned has waited until after the transcript was filed in order to issue this decision.

At the very least, the undersigned can say that petitioner’s counsel never prepared Dr. Hughes’ testimony fully or understood his opinion or petitioner’s counsel would have known there was no reasonable basis for going forward to hearing in this case. This lack of a reasonable basis will affect the award of attorney’s fees and costs to petitioner. As the Federal Circuit stated in Perreira v. Secretary of HHS, 33 F.3d 1375, 1377 (Fed. Cir. 1994), “[W]hen the reasonable basis that may have been sufficient to bring the claim ceases to exist, it cannot be said that the claim is maintained in good faith.”

Moreover, petitioner’s counsel have failed in their responsibilities as officers of this court. The Federal Circuit also states in Perreira, “[C]ounsel’s duty to zealously represent their client does not relieve them of their duty to the court to avoid frivolous litigation.” *Id.* at 1377.

If petitioner's counsel had asked Dr. Hughes in the eight months between the filing of his report and the hearing date how long he thought petitioner had had a probable vaccine reaction, the undersigned assumes Dr. Hughes would have told them three to four months and they would have realized that petitioner did not have a prima facie case.

In light of the lack of a prima facie case, petitioner's counsel's oral motion to file a posthearing brief is denied.

### **FACTS**

Petitioner was born on June 11, 1973.

On May 9, 2000, petitioner complained of dizziness. Med. recs. at Ex. 2, p. 7.

On May 15, 2000, petitioner lost a fetus at 17 and one-half weeks due to placental abruption. Med. recs. at Ex. 3, p. 413.

On December 12, 2000, petitioner went to University of Colorado Hospital Emergency Department, complaining of feeling dizzy and feeling faint for several days which had become worse that day. Med. recs. at Ex. 3, p. 194. She felt lethargic. Med. recs. at Ex. 3, p. 195.

On December 13, 2000, petitioner went to University of Colorado Hospital, where she told Dr. Kennon J. Heard, instructor/fellow in emergency medicine, that, for several days, she had been having dizzy spells. She felt as if she were going to faint but did not. They lasted about 10-15 minutes and resolved when she lay down. They were not associated with tachycardia, shortness of breath, or chest pain. She said she felt somewhat nauseated with them. The last episode was earlier that day. On neurological examination, her cranial nerves were intact, and she had normal gait, balance, and strength. She was neurologically stable. Med. recs.

at Ex. 3, p. 190. Dr. Heard's impression was mild lightheadedness. She was possibly mildly dehydrated. Med. recs. at Ex. 3, p. 191.

On December 20, 2000, petitioner went to the University of Colorado Hospital, where she told nurse practitioner Keith A. Meier that she had had four to five episodes of lightheadedness over the last couple of weeks, off and on, lasting perhaps five minutes. The most severe episode was the day before when she was in the shower. She felt as if she could not catch her breath, her heart beat fast, and she got all shaky and nervous inside. She lay down and it resolved. Then she had a bit of a headache which went away with Tylenol. She stated that, most of the time, she had a shaky feeling inside. She felt groggy after each episode, which cleared after half an hour to an hour, depending on the severity of the attack. She told FNP Meier that these attacks seemed like panic attacks to her and she was concerned about them. Med. recs. at Ex. 3, p. 96. On neurological examination, the Romberg test was negative and her cranial nerves were normal. FNP Meier diagnosed panic attacks and prescribed Tylenol for headaches. Med. recs. at Ex. 3, p. 97.

On December 21, 2000, petitioner complained to her doctor about headaches and dizziness. She was 14 weeks pregnant and the doctor queried whether she had anxiety. Med. recs. at Ex. 1, p. 3. In a separate record of the same day, she was noted to have had a couple of attacks which sounded like panic attacks. One was in the shower and she was dizzy. She had some palpitations and shortness of breath, and felt the room closing in on her. The doctor discussed this at length with petitioner and suggested biofeedback, exercise, and deep breathing. She was to return in two weeks and start some serotonin reuptake inhibitor if this did not improve. Med. recs. at Ex. 1, p. 9.

On March 13, 2002, petitioner saw her doctor, complaining of dizziness and lethargy for one to two weeks. Med. recs. at Ex. 14, p. 218. She also complained of a recent weight loss which was subjective. She was started on Meclizine for dizziness. *Id.*

On May 13, 2002, petitioner received her first hepatitis B vaccination. Ex. 5, p. 87.

On Wednesday, June 12, 2002, petitioner received her second hepatitis B vaccination. Ex. 5, p. 88.

On Wednesday, June 19, 2002, petitioner saw Dr. Phillip Rosenblum, complaining of a two- to three-day history of extreme fatigue and malaise. She felt feverish but was not running a fever. The onset of her symptoms was Saturday, June 15, 2002 (three days after her second hepatitis B vaccination). She had her second hepatitis B vaccination last week and also was bit by a bug last week, which crusted but healed now. Med. recs. at Ex. 5, p. 86. She complained of sort of a sore throat, but it was negative on examination. She had chills and sweats and was very tired. The doctor diagnosed a viral syndrome and questioned if it were related to hepatitis B vaccine because the symptoms started shortly after the injection and seemed to be worsening a little bit each day. *Id.*

On June 20, 2002, petitioner called her doctor telling him that her symptoms were worse. Her head pounded and she was more tired. The back of her neck hurt. Med. recs. at Ex. 5, p. 65.

On June 21, 2002, petitioner went to HealthOne North Suburban Medical Center Emergency Department, complaining of headache, dizziness, and lethargy. Med. recs. at Ex. 9, p. 9. She was in good health until about a week ago when she developed symptoms of headache, dizziness, and lethargy the day after her second hepatitis B vaccination. The first vaccination made her feel tired. She had some very slight nausea but no vomiting or diarrhea. She ate and

drank okay but complained of slight neck discomfort. The headache was mild. She denied blurred or double vision, numbness, tingling, weakness, cough, chest pain, or abdominal pain. She had no fever. She has not had any fever throughout the week. Her vital signs were normal. *Id.* She did not appear to be profoundly lethargic. She had complete range of motion of her neck. Her neurologic examination was normal. Her HEENT examination was completely normal. She had a possible adverse reaction to hepatitis vaccine or a possible viral illness. Med. recs. at Ex. 9, p. 10. She was not acutely ill and was sent home in good condition. *Id.*

On June 24, 2002, petitioner had blood drawn which showed a low fasting glucose of 53 (normal range being 65-109). Med. recs. at Ex. 5, p. 13.

On July 29, 2002, petitioner saw her doctor, complaining that she still was having dizzy spells and extreme fatigue. She said she was stressed because she started going to dental hygienist school. Med. recs. at Ex. 5, p. 85.

On August 12, 2002, petitioner saw her doctor, complaining of dizzy spells and fatigue. She was lightheaded with occasional vertiginous episodes. The doctor wondered if this were due to anxiety since she noted her anxiety increased when she started school. Med. recs. at Ex. 5, p. 84.

On August 16, 2002, petitioner saw Dr. Dennis V. Barcz, an otolaryngologist, complaining of two months of dizziness. She described occasional spinning but more of a constant groggy lightheaded feeling associated with general fatigue. There was some nausea but no vomiting. She denied ear problems. She dated the symptoms to a hepatitis B vaccination. On examination, her ears were normal. Neuro-otologic testing was normal. Dr. Barcz put her on

Meclizine in case she had an inflammatory labyrinthitis. Med. recs. at Ex. 5, p. 61. Labyrinthitis can be associated with viral infections. He was not sure if the vaccination caused this. *Id.*

On August 19, 2002, petitioner had a brain MRI which was normal. Med. recs. at Ex. 6, p. 7.

On October 8, 2002, petitioner saw her doctor, saying she was told in dental hygiene school that her thyroid felt big. She saw Dr. Barcz for dizziness and had a brain MRI which was negative. She still felt dizzy and almost passed out in class. Her left arm was shaking. Med. recs. at Ex. 5, p. 83.

On October 30, 2002, petitioner saw Dr. Hua Judy Chen, a neurologist, for dizziness, shaking, and numbness. She said she had been healthy until June 2002 when she received hepatitis B vaccine. She had a two-week illness including body fatigue, chills, dizziness, and pain behind her eyes. She stayed in bed for that period of time. After two weeks, the mild fatigue and episodic dizziness continued. The dizziness could occur a few times a day or every day for a few days. Sometimes, it was as if the room were spinning. A brain MRI in August was normal. She also had been having episodic shaking inside her body. Her eyes felt as if they were jerking but she never had double vision. Occasionally, she saw tremor in her hands during the shaking. For the past few days, she had numbness in the right 4<sup>th</sup> and 5<sup>th</sup> fingers at night which lasted a few hours. She did not have neck or arm pain. She told Dr. Chen she had not been on any medications. Her examination was normal except for subtle decreased pinprick in the right hypothenar area. Med. recs. at Ex. 5, p. 59. Dr. Chen's impression was transient neurological symptoms after viral or virus immunization. She had a possible right ulnar nerve mononeuropathy across the elbow. Med. recs. at Ex. 5, p. 60.

On November 2, 2002, petitioner went to the Emergency Department of HealthOne North Suburban Medical Center, complaining of hand and foot numbness. Med. recs. at Ex. 9, p. 34. She said she developed some hand, leg, and foot numbness, then face numbness and carpopedal spasms lasting 10 minutes about a 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 systems was negative. *Id.* The impression was hyperventilation. Med. recs. at Ex. 9, p. 35.

On November 7, 2002, petitioner had a thyroid ultrasound because she claimed an enlarged thyroid. Med. recs. at Ex. 9, p. 41. No mass was identified and there was no significant enlargement of the gland. *Id.*

On November 10, 2002, petitioner went to HealthOne North Suburban Medical Center Emergency Department, complaining of substernal uncomfortable aching pain. She stated her arms began to ache the day before. She was on Klonopin<sup>3</sup> until the prior week for anxiety. Med. recs. at Ex. 9, p. 45. She had the pain when she stopped the Klonopin abruptly. She had an anxiety disorder. Med. recs. at Ex. 9, p. 55. Her EKG was normal. Med. recs. at Ex. 9, p. 56.

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<sup>3</sup> “Klonopin is indicated for the treatment of panic disorder.... Panic disorder is characterized by the occurrence of unexpected panic attacks and associated concern about having additional attacks.... Panic disorder ... is characterized by recurrent panic attacks, ie, 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.” In clinical trials, 37% of adverse events were somnolence. Physicians’ Desk Reference (PDR), 61<sup>st</sup> ed. (2007) at 2778, 2780.

Her pain could be musculoskeletal or a reaction to stopping the Klonopin abruptly or it could be anxiety-related. Med. recs. at Ex. 9, p. 57.

On November 10, 2002, petitioner had a chest x-ray because of chest pain. The x-ray was negative. Med. recs. at Ex. 9, p. 59.

On November 11, 2002, petitioner saw Dr. Rosenblum as a follow-up to an ER visit for chest pain. Her tests were normal, but it felt like indigestion. She was still having panic attacks on and off. She had two that day. Med. recs. at Ex. 5, p. 81.

On November 12, 2002, petitioner phoned her doctor. She received a prescription for Zoloft<sup>4</sup>. She had recently taken Klonopin. She felt 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. She phoned again that day and said her panic attacks were worse on Zoloft. The nausea was better, but she just could not calm herself. She complained of chest pain, muscle twitching, and loss of appetite. She went to the ER and they said it was due to anxiety. Med. recs. at Ex. 5, p. 73.

On November 14, 2002, petitioner went to HealthOne North Suburban Medical Center Emergency Department for anxiety. She had shortness of breath, left-sided chest pain, and dizziness. Med. recs. at Ex. 9, p. 63. She had been on Zoloft since Monday. *Id.* She was having repeated anxiety attacks which had been occurring over the prior several weeks. Med. recs. at Ex. 9, p. 68. She had some emotional distress at leaving her 6-year-old child for the first time

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<sup>4</sup> Zoloft is a selective serotonin reuptake inhibitor. PDR at 2586. It is an anti-depressive. It is also used to treat panic disorder. PDR at 2587, 2588. In clinical trials, 25% of adverse events were headache; 12% were dizziness. *Id.* at 2592.

since she had gone back to school. She also had dizzy spells. *Id.* Dr. Joseph B. Friedman concluded she had an identified anxiety disorder. Med. recs. at Ex. 9, pp. 69-70.

On November 16, 2002, petitioner saw Dr. Rosenblum, complaining of a reaction to medicine including difficulty swallowing, muscle spasms, trembling inside, which was getting worse. Med. recs. at Ex. 5, p. 79. She was diagnosed with panic attacks. *Id.*

On November 20, 2002, petitioner telephoned her doctor and said she saw the nurse practitioner on Saturday, November 16<sup>th</sup>, for Zoloft and was told to discontinue it and switch to Effexor<sup>5</sup> which made her extremely tired and dizzy. She could not even drive. Med. recs. at Ex. 5, p. 76.

On November 26, 2002, petitioner saw Dr. Chen, the neurologist. Her examination was normal. Dr. Chen's impression was "unexplained neurological symptoms" likely related to viral or virus immunization. Med. recs. at Ex. 5, p. 58.

On December 3, 2002, petitioner saw her doctor, questioning him about her anxiety medications. She had chest aches for three days. She had fatigue and lightheadedness. Med. recs. at Ex. 5, p. 77.

On December 6, 2002, petitioner saw her doctor for a follow up for chest discomfort and pain. Petitioner's report of her symptoms crossed over multiple systems. Med. recs. at Ex. 5, p. 74.

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<sup>5</sup> Effexor is an antidepressant. PDR at 3411. Adverse reactions included anxiety, nervousness, and insomnia. *Id.* at 3413.

On December 6, 2002, petitioner had blood drawn which showed a negative antinuclear antibody (ANA)<sup>6</sup> and a negative rheumatoid factor. Med. recs. at Ex. 5, p. 6.

On December 10, 2002, petitioner had an echocardiogram which showed a mild degree of anterior mitral leaflet prolapse with a minor degree of leaflet thickening, but without mitral regurgitation, according to Dr. Peter P. Steele. Med. recs. at Ex. 5, pp. 51-52.

On December 16, 2002, petitioner saw Dr. Chen. She had finished her semester and her shaking episodes disappeared. She had one week of eye pain with intermittent black spots and blurring. Sometimes she was nauseated. She had an ophthalmological test which was normal. Dr. Chen's impression was "Unexplained dizzy and shaking symptoms possibly related to anxiety." Med. recs. at Ex. 5, p. 57. Her current eye pain, visual disturbance, and nausea might be migraine. *Id.*

Also on December 16, 2002, petitioner had a visual field test which was basically normal, according to Dr. Matthew C. Sanderson. Med. recs. at Ex. 10. p. 2.

On January 6, 2003, petitioner saw Dr. Jill R. Breen, another neurologist, for chronic dizziness. Med. recs. at Ex. 5, p. 53. She gave a history of receiving hepatitis B vaccine on June 13, 2002 (it was June 12, 2002). On the day following the vaccination, she was groggy and dizzy. She did not have fever. She improved incompletely over the next two weeks. Ever since then, she continued to have grogginess, lightheadedness, photophobia, pain when she focused her

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<sup>6</sup> 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, 30<sup>th</sup> ed. (2003) at 100.

eyes, and a dull ache behind her eyes. There was no throbbing or unilaterality. She initially had some nausea when she was lightheaded but no vomiting. A couple of times, the room looked hazy and dim. This lasted 20 to 30 minutes and was associated with an increase in pain. Her symptoms waxed and waned during the day and over the course of several days. She felt better if she slept, but there was no improvement since six months previously. *Id.* Dr. Chen evaluated her and diagnosed possible migraines without headache as well as possible nerve damage from the vaccination. Her primary care physician found no cause. ENT evaluation was negative as was ophthalmologic evaluation. The patient said she was very active, used a treadmill at school, and walked frequently during the day. She denied arthralgias and myalgias, but occasionally her right leg felt heavy from the knee down, lasting from 15-20 minutes. She had no neck or back pain. She slept through the night, about nine hours per night, and fell asleep right away. Some mornings, she felt fatigued, but, at other times, she felt well-rested. *Id.*

Petitioner had occasional muscle twitch in random areas. One leg might twitch briefly and stop. Then the twitch would move to another area. Med. recs. at Ex. 5, p. 54. She had no cramping or ongoing fasciculation activity. She has tried Pamelor, Effexor, and Zoloft, all of which increased her anxiety. She also tried Clonazepam which made her dysfunctional. *Id.* Her thyroid test was within normal limits. Med. recs. at Ex. 5, p. 55.

Petitioner's neurological examination was normal. *Id.* All her tests were normal. Dr. Breen stated, "I do not find any evidence of primary neurologic disease. I do not find any evidence for multiple sclerosis, CNS vasculitis, etc." *Id.* Dr. Breen thought petitioner's symptoms would be most consistent with a chronic fatigue syndrome (CFS) which could be due to virus, nondefined immune-mediated abnormality, depression, and anxiety. Med. recs. at Ex. 5,

p. 56. Dr. Breen recommended no further neurologic evaluation, but medication to treat CFS. She discussed Paxil<sup>7</sup> because Zoloft caused her to be anxious. *Id.*

On January 24, 2003, petitioner saw Dr. Steele, the cardiologist. She had had reasonably consistent mitral prolapse symptoms, non-predictable effort-induced chest pain, and dyspnea. These created a perception of arrhythmia. The issue was sympathetic nervous system dysfunction rather than cardiac response. Med. recs. at Ex. 5, p. 50.

On January 30, 2003, petitioner saw Dr. Rosenblum. She had mitral valve prolapse and had been getting dizzy. She complained of episodic dizziness and lightheadedness, not associated with palpitations or chest pain which she got occasionally. She complained of anxiety. Med. recs. at Ex. 5, p. 72.

On February 2, 2003, petitioner saw Dr. Rosenblum, complaining of a rapid heart beat for four days. She had worse chest pain and shortness of breath. It got worse after drinking hot chocolate the day before. The doctor diagnosed mitral valve prolapse, palpitations, and anxiety. Med. recs. at Ex. 5, p. 71.

On February 7, 2003, petitioner saw Dr. Steele, the cardiologist, complaining of a continuation of a kind of vertigo. He did not think it was related to prolapse. He spoke to her about the potential for Xanax for inner dizziness. Med. recs. at Ex. 8, p. 2.

On March 15, 2003, petitioner saw Dr. Michael A. Volz, a specialist in allergy, asthma, and immunological disorders, complaining of dizziness and fatigue, a history of mitral valve prolapse, and minimal cervical lymphadenopathy. Med. recs. at Ex. 5, p. 20. Dr. Volz found the

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<sup>7</sup> Paxil is a psychotropic drug. PDR at 1530. It treats depression and panic disorder. *Id.* Of those with adverse events, 26% complained of nausea, 23% complained of somnolence, 18% complained of headaches, and 13% complained of dizziness. *Id.* at 1535.

origin of her dizziness and fatigue uncertain. There had been no objective findings, but interestingly the onset occurred within 24 hours of her second hepatitis B vaccination. [This is unlike the initial history she gave Dr. Rosenblum that onset was three days after vaccination.] She had previously received two hepatitis B vaccinations ten years earlier without incident. The complex of symptoms came and went, and had not changed in frequency or severity over the prior several months. The minimal cervical lymphadenopathy suggested some persistent upper respiratory tract inflammation. *Id.*

Petitioner's history to Dr. Volz was that, within 24 hours of receiving her second hepatitis B vaccination on June 13, 2002 (it was June 12<sup>th</sup>), her symptoms began and were most severe during the first few weeks. Since that time, they waxed and waned without changing patterns in terms of severity, frequency, disruption, or length of time. Initially, the symptoms were severe enough to keep her in bed for several days to two weeks. She may have gone up to several days to two or more weeks without any symptoms. She had been told this was a virus-like reaction, but she had not experienced any fevers. She sometimes had a floaty feeling when she was lightheaded. "So far she has visited her primary doctor, one otolaryngologist, one cardiologist, one ophthalmologist, and two neurologists with **no abnormal objective findings** [emphasis added]." *Id.* Petitioner had received two hepatitis B vaccinations in 1992 with no reactions at that time. Med. recs. at Ex. 5, p. 21.

On examination, objective findings showed rhinitis and non-tender anterior cervical lymphadenopathy. They could have been totally unrelated to her chief complaints. Dr. Volz found notable the absence of other palpable lymph node groups and objective or subjective fever. The onset of her symptoms within 24 hours of hepatitis B vaccination could have been

coincidental, but maybe it stimulated an enhanced hypersensitive immunologic reaction. Med. recs. at Ex. 5, p. 22.

On March 15, 2003, nine months after petitioner's second hepatitis B vaccination at issue, petitioner had an ANA test which was 1:40, whereas negative is below 1:40. Med. recs. at Ex. 14, p. 251.

On May 24, 2003, petitioner filled out a 14-page questionnaire for Dr. Andrew W. Campbell (titled "Immune Dysfunction Questionnaire"), at the end of which she stated: "I began to have anxiety issues when I started 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." Med. recs. at Ex. 14, p. 36.

On May 28, 2003, petitioner saw Dr. Breen, the neurologist, for chronic dizziness. Med. recs. at Ex. 11, p. 5. She described a sense of being off balance. The dizziness was worse on awakening but better by noon. At night, she had no dizziness. Occasionally, she had pain behind both eyes. Her ophthalmologist told her she was normal and did not have optic neuritis. Photosensitivity could last one to two days. This was not associated with her dizziness. She had no nausea, vomiting, headache, or blurred or double vision associated with light sensitivity or eye pain. She slept well and woke feeling rested. Muscle twitching occurred during a one- to two-

week period when she sat in chairs or lay in bed. *Id.* Her examination was normal. Med. recs. at Ex. 11, p. 6.

On June 2, 2003, petitioner had an electronystagmography (ENG) test for balance. Clinical audiologist Karen Schroer found that caloric testing with air irrigation produced a 25% left unilateral weakness with no significant directional preponderance. Her ocular-motor testing, static positional tests, and positioning tests were normal. From these findings, audiologist Schroer concluded the results of the ENG were abnormal, suggesting a peripheral pathology. Med. recs. at Ex. 14, p. 115.

On June 4, 2003, petitioner had an EEG which was normal. Med. recs. at Ex. 7, p. 3.

On July 7, 2003, petitioner saw her ophthalmologist, complaining of sharp shooting pain in her right eye for two days and headache. The doctor stated the eye pain was of an unknown nature. Med. recs. at Ex. 10, p. 1.

On August 1, 2003, petitioner saw Dr. Andrew W. Campbell. Med. recs. at Ex. 14, p. 18. The day after her second hepatitis B vaccination in 2002, she was lightheaded, dizzy, and had headaches and severe fatigue. *Id.* She told him her ENG on June 13, 2003 was abnormal, suggesting a peripheral pathology. Med. recs. at Ex. 14, p. 19. She told Dr. Campbell she had an elevated ANA in March 2003. Med. recs. at Ex. 14, p. 20.

On August 12, 2003, petitioner had a somatosensory evoked potential (SEP) of her posterior tibial nerve which was normal, according to Dr. Patricia J. Burcar. Med. recs. at Ex. 5, p. 1.

Also on August 12, 2003, petitioner had auditory evoked responses which were normal. Med. recs. at Ex. 13, p. 5.

Also on August 12, 2003, petitioner had visual evoked responses which were normal. Med. recs. at Ex. 13, p. 6.

Also on August 12, 2003, petitioner had a somatosensory evoked potential of her median nerves which was normal. Med. recs. at Ex. 13, p. 7.

On August 29, 2003, a nerve conduction study (NCS) was performed to determine if petitioner had demyelination. Med. recs. at Ex. 11, p. 8. On examination, she had normal strength, sensation, and reflexes. The NCS showed slowing of the peroneal nerve impulses across the fibular head, which most commonly resulted from focal compression of the nerve. Petitioner was asymptomatic and without neurological signs from this slowing. The remainder of the study including H-reflexes was normal in both lower extremities. There was no evidence for a demyelinating process. *Id.*

On September 9, 2003, petitioner had an EMG. Dr. James A. Crosby stated there was a slight latency delay across the right median motor nerve distally which might signify carpal tunnel syndrome. Otherwise, the EMG of the right upper and lower extremities was normal. Med. recs. at Ex. 7, pp. 1-2.

On September 12, 2003, Dr. Campbell wrote a "To Whom It May Concern" letter stating that petitioner had been diagnosed with a demyelinating polyneuropathy with immune suppression (presumably, Dr. Campbell, who is not a neurologist or an immunologist, made this diagnosis). Med. recs. at Ex. 12, p. 4. He states she had an abnormal neurological examination with hyporeflexia in all four extremities. He also states she had an abnormal nerve conduction study and an abnormal brainstem auditory evoked response potential. *Id.* This was in spite of

the normal nerve conduction study and reflex examination of August 29, 2003. (It is impossible to have demyelinating polyneuropathy when there is no demyelination and no polyneuropathy.)

On November 9, 2003, Dr. James A. Crosby wrote to Dr. Campbell about petitioner's EMG results. Because the right side was almost completely normal, the left side was not tested. Med. recs. at Ex. 14, p. 41. Although petitioner might have a mild carpal tunnel syndrome, her EMG of her right upper and lower extremities was normal. Med. recs. at Ex. 14, p. 42.

Astonishingly, Dr. Campbell attempted to obtain IVIG treatment for petitioner. Med. recs. at Ex. 14, p. 85.

On what looks like October 24, 2003, someone taking notes for Dr. Campbell or Dr. Campbell himself notes that he called Park Infusion and spoke with Jerry who stated that neither petitioner's personal care physician nor her neurologist wanted to write an order for petitioner to receive intravenous immunoglobulin (IVIG)<sup>8</sup> treatment. Med. recs. at Ex. 17, p. 275. 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. She felt she was going to faint three times over the prior week. She had an increase in memory problems. She complained of dysequilibrium. She had vision problems and headaches behind her eyes. She felt groggy in her head. *Id.*

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<sup>8</sup> 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, 13<sup>th</sup> ed., Vol. 1 (1994) ed. Isselbacher, et al., at chap. 82, p. 507.

On May 7, 2004, petitioner saw Dr. Steele, the cardiologist, because of dizziness. Med. recs. at Ex. 18, p. 1. It was quite typically inner ear. It was orthostatic, but also occurred if she moved her head. Dr. Steele was pretty sure it was inner ear dizziness. *Id.*

On October 15, 2004, petitioner saw physician's assistant Gina Bollinger, complaining of dizziness. Med. recs. at Ex. 23, p. 75. She had mild upper respiratory symptoms a few days earlier. *Id.*

On November 19, 2004, petitioner took another nerve conduction study. Dr. Everton A. Edmonson found her to be normal although there may have been some technical artifact because there was a discrepancy between the left and right H-reflexes but also a significant difference in the amplitudes. Dr. Edmondson tested petitioner's bilateral upper and lower extremity nerve conduction involving median, ulnar, common peroneal, superficial peroneal, and tibial nerves. Med. recs. at Ex. 17, p. 150.

Also on November 19, 2004, petitioner took an NTI Postural Sway (Balance) Test, which she passed. Med. recs. at Ex. 17, p. 148. On the same date, she took an NTI Reaction Time Test, which she passed. Med. recs. at Ex. 17, p. 147.

Also, on November 19, 2004, blood was drawn for autoimmune testing. Med. recs. at Ex. 14, p. 135. Petitioner's ANA by HEp-2<sup>9</sup> was normal at 1:20 (the reference range was 1:20). *Id.*

On November 30, 2004, petitioner took another EEG which was normal. Dr. Richard Foa compared this EEG with the one on August 12, 2003 that was also normal. The conduction in

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<sup>9</sup> HEp-2 is the choice of substrate, here human epithelial tumor line. Textbook of Rheumatology, 5<sup>th</sup> ed., Vol. 1 (1997) at chap. 17, p. 250.

her auditory nerve in its peripheral course apparently improved since the prior test. Med. recs. at Ex. 17, p. 142.

On November 30, 2004, petitioner underwent a brainstem evoked response. Med. recs. at Ex. 23, p. 62. Dr. Richard Foa found the latencies within normal bilaterally. *Id.*

On December 2, 2004, petitioner took another brain MRI, which was normal and unchanged compared to the brain MRI of August 19, 2002. Med. recs. at Ex. 17, p. 140.

However, petitioner's normal tests did not dissuade Dr. Campbell from diagnosing petitioner with chronic demyelinating polyneuropathy, immune suppression, chronic lymphocytic thyroiditis, and chronic fatigue syndrome in the record of a telephone conference dated January 6, 2005. Med. recs. at Ex. 17, p. 129. Dr. Campbell felt that petitioner's new elevated antibody levels to a number of neuronal tissues were a result of her painting with a number of different paints in her home. Med. recs. at Ex. 17, p. 128.

On January 27, 2005, petitioner saw Dr. Rosenblum with allergic rhinitis and acquired hypothyroidism. Med. recs. at Ex. 23, pp. 59, 60.

On March 10, 2005, petitioner saw Dr. Rosenblum, who diagnosed her with dizziness, vertigo, anxiety state, common migraine, and acquired hypothyroidism. Med. recs. at Ex. 23, p. 50. Dr. Rosenblum explained to petitioner that there was a very common association between mitral valve prolapse and anxiety and also with hypothyroidism and anxiety. Med. recs. at Ex. 23, p. 51.

On March 31, 2005, petitioner saw Dr. Rosenblum, who diagnosed her with acquired hypothyroidism, anxiety state, and common migraine. Med. recs. at Ex. 23, p. 42.

On April 21, 2005, petitioner saw Dr. Rosenblum, who diagnosed her with acquired hypothyroidism, anxiety state, and common migraine. Med. recs. at Ex. 23, p. 40.

On May 26, 2005, petitioner phoned Dr. Campbell to report severe episodes of muscle jerking, most noticeable at rest, more headaches behind her eyes, and fatigue. Med. recs. at Ex. 17, p. 9.

On June 17, 2005, petitioner saw Dr. Campbell. Med. recs. at Ex. 17, p. 5. On examination, her cervical and submandibular lymph nodes were enlarged. *Id.* He found deep tendon reflexes either absent or diminished in the arms. Med. recs. at Ex. 17, p. 6. He diagnosed petitioner with feeling tired or poorly, dizziness, numbness, adenopathy, mitral valve disorder, adverse effect of vaccines, Hashimoto's thyroiditis, headache syndromes, movement disorder, demyelinating disorders, inflammatory polyneuropathy, and immunodeficiency with predominant T-cell defect. He ordered an extraordinary number of tests. *Id.*

On June 17, 2005, petitioner's ANA by HEp-2 was 1:160 when normal is 1:20. Med. recs. at Ex. 24, p. 232.

On July 18, 2005, Dr. Campbell diagnosed petitioner with restless leg syndrome, and noted high thyroid peroxidase serum antibodies, high thyroglobulin serum antibodies, and abnormal lymphocytes natural killer cells activity. Med. recs. at Ex. 17, p. 4.

On November 3, 2005, petitioner saw Dr. Rosenblum who diagnosed her with anxiety state and common migraine. Med. recs. at Ex. 23, p. 38.

On November 18, 2005, petitioner's ANA measured 15 when the normal range was <7.5. Med. recs. at Ex. 24, p. 198.

On March 13, 2006, petitioner saw physician's assistant Gina Bolinger who diagnosed her with an anxiety state. Her current medication was not working. Med. recs. at Ex. 23, pp. 33, 35.

On May 1, 2006, petitioner returned to Dr. Campbell who found her deep tendon reflexes minimally diminished in the upper extremities bilaterally, normal in the right and left lower extremities with improvement noted. She had normal lower bilateral sensation to light touch, pin prick, and vibration. Med. recs. at Ex. 24, p. 281. He did a mental status exam on petitioner and she scored 30 out of 30. *Id.* He ordered two pages of tests for her. Med. recs. at Ex. 24, pp. 282-83,

On May 22, 2006, petitioner saw Dr. Richard L. Hughes, a neurologist. Med. recs. at Ex. 23, p. 24. On examination, petitioner had 5 out of 5 strength symmetrically in all extremities. Med. recs. at Ex. 23, p. 25. She had slightly delayed reflexes on her triceps and biceps. Her reflexes were 2+ and symmetric throughout. Sensation was intact. Her gait was normal and she had a normal Romberg. Her cerebellar exam and fine motor exam were normal. *Id.* Dr. Hughes found it "difficult to completely substantiate" the diagnosis of CIDP because of the lack of a lumbar puncture. Med. recs. at Ex. 23, p. 26. Dr. Hughes suggested petitioner increase her sleep, exercise, fluid, and salt intake, as well as eat right and lose weight to deal with her fatigue and dysequilibrium. *Id.*

On May 30, 2006, petitioner had auditory evoked responses in both ears as a follow-up to two previous auditory evoked responses (which were normal) because of residual dizziness. Med. recs. at Ex. 24, p. 16. Dr. John B. Woodward interpreted petitioner's auditory evoked responses as normal. *Id.*

On September 19, 2006, petitioner telephoned Dr. Campbell for a refill of her prescriptions. Dr. Campbell's impressions were autoimmune thyroiditis, anxiety, dizziness, giddiness, dysfunctions associated with sleep stages or arousal from sleep, fatigue, lightheadedness, other sleep disturbances, neurological problems, toxic encephalopathy, other demyelinating diseases of the central nervous system, abnormal nerve conduction velocity, chronic inflammatory demyelinating polyneuropathy or polyneuritis, demyelinating disorders, accidental poisoning by other anti-infectives, other selective immunoglobulin deficiencies, immunodeficiency with predominant T-cell defect, and combined immunity deficiency. Med. recs. at Ex. 24, pp. 254, 255.

On November 13, 2006, petitioner saw Dr. Hughes. Med. recs. at Ex. 23, p. 17. He had previously seen her in May 2006, at which time he suggested she improve her sleep, increase her exercise, fluid, and salt intake, and begin to eat better. She took this advice and had dramatically improved. Dr. Hughes thought petitioner had a significant reaction to hepatitis B vaccine because of the temporal relationship, but "the exact nature of this reaction is not well understood nor will there ever be absolute certainty about it. It certainly is plausible that a second, completely unrelated diagnosis could have been made at that time, unrelated to the hepatitis B vaccine." *Id.* Her EMG did not well characterize her reported general weakness. *Id.* Brain studies and EEG did not demonstrate any specific brain injury and Dr. Hughes believed her brain was fine. Med. recs. at Ex. 23, p. 18.

On November 28, 2006, petitioner saw Dr. Suzanne C. Nash with a sore throat and nasal congestion for a few days. Med. recs. at Ex. 23, p. 14.

On July 3, 2007, petitioner saw Dr. Rosenblum to get refills of Synthroid and Lexapro. She was also taking Celexa<sup>10</sup> and Wellbutrin.<sup>11</sup> Med. recs. at Ex. 23, p. 2. Her deep tendon reflexes were 2+/4 and symmetrical. Med. recs. at Ex. 23, p. 4. She had a normal energy level and no complaints of feeling fatigued or having difficulties in vision. Med. recs. at Ex. 23, p. 3. She had no back pain, muscle cramps, muscular pain, headaches, dizziness, numbness, or tingling. She slept well and had no depressive symptoms. *Id.*

Dr. Andrew W. Campbell

By Order dated January 8, 2007, the undersigned informed the parties that the Texas Medical Board was considering suspending Dr. Andrew Campbell's medical license for unprofessionalism and dishonorable conduct.

On June 6, 2007, the Texas Medical Board issued a 26-page Final Order in In the Matter of the Complaint Against Andrew William Campbell, M.D., SOAH Docket No. 503-04-5717, License No. G-7790, suspending Dr. Campbell's medical license until February 8, 2008, at which point his suspension will end if he fulfills a number of requirements and pays an administrative penalty of \$210,000.00 plus transcription costs. If he satisfies these requirements, he will be placed on probation for five years under the close supervision of another medical doctor for whose services he would have to pay. If he does not satisfy the listed requirements, the Board will revoke his medical license as of February 8, 2008. The Board states that its Final Order constitutes a PUBLIC REPRIMAND (the capital letters are in the Final Order) of Dr. Campbell.

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<sup>10</sup> Celexa is a selective serotonin reuptake inhibitor. PDR at 1176. It is an antidepressant. *Id.* at 1177.

<sup>11</sup> Wellbutrin is an antidepressant. PDR at 1603. Of those experiencing adverse events, 25.7% had headache/migraine, 22.3% had dizziness, and 14.6% had blurred vision. *Id.* at 1606.

The pages cited below are from the Final Order.

The Board reached the following conclusions:

1. Dr. Campbell failed "to practice medicine in an acceptable professional manner consistent with public health and welfare." (p. 18).
2. "Dr. Campbell's failure to practice medicine in an acceptable manner consistent with public health and welfare includes the failure to treat a patient according to the generally accepted standard of care." (p. 18).
3. "Dr. Campbell engaged in a prohibited act or practice...by prescribing or administering a drug or treatment that was nontherapeutic in the manner the drug or treatment was administered or prescribed." (p. 18).
4. "Dr. Campbell engaged in a prohibited act or practice...in engaging in unprofessional or dishonorable conduct that is likely to deceive or defraud the public or injure the public." (p. 18).
5. "Dr. Campbell committed a prohibited act or practice...by the commission of an act that violates any law of this state if the act is connected with [his] practice of medicine." (p. 18).
6. "Dr. Campbell committed a prohibited act or practice...by violating Section 311.0025 of the Texas Health and Safety Code, which provides that a health care professional may not submit to a patient or a third party payor a bill for a treatment that professional knows was not provided or knows was improper, unreasonable, or medically or clinically unnecessary." (p. 18).
7. "Reliance upon antibody testing--at its substantial cost to the patient and insurers--in the absence of testing first for other, more probable causes of illness and without established ranges of values, is not within the standard of care." (p. 19).

8. "The use of a diagnostic test on a trial basis without prior disclosure to the patient of the unaccepted status of the test is not within the standard of care." (p. 19).

9. "Quantitative electroencephalographic tests may be of investigational value for scientific purposes but are not within the standard of medical care absent a showing of a particular need, coupled with the skill of the physicians involved in the administration and interpretation of the test's results." (p. 19).

10. "The use of IVIg by [Dr. Campbell] in four patients was not appropriate because [Dr. Campbell] failed to do adequate clinical examinations and electro-diagnostic testing to determine if the patients had neuropathy or polyneuropathy, which made the use of IVIg medically unnecessary and unreasonable, and was not within the standard of medical care." (p. 19).

The Texas Board of Medicine believes that Dr. Campbell can be rehabilitated, although the first step in rehabilitation "is an acknowledgment of wrongdoing and a willingness to implement changes that will conform the physician's practice to that of a reasonable and prudent physician." (p. 20). Dr. Campbell has not demonstrated such an acknowledgment so far in the record.

The Board suspended Dr. Campbell's Texas license until February 8, 2008. (p. 20).

The Board ordered Dr. Campbell to enroll in and successfully complete one or more educational courses totaling at least 25 hours in duration on "the legal obligations of a physician that accompany the physician-patient relationship." (p. 20). The Board also ordered Dr. Campbell to enroll in and successfully complete one or more educational courses totaling at least 25 hours on "the standard of care for a physician to use newly available techniques or medications or use existing techniques and medications in new ways." (p. 21).

The Board ordered Dr. Campbell to prepare a paper relating to the standard of care for a physician using newly available techniques or medications or use existing techniques and medications in new ways, sufficient in quality to meet the content and format requirements for publication in a scholarly medical journal. The paper must demonstrate Dr. Campbell's understanding and acceptance of the Board's findings of fact and conclusions of law and his commitment to rehabilitation. (p. 21). Dr. Campbell shall transfer all rights to the paper to the Board, including intellectual property rights, so that the Board may publish the paper if deemed appropriate. (p. 21).

The Board ordered Dr. Campbell to pay an administrative penalty of \$210,000.00 on or before February 8, 2008. (p. 21). The Board calculated the amount by assessing a penalty of \$5,000.00 for each of Dr. Campbell's 42 violations of the Medical Practice Act, as itemized in Attachment A to the Final Order. (p. 21).

The Board ordered Dr. Campbell to appear before it at its meeting to be held on February 8, 2008 to show he has complied with the requirements of the Board's Final Order. (p. 22). If Dr. Campbell has complied with all the requirements of the Board's Final Order, the Board will place Dr. Campbell on probation for five years from February 8, 2008 under the following conditions:

(a) A physician shall monitor Dr. Campbell's practice. (p. 22).

(b) Dr. Campbell shall prepare and provide complete legible copies of selected patient medical and billing records for at least 30 patients during each three-month period following the last day of the month of entry of the Final Order. (p. 22).

(c) The monitor physician shall personally review the selected records, and prepare written reports documenting any perceived deficiencies and any recommendations to improve Dr. Campbell's practice of medicine. Dr. Campbell shall compensate the monitor physician through the Board. Dr. Campbell shall not charge the monitor's compensation and costs to Dr. Campbell's patients. (p. 23).

(d) Dr. Campbell's medical records shall include a written consent from each patient to proceed with diagnostic testing and/or treatment. The informed consent form shall state whether the laboratory tests include established ranges recognized generally within the medical community; whether the laboratories and tests to be used have state regulatory approval; whether the laboratory tests to be used have general acceptance in the medical community as a valid basis upon which diagnoses may be made; whether the utility and results of the neurological tests and testing equipment to be used have been accepted by professional associations of neurologists; whether the dosage or administration of IVIG used by Dr. Campbell is generally recognized by the medical community; Dr. Campbell's average charge for all diagnostic tests and treatments (this disclosure must be accurate, clear, and in writing); and the risk that insurance may not pay for these charges. (pp. 23-24).

If at the Texas Board meeting to be held on February 8, 2007, the Board determines that Dr. Campbell has not complied with the requirements in the Final Order, then the Board will revoke Dr. Campbell's medical license, effective February 8, 2008.

The entry of the Final Order "shall constitute a PUBLIC REPRIMAND by the Board."  
(p. 24—emphasis included).

The Board assessed Dr. Campbell the costs of transcription in the amount of \$8,396.50. (p. 24).

Attachment A lists all 42 of Dr. Campbell's violations and the amount of penalties assessed therefor. (p. 26). They include improperly coded initial office visits, unnecessary initial blood tests ordered, unnecessary initial neurological tests ordered, unnecessary and unsupported prescriptions of IVIG treatment, improperly coded follow-up office visits, and unnecessary follow-up blood tests. (p. 26).

The undersigned put all of the above in a published Report to the Parties in Ottenweller v. Secretary of HHS, No. 99-519V, 2007 WL 2241875 (Fed. Cl. Spec. Mstr. July 17, 2007).

Petitioner's counsel, in the instant action, has been on notice since January of this year that reliance upon Dr. Campbell's diagnoses and test results (as petitioner's neurologic expert Dr. Hughes had done in his reports) was unwise because Dr. Campbell's conduct was fraudulent. At the hearing, Dr. Hughes very carefully separated himself from being influenced at all by Dr. Campbell (unlike in Dr. Hughes' expert report where he relied on Dr. Campbell's ANA findings). At the very least, anyone reading petitioner's medical records can see that after petitioner had a normal neurological examination, including normal nerve conduction and electromyography testing, Dr. Campbell diagnosed her with demyelinating polyneuropathy and prescribed IVIG.

#### Medical Literature

Respondent's expert Dr. Bielawski submitted seven articles with his expert opinion. These include "Range of Antinuclear Antibodies in 'Healthy' Individuals," by E.M. Tan, et al., 40 *Arthritis & Rheumatism* 9:1601-11 (1997). The authors found that healthy individuals had a

range of ANA readings, including 31.7% at 1:>40 serum dilution, 13.3% at 1:80, 5.0% at 1:160, and 3.3% at 1:320. *Id.* at 1601.

Another of these articles includes “Autoantibody Tests in Autoimmune Thyroid Disease: A Case-Control Study,” by M. Petri, et al., 18 *J Rheumatol* 1529-31 (1991). The authors found that individuals with autoimmune thyroid disease, including Hashimoto’s thyroiditis, commonly had positive ANA tests. *Id.* at 1531.

### TESTIMONY

Dr. Richard L. Hughes, a neurologist who saw petitioner for the first time on May 22, 2006, testified for petitioner. Tr. at 4, 8. At the time he first saw her, he did not have any of her records. Tr. at 8. Petitioner was concerned about a variety of nonspecific symptoms, including some sort of numbness, and told him that she had been diagnosed with CIDP and a brain injury which she said was due to a vaccination. *Id.* He told her that it was pretty clear at that time that she did not have a brain injury and he really had a lot of doubts that she had CIDP or anything like it. Tr. at 9.

What petitioner described as her symptoms after the hepatitis B vaccination were typically nonspecific where people get a headache, fatigue, dizziness, numbness, and aches, which is not distinguishable from a whole lot of other things. *Id.* It eventually came to light that petitioner had also had some of these symptoms before the hepatitis B vaccination: headache, fatigue, numbness, and dizziness. Tr. at 9-10. These symptoms can come from any source, including IVIG or the flu. They are non-specific symptoms and also typical of vaccine reactions. They are self-limiting. Tr. at 10.

The undersigned read to Dr. Hughes a definition of panic disorder<sup>12</sup> from Harrison's Principles of Internal Medicine, a medical text whose reliability he accepts. Tr. at 11. He stated that petitioner had at least four symptoms, if not a few others, of panic disorder. Tr. at 12. But these symptoms are not specific just for panic disorder. *Id.* He explained petitioner's pre-hepatitis B vaccination anxiety and panic in 2000 to her having lost a fetus at 17 weeks. Tr. at 13.

When Dr. Hughes spoke to petitioner in May 2006, he thought she was fine. *Id.* He considered her vaccine reaction to be transient. He told her to declare herself normal and she did just that. Tr. at 14. He thought maybe petitioner had a general systemic set of non-specific symptoms after hepatitis B vaccination which indicated a general inflammatory process. Tr. at 17. Dr. Hughes thought petitioner had a transient sort of normal reaction to the vaccine that lasted longer than normal. Tr. at 18. He even thought she might have small fiber sensory polyneuropathy. Tr. at 19. When the undersigned asked how someone could have small fiber

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<sup>12</sup> "At least four of the following symptoms developed during at least one of the attacks.

1. Shortness of breath (dyspnea) or smothering sensations
2. Dizziness, unsteady feelings, or faintness
3. Palpitations or accelerated heart rate
4. Trembling or shaking
5. Sweating
6. Choking
7. Nausea or abdominal distress
8. Depersonalization or derealization
9. Numbness or tingling sensations (paresthesias)
10. Flushes or chills
11. Chest pain or discomfort
12. Fear of dying
13. Fear of going crazy or of doing something uncontrolled."

Harrison's Principles of Internal Medicine, 13<sup>th</sup> ed., Vol. 2, ed. Isselbacher, et al. (1994), pt. 14, at 2410.

sensory polyneuropathy without having pain, Dr. Hughes suggested someone could have small fiber sensory polyneuropathy with numbness or nonspecific tingling instead of pain. Tr. at 20. However, Dr. Hughes admitted he was not diagnosing petitioner with either CIDP or small fiber sensory polyneuropathy. *Id.* This was certainly not clear-cut or permanent. Tr. at 21.

In a broad sense, Dr. Hughes thought petitioner had a generalized systemic reaction to vaccination. Tr. at 22. He described three types of reaction to vaccination: (1) a local systemic reaction at the vaccine site; (2) a generalized sort of systemic reaction with fatigue, malaise, dizziness or lightheadedness (which petitioner had); or (3) a severe neurologic event like CIDP, Guillain-Barré syndrome, transverse myelitis, or MS. Tr. at 23. Petitioner was not in that third group. Tr. at 24. She had a mild reaction. *Id.* He did not disagree with petitioner's primary doctor, Dr. Rosenblum, who diagnosed petitioner with panic disorder and anxiety and prescribed Lexapro and Wellbutrin to treat them. *Id.*

Dr. Hughes stated that Dr. Andrew Campbell ran a practice whose goal was to encourage people to have more symptoms and to believe that they are victims. Tr. at 32. Petitioner did not have CIDP and Dr. Hughes stated that he ignored Dr. Campbell's diagnosis. *Id.* He thinks hepatitis B vaccine was the probable cause of petitioner's condition because of the temporal relationship and appropriate initial symptoms. Tr. at 33.

The undersigned asked Dr. Hughes how long he thought petitioner's reaction to hepatitis B vaccine probably lasted. He attributed her pre-vaccination dizziness, nervousness, shakiness, and panic attacks in 2000 to having a miscarriage and getting pregnant again. Tr. at 36. He accepted the diagnosis of her panic attacks in 2000. Tr. at 37. Dr. Hughes stated that petitioner probably had a vaccine reaction for a couple of weeks and, after the first couple of weeks, it was

possible. Tr. at 39. He said this was obviously speculative, but he thought he was okay with a probable vaccine reaction for the first month, maybe two months. *Id.* It was possible about three months later. Tr. at 40. Dr. Hughes said he would not argue with a vaccine reaction of two or four months, somewhere around there. He would not argue with six weeks. *Id.* Dr. Hughes finally said that it would be fair to say that he would accept a probable vaccine reaction up to three or four months, but after that time period, a vaccine reaction would be possible. *Id.*

Petitioner's counsel Ms. Ho interjected that she thought Dr. Hughes did not know the difference between "probable" and "possible." Tr. at 43. The undersigned defined "probable" as being more likely than not, and "possible" as being maybe/maybe not, and asked Dr. Hughes if he had a problem with those definitions. Tr. at 43-44. He said he had no problem with those definitions. Tr. at 44. He said that was how he had been trying to use those terms. Tr. at 45.

Dr. Hughes repeated his opinion about how long petitioner's vaccine reaction lasted. Tr. at 46. He thought it was probable that she had a vaccine reaction that lasted for the first three, maybe four months. *Id.* He believes it was probable that petitioner was normal in the summer of 2003, but other than that, it was hard for him to say. *Id.*

Dr. Martin Bielawski, a neurologist, testified for respondent. Tr. at 51. His opinion is that petitioner had a local reaction to hepatitis B vaccine and nothing more. Tr. at 55. Generally, local reactions last several days. She had residual symptoms for one to two weeks. Probably, beyond a few weeks, petitioner did not have a vaccine reaction. *Id.* Her laboratory findings do not document a vaccine reaction. Tr. at 56. On June 21, 2002, she went to Suburban Hospital ER (Ex. 9, p. 9), and was described as afebrile, with normal vital signs, and a normal examination. *Id.* She was described as pleasant and in no distress. *Id.* Her blood test, including

testing of her white blood cells (which are a marker for inflammation or infection), was normal. *Id.* She had four EMGs in August and September 2003 and in May and November 2004 which showed she did not have generalized demyelinating polyneuropathy. Tr. at 57. Her minor findings on EMG were due to technical problems. Tr. at 57-58. She had a prolonged right wrist motor study which was just above normal, but 10 days later, her EMG found no abnormalities. Tr. at 58.

Petitioner had dizziness and panic attacks prior to her hepatitis B vaccinations. Dr. Bielawski does not accept Dr. Hughes' opinion that her dizziness and panic attacks were all due to pregnancy. Tr. at 59. She had repeated anxiety and multiple visits to doctors who diagnosed panic attacks. *Id.* She also had inner ear weakness found on an electronystagogram (ENT). *Id.* The inner ear dysfunction in her left ear can account for some of her vertigo symptoms which she described as dizziness and is unrelated to hepatitis B vaccination. Tr. at 59-60. Throughout the medical records, petitioner had a history of stress, sometimes related to her job. Tr. at 60.

Dr. Bielawski stated petitioner did not have small fiber sensory polyneuropathy. Usually patients with this disease have pain as well as dysesthesia (uncomfortable feelings). Tr. at 61.

Dr. Bielawski noted that one week before petitioner received hepatitis B vaccine, she had an insect bite that crusted over. Tr. at 61-62. She could have had a reaction to this bite which would be inflammatory and cause systemic symptoms. Tr. at 62.

He agreed that petitioner had a local vaccine reaction that was self-limited. *Id.* The numbness in her right hand in the fourth and fifth fingers was due to local nerve compression at her elbow. Tr. at 62-63. Other neurological symptoms were non-specific and not related to vaccination. Tr. at 63. Petitioner's complaints from 2000 through 2007 fit within the diagnosis

of anxiety and panic attacks. Tr. at 64. When petitioner had anxiety and panic attacks in November 2002, her facial, hand, and foot numbness, spasms, tingling in the fingertips, shortness of breath, and chest pain were textbook symptoms for hyperventilation syndrome, often associated with panic attacks. Tr. at 64. An elbow neuropathy comes from leaning too hard on or hitting one's elbow. Tr. at 65. Dr. Bielawski stated that throughout the course of petitioner's postvaccination evaluations, a lot of her experiences are attributable to panic and anxiety. *Id.*

### **DISCUSSION**

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must “show by preponderant evidence that the vaccination brought about her injury by providing: (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[.]”

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said “we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen....”

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6<sup>th</sup> Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had chronic polyneuropathy or unspecified vaccine reaction, but also that the vaccine was a substantial factor in bringing about her chronic polyneuropathy or unspecified vaccine reaction. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

There are a number of problems with this case. The first problem is that petitioner did not have a neurological disorder. Petitioner did not have demyelinating disease, much less MS, TM, GBS, or CIDP which were the diseases discussed in the Omnibus proceeding concerning hepatitis B vaccine and demyelinating diseases. Therefore, the undersigned's holdings in the four paradigm cases in the Omnibus proceeding do not apply to her.

Petitioner saw two neurologists, an otolaryngologist, and other doctors before she found Dr. Campbell. None of the doctors before she saw Dr. Campbell in August 2003 opined that she had a neurologic disease. She might have mild carpal tunnel syndrome. She might have compressed an elbow nerve. She might have had an inner ear problem.

The undersigned finds Dr. Hughes' opinions not credible. He dismissed petitioner's diagnosis of panic disorder, even though he said she had more than the required minimum four symptoms of panic disorder to justify the diagnosis. He said she was panicked in 2000 because she had just lost a fetus and was pregnant again. But Dr. Hughes omits consideration of petitioner's trip to a doctor two months before her first hepatitis B vaccination in 2002 when she

complained of dizziness and lethargy for one to two weeks and subjective weight loss. She was not pregnant at the time. Moreover, all of petitioner's other doctors diagnosed her with anxiety and panic disorder, and she remains on drugs to treat these disorders to this day. In the medical records, she was diagnosed with anxiety or panic attacks 16 times. The undersigned finds that Dr. Bielawski, respondent's expert, is much more credible on the issue of whether petitioner had and has panic disorder. She did and does.

Dr. Hughes is also not credible when he testified that petitioner had small fiber sensory polyneuropathy as an explanation for why her nerve conduction tests and electromyography were normal. When the undersigned asked Dr. Hughes whether pain was the hallmark of small fiber sensory, yet petitioner never complained of pain, he said that numbness could also be a symptom. But petitioner never had numbness except for a couple of fingers when she was diagnosed with an ulnar nerve problem either from hitting her elbow or leaning on it. Dr. Hughes retreated from his diagnosis of small fiber sensory polyneuropathy. The undersigned finds that Dr. Bielawski is much more credible on the issue of whether petitioner ever had small fiber sensory polyneuropathy. She did not. (And Dr. Hughes finally admitted that she did not have this.)

The only opinion that petitioner had a neurologic disease came from Dr. Campbell, who is not a neurologist or an immunologist (and now cannot legally practice medicine). The audiologist who thought she might have peripheral pathology is not a medical doctor and the undersigned does not accept medical opinions from persons who are not medical doctors. Domeny v. Secretary of HHS, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999), aff'd, (Fed. Cl. May 25, 1999) (unpublished), aff'd, 232 F.3d 912 (Fed. Cir. 2000) (per curiam) (unpublished) (proffer of dentist's testimony for diagnosis of a neuropathy rejected).

To every doctor that petitioner saw after she received her 2002 hepatitis B vaccinations, she gave a history that her symptoms of lightheadedness, dizziness, and weakness started right after the second vaccination and that, before the vaccinations, she was healthy. This history is untrue. Her own medical records show that two years before she received the 2002 vaccinations, petitioner complained of lightheadedness, dizziness, and weakness. She was diagnosed in 2000 with panic disorder and anxiety. On March 13, 2002, two months before she had her first hepatitis B vaccination, petitioner saw her doctor, complaining of dizziness and lethargy for one to two weeks, and a weight loss which her physician found subjective. Dr. Hughes ascribed her 2000 dizziness and panic attacks to her having lost a fetus and becoming pregnant again. But petitioner was not pregnant on March 13, 2002. Yet the same symptoms she complained about after the vaccinations were the ones she had before them even when not pregnant. Petitioner was diagnosed with panic disorder constantly in her records dating from 2000 to 2007, and her treating doctors are still prescribing medication to deal with her anxiety and panic disorder.

According to Dr. Hughes, her vaccine reaction probably lasted three to four months, which means that by mid-October 2002, she was probably no longer ill from vaccination. Yet, for the last five years, she has been under treatment for panic disorder and anxiety for the very same symptoms she has been complaining about since 2000.

To every doctor that petitioner saw after she began seeing Dr. Andrew W. Campbell, who diagnosed her with CIDP and started her on IVIG therapy, she gave a history that she had CIDP. This includes Dr. Hughes, the neurologist who testified for her. But a reading of Dr. Campbell's own records shows that, in spite of petitioner's having a normal nerve conduction study, normal electromyography, and normal reflexes, Dr. Campbell diagnosed her with CIDP. It is impossible

to have CIDP without demyelination. It is also impossible to have CIDP without polyneuropathy.

The Texas Medical Board finally caught up to Dr. Campbell's unprofessional and fraudulent behavior, suspending his medical license until February 8, 2008, subject to his undergoing rigorous training and fulfilling other criteria specified above.

Dr. Hughes stated petitioner is healthy because he convinced her in May 2006 to think of herself as a healthy person and to develop healthy habits such as getting more sleep, exercise, salt, and fluid intake. When he saw her in November 2006, he thought she looked great. However, her treating physician Dr. Rosenblum still has her on anti-anxiety medication. Dr. Hughes has deliberately overlooked petitioner's longstanding and continuing panic disorder and anxiety in his testimony. As respondent's expert Dr. Bielawski testified, the symptoms of panic disorder fit her complaints perfectly.

But, beyond Dr. Hughes' refusal to give credence to petitioner's panic disorder, petitioner has a legal problem with his opinion: he testified that her vaccine reaction probably lasted three or four months. (The undersigned notes that Dr. Hughes' first description of how long petitioner's vaccine reaction lasted was two weeks. He then went to a month or two, and finally ended at three to four months. This was as far as he would go in terms of probable reaction.) After four months, he testified that petitioner had only a possible vaccine reaction. He admitted he was speculating. He would say only that when she reached mid-summer 2003 (when she went to Texas to seek out Dr. Campbell), she was probably normal.

Petitioner's burden is to prove that she had a vaccine injury that more probably than not lasted more than six months. Dr. Hughes has not satisfied petitioner's burden since his testimony is that her vaccine reaction lasted probably only three to four months. He would not go beyond

that time limit, although petitioner's counsel encouraged him to do so. Petitioner's counsel tried the gambit that Dr. Hughes did not understand the difference between "probable" and "possible," but, when the undersigned defined the two words for him, he agreed totally with the undersigned's definitions.

Petitioner's counsel was under the impression at the end of this short hearing that since Dr. Hughes said petitioner was probably normal in the summer of 2003, he had changed his testimony from probable vaccine reaction of three to four months to probable vaccine reaction for longer than the statutorily-required six months. But Dr. Hughes did not change his testimony. He opined that petitioner's probable vaccine injury lasted three to four months, that she was probably normal in summer 2003, and that it would be hard for him to say anything else. In other words, Dr. Hughes stayed with his prior testimony that any vaccine reaction after three to four months was possible, not probable.

It was incumbent upon petitioner's counsel to find out before the hearing whether or not Dr. Hughes' opinion would satisfy petitioner's burden of proof. That petitioner's counsel obviously did not do so (and the undersigned assigns the major blame to Mr. Homer who has vast experience in the Vaccine Program) means that there was no reasonable basis to go forward with this case to hearing. Not only were Dr. Hughes' and Dr. Bielawski's busy schedules imposed upon in order for them to prepare for and testify in this case, but also counsel's and the undersigned's time and efforts were unnecessarily expended in this case because petitioner's counsel would not recognize that petitioner could not make a prima facie case. The undersigned expressly warned petitioner's counsel Mr. Homer and Ms. Ho during a status conference on

November 1, 2007 that the undersigned believed there was no reasonable basis for having a hearing. Mr. Homer insisted on going forward with the hearing.

If petitioner's counsel had appropriately discussed this case with Dr. Hughes, they would have learned that his opinion does not satisfy the Vaccine Act's requirement for proving a prima facie case by preponderant evidence that the vaccine injury lasted more than six months. The undersigned can only assume petitioner's counsel never asked Dr. Hughes how long petitioner had a probable vaccine reaction, and was unpleasantly surprised when he answered at the hearing that it probably lasted only three to four months.

Petitioner has failed to prove a prima facie case of causation in fact.

### **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.<sup>13</sup>

**IT IS SO ORDERED.**

December 17, 2007  
DATE

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

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<sup>13</sup> 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.