In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. [redacted] V
Originally Filed: May 24, 2010
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To be Published

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JANE DOE/68,	*	
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Petitioner,	*	
	*	
v.	*	Hepatitis B vaccine; fatigue;
	*	long history of chronic
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	inflammation
	*	
	*	
Respondent.	*	
* *		

Clifford J. Shoemaker, Vienna, VA for petitioner.
Heather Pearlman, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Petitioner filed a petition on July 28, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she received hepatitis B vaccine on January 5, 1995, February 17, 1995, and August 2, 1995 and experienced an adverse reaction. Petitioner submitted proof of vaccination. Med. recs. at Ex. 14, p. 1.

[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.

Between petitioner's second and third hepatitis B vaccination, she sustained an injury to one of her breast implants while wrestling on the floor with her family. After the third hepatitis B vaccination, petitioner complained of extreme fatigue. Four years later, she had her breast implants removed.

On July 28, 1999, the case was assigned to former chief special master Gary J. Golkiewicz.

On August 13, 1999, then-chief special master Golkiewicz issued an Order in this and 80 other cases that petitioners must file required medical documentation.

On December 19, 1999, petitioner's counsel filed a Motion to Designate Master File in this and in 135 other cases, requesting then-chief special master Golkiewicz to designate Dunbar v. Sec'y of HHS, No. 98-627V,[2] as a master file for the purpose of filing documents that would be common to all 136 cases.

On January 5, 2000, respondent filed a Response to Petitioner's Motion to Designate Master File, recommending denial of the motion. Cases concerning hepatitis B vaccine with varying medical conditions alleged as reactions numbered 275, of which petitioner's counsel represented 137 clients.

On February 14, 2000, then-chief special master Golkiewicz denied petitioner's motion to designate.

On February 15, 2000, May 16, 2000, August 21, 2000, and December 2, 2000, petitioner filed a status report stating she was attempting to gather medical records.

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[2] The undersigned issued a Ruling on Entitlement in petitioner's favor in Dunbar on September 14, 2007. 2007 WL 2844826. The undersigned issued an unpublished decision on damages in Dunbar on October 2, 2009. Judgment entered on October 16, 2009.

On March 15, 2001, petitioner filed a status report stating she was working on her affidavit.

On April 5, 2001, then-chief special master Golkiewicz transferred this case to special master Richard Abell.

On July 31, 2001, petitioner moved for authority to issue subpoenas which, on August 14, 2001, special master Abell granted in an Order.

On July 9, 2002, special master Abell issued an Order reflecting that there was a Hep B Committee formed to handle cases of this sort and petitioner could temporarily stay the action or else file a medical expert report by August 29, 2002.

On July 19, 2002, petitioner filed a status report that she elected to participate in the resolution process created by the Hepatitis B Steering Committee.

On December 5, 2002, then-chief special master Golkiewicz transferred this case back to himself to pursue proceeding with a Hepatitis B Steering Committee. The case was categorized as hepatitis B-neurological-demyelinating.

On May 7, 2003, the Committee having not resolved the issues, then-chief special master Golkiewicz transferred this case to then-special master (now Judge) Margaret M. Sweeney as part of a hepatitis B-neurological demyelinating Omnibus proceeding.

On May 20, 2003, then-special master Sweeney issued an Order reflecting the selection of lead or paradigm cases in the Omnibus proceeding.

On July 24, 2003 and August 29, 2003, petitioner filed medical records (Exs. 14-24) and, on December 19, 2003, she filed her affidavit.

From October 13-15, 2004, former special master Sweeney held an Omnibus hearing in the 65 hepatitis B vaccine-demyelinating injury cases.

In January 2006, the 65 cases comprising the Omnibus proceeding were transferred to the undersigned. The instant action was transferred to the undersigned on January 11, 2006. In the four paradigm decisions from the Omnibus proceeding that the undersigned issued[3] concerning hepatitis B vaccine and demyelinating diseases, the undersigned held that hepatitis B vaccine could and did cause the diseases, and that the medically appropriate time frame between hepatitis B vaccine and the onset of Guillain-Barré syndrom (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP), transverse myelitis (TM), and multiple sclerosis (MS) is between three and 30 days, based on the testimony of petitioners' expert Dr. Vera Byers and respondent's expert Dr. Roland Martin. Stevens v. Secretary of HHS, No. 99-594, 2006 WL 659525, at *12, *15 (Fed. Cl. Feb. 24, 2006).

On October 20, 2006, petitioner in the instant action filed more medical records (Ex. 25).

On December 15, 2006, the undersigned issued an Order to Show Cause to petitioner to show why the case should not be dismissed because the only doctor among many that petitioner saw who diagnosed her with chronic inflammatory demyelinating polyneuropathy was the notorious Dr. Andrew W. Campbell. Order at p. 29. The undersigned recounted Dr. Campbell's

[3] Stevens v. Secretary of HHS, No. 99-594, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006) (hepatitis B vaccine caused TM; onset was 12 or 13 days after first vaccination with recovery; onset of TM was one week after second vaccination); Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006) (hepatitis B vaccine caused GBS and CIDP; onset was 21 days after second vaccination); Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006) (hepatitis B vaccine caused MS; onset was one month after second vaccination); Peugh v. Secretary of HHS, No. 99-638V, 2007 WL 1531666 (Fed. Cl. Spec. Mstr. May 8, 2007) (hepatitis B vaccine caused GBS and death; onset of GBS was eight days after fourth vaccination).

travails with the Texas Medical Board as it attempted to suspend his medical license. Order at pp. 29-30.

On February 23, 2007, petitioner filed her response to the undersigned's Order to Show Cause, admitting that petitioner never had a diagnosis of a demyelinating disease but emphasizing that she was ill after her second and third vaccinations. Response at pp. 16-17. Petitioner wanted the opportunity to have an expert review the case. (This was eight years after petitioner filed her petition.)

On February 26, 2007, the undersigned issued an Order for petitioner to file an affidavit and expert report by April 27, 2007.

On April 27, 2007, petitioner filed her affidavit (Ex. 26). On the same day, she moved for an extension of time until May 29, 2007 to file an expert report which the undersigned granted on the day of her motion.

On May 28, 2007, petitioner moved for another extension of time to file Dr. Joseph Bellanti's report which she then filed on May 29, 2007 (Ex. 27). Dr. Bellanti is an immunologist. After recounting petitioner's lengthy medical consultations, including feeling faint, and having low blood sugar, frequent urinary infections, fatigue, and memory loss, Dr. Bellanti states at p. 7 of his report that "it appears that some 11 years after her vaccinations, there was no discernible neurologic injury, and most of [petitioner]'s symptoms were attributed to anxiety and possible depression." He notes that petitioner complained of "a peculiar illness" after her second hepatitis B vaccination about which she informed her gynecologist two months later, but her subsequent assertion in her affidavit that she had the same but worse symptoms after her third hepatitis B vaccination was not documented because she did not seek medical

assistance. Id. Therefore, he says there is no documentation to support a conclusion of positive rechallenge. Id. Dr. Bellanti focuses on a pathology note dated April 1, 1999 (Ex. 8, pp. 10-11) revealing that microscopic examination showed crystalloid material of silicone beyond the surface capsule in the right breast scar tissue (where petitioner had injured herself wrestling with her family) and present in the histiocytes[4] in the left breast. Petitioner had silicone-capsuled saline breast implants inserted in 1989. Id. at 1, 5, 6. Dr. Bellanti questions at p. 7 of his report whether petitioner's fatigue and other symptoms were due to low-grade silicone toxicity which perhaps hepatitis B vaccinations in January, February, and August 1995 exacerbated. The presence of silicone in histiocytes clearly suggested to Dr. Bellanti that petitioner had a systemic reaction to the presence of silicone. He continues, "It is entirely possible that in combination with her implants, which may have caused some autoimmune response, the immunizations exacerbated that response and led to a more extensive autoimmune reaction." Id. at 7-8. Commenting that petitioner's first complaint of fatigue was between her second and third hepatitis B vaccinations, Dr. Bellanti concludes:

> [T]here was a pathological reaction to silicone, even though there was little clinical evidence of it. There was evidence of an autoimmune reaction following the vaccinations.... The client's story is cohesive, and the records tend to support it, even though the workup at the time was inadequate to conclusively document an autoimmune reaction. It is my opinion that, more likely than not, the hepatitis B vaccinations acted as triggers to express

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[4] A histiocyte is a macrophage. Dorland's Illustrated Medical Dictionary (30th ed.) (2003) at 855. A macrophage is "any of the many forms of mononuclear phagocytes found in tissues. ... Their functions include nonspecific phagocytosis...; ...killing of ingested microorganisms; digestion and presentation of antigens to T and B lymphocytes...." Id. at 1085. A phagocyte is "any cell capable of ingesting particulate matters.... Such cells ingest microorganisms and other particulate antigens that are opsonized (coated with antibody or complement), a process mediated by specific cell-surface receptors...." Id. at 1413.

> [petitioner]'s underlying autoimmune reaction to the breast implants. In other words, the vaccinations were like blasting caps that trigger an explosion that is set to take place.

Id. at 8.

On July 16, 2007, petitioner filed a statement from her daughter Jessica (Ex. 28) and a friend Laurie (Ex. 29). Jessica stated her mother was always very active and vibrant until the spring of 1995. Ex. 28. Petitioner's symptoms were gradual but she became extremely fatigued and slept a lot. Id. She began to recover over two years and is now almost back to normal. Id. Laurie states that she has been petitioner's friend for 37 years and petitioner had always been healthy and energetic. Ex. 29. When petitioner became ill in 1995, Laurie was very concerned. Petitioner spent 18 hours in bed a day. Id.

On July 17, 2007, the undersigned issued a Report to the Parties discussing Dr. Andrew W. Campbell's legal dispute with the Texas Medical Board and the Board's suspension of his medical license. (Dr. Campbell was the doctor who diagnosed petitioner with CIDP and gave her intravenous immunoglobulin or IVIG treatments.)

On July 25, 2007, respondent filed her Rule 4(c) Report. Respondent questioned whether petitioner ever had CIDP, particularly since her treating neurologist Dr. Bhat stated that she did not have a demyelinating condition and her symptoms were most likely due to anxiety and possible depression. Report at 8. Respondent sent the case to Dr. Alan Brenner for review, and concluded that Dr. Bellanti's opinion is not persuasive since none of petitioner's doctors linked petitioner's having an adverse reaction to silicone implants with hepatitis B vaccination. Id. at 9.

On August 21, 2007, respondent filed the expert report of Dr. Alan I. Brenner (Ex. A) together with his C.V. (Ex. B). Dr. Brenner was a rheumatologist.[5] Dr. Brenner noted that even prior to her first hepatitis B vaccination on January 5, 1995, petitioner had considerable evidence of multiple medical problems including several spontaneous miscarriages, an automobile accident with cervical injury (with another automobile accident on July 11, 1995), a long history of urinary tract symptoms without cultures positive for bacteria, and commonly reported complaints of fatigue, headache, nausea, and backache. Ex. A at 3.

Petitioner wrote in an answer to a questionnaire for Dr. Campbell on October 21, 1998 that she had a 25-year history of irritable bowel syndrome, although no medical record confirms this history. Id. On September 10, 1996, petitioner's CA 125[6] level was elevated at 52 (the normal range is 0-35). A subsequent CA 125 on October 18, 1996 was reported as 25. Id. at 4. Petitioner saw Dr. William Smits, an allergist, on February 19, 1998 who diagnosed her with allergy to foods, dust/dander, hay fever, and dyspepsia.[7] Id. Dr. Smits initiated immunotherapy, treating petitioner with 80 mg. of Dep Medrol.[8] Id. Dr. Kenneth Smith, a rheumatologist, diagnosed petitioner in 1998 with fibromyalgia and thought she did not have an underlying

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[5] Dr. Brenner unfortunately died recently.

[6] CA 125 is a test "for cell-surface antigen found on derivatives of coelomic epithelium. Elevated levels of this antigen are associated with ovarian malignancy and benign pelvic disease such as endometriosis." Stedman's Medical Dictionary (27th ed.) (2000) at 1800.

[7] Dyspepsia is "epigastric discomfort following meals" reflecting "impairment of the power or function of digestion." Dorland's Illustrated Medical Dictionary (30th ed.) (2003) at 576.

[8] Medrol is methylprednisolone. Dorland's Illustrated Medical Dictionary (30th ed.) (2003) at 1112. Methylprednisolone is "a synthetic glucocorticoid derived from progesterone, used in replacement therapy for adrenocortical insufficiency and as an antiinflammatory and immunosuppressant in a wide variety of disorders...." Id. at 1147.

inflammatory process. Id. at 5. After Dr. Joseph Mlakar removed petitioner's breast implants in 1999, a pathology report noted focal chronic inflammation from both implants. Id. Petitioner had extensive calcification and leaking of silicone in both breasts, more on the right than the left. Id.

In 2006, petitioner was examined and tested by the neurologist Dr. Madhav Bhat and found to have negative/normal results for any neurologic illness. Id. at 6. He ascribed her symptoms to underlying anxiety and possible depression, prescribing Prozac. Id. Dr. Brenner noted that the medical records document fatigue in association with urinary tract symptoms, nausea, headache, and back pain as far back as November 30, 1993, continuing through September 21, 1995. Id. Dr. Brenner expressed doubt that petitioner had an autoimmune disease due to breast implants because they were not removed until March 9, 1999 whereas the tests done for autoantibodies in 1997 were negative (and this was after 10 years of silicone exposure). Id. at 7. Dr. Brenner stated:

> Thus, there is no evidence, from the medical record or relevant medical literature supporting Dr. Bellanti's theory of silicone induced autoimmunity then triggered by hepatitis B vaccinations into the development of an autoimmune disease. Indeed, there is no evidence that [petitioner]'s condition was in any way autoimmune in nature. Her very long history of noninfectious urinary tract symptoms, her history as per her report by data form to Dr. Campbell of irritable bowel syndrome (IBS), the concomitant development of depression, diffuse musculoskeletal pain, disordered sleep, perceived memory deficit and difficulty with concentration would much more indicate a diagnosis of fibromyalgia (FMS) with multiple co-morbid functional syndromes (the central sensitivity syndromes) with onset long predating hepatitis B vaccination, likely as far back as the onset of her urinary tract complaints and consistent with the 25 years of IBS reported by the history form to Dr. Campbell. Despite Dr. Smith's failure to document a tender (not trigger) point examination, this would argue strongly in favor of his diagnosis of

> FMS and is supported by the studies and opinions expressed in 2006 by Dr. Bhat. (Ex. 25, P. 21 & P 4) It should also be noted that a tender point exam is not required for the clinical diagnosis of FMS, only for the classification of a musculoskeletal pain syndrome as FMS for patient grouping for study purposes. With the wealth of supporting history and the lack of any evidence of an immune inflammatory process, FMS appears a most logical and appropriate diagnostic appellation to describe [petitioner]'s condition.

Id. at 7. Dr. Brenner concluded that there was no association between the hepatitis B vaccinations of January 5, 1995, February 17, 1995, and August 2, 1995 and petitioner's "multiple central sensitivity syndromes whose onset documents long predates her vaccinations." Id.

On August 28, 2007, the undersigned held a telephonic status conference with the parties during which petitioner's counsel agreed that this was not a strong case. He wanted to talk to petitioner and to Dr. Bellanti who did not write a strong opinion.

On October 4, 2007, petitioner filed her husband's statement. Ex. 30. He states that before the vaccinations, his wife was very healthy and exercised regularly. After the vaccinations, her health deteriorated and she was fatigued. Id.

On October 11, 2007, respondent filed Ex. C, tabs 1-13, comprising medical literature upon which Dr. Brenner relied.

On October 24, 2007, petitioner filed additional medical records (Exs. 31-33).

On November 15, 2007, the undersigned held a telephonic status conference with the parties. Petitioner's counsel was in exactly the same posture as at the end of August: he wanted to set up a conference call with petitioner and Dr. Bellanti to discuss if the case should go forward.

On January 18, 2008, the undersigned held a telephonic status conference with the parties. Petitioner's counsel stated that Dr. Bellanti was working on a supplemental report and Dr. Yehuda Shoenfeld, another immunologist, was reviewing the medical records. By Order of the same date, the undersigned gave petitioner until March 18, 2008 to file a supplemental report from Dr. Bellanti and an expert report from Dr. Shoenfeld.

On March 18, 2008, petitioner moved for an enlargement of time, saying that Dr. Bellanti and Dr. Shoenfeld needed 30 more days.

On April 18, 2008, petitioner's counsel orally moved for another 30-day extension which the undersigned granted on that same date.

On May 19, 2008, petitioner's counsel orally moved for another 30-day extension which the undersigned granted on May 22, 2008.

On June 19, 2008, petitioner's counsel orally moved for another 30-day extension to file Dr. Bellanti's report which the undersigned granted on that same date. Petitioner filed Dr. Shoenfeld's expert report and C.V. (Exs. 34 and 35).

Dr. Shoenfeld states that he is the founder and director of the Center for Autoimmune Diseases at the Sheba Medical Center which is affiliated with the Sackler Faculty of Medicine at Tel Aviv University and he has headed the Department of Medicine there since 1984. Ex. 34, p. 1. His clinical and scientific works focus on autoimmune/rheumatic diseases. Id. He has published more than 1,400 papers in peer-reviewed journals and his works have been cited more than 10,000 times. Id. He has authored and edited 10 books which Elsevier has published and is on the editorial board of 32 journals in the fields of autoimmunity and rheumatology. Id.

Dr. Shoenfeld states that petitioner's recurrent cystitis began in 1973. Until 1989 (when petitioner had breast implants), petitioner complained on three occasions of fatigue, nausea, and backache in association with urinary tract symptoms. Id. at 2. After the vaccinations and an injury to her right breast with local inflammation and lymphadenopathy, Dr. Shoenfeld opines that petitioner had central sensitivity (pain) syndrome. Id. at 7. He defines this syndrome as encompassing a "spectrum of fatigue and pain syndromes as chronic fatigue, fibromyalgia, temporomandibular joint disorder, irritable bowel and the gulf war syndromes." Id.

He further states that petitioner had a complex disease that includes immunological and neurological insults. He states the immunological insults were not compatible with a defined autoimmune disease. Neurologically, she had an unspecified demyelinating illness. Id. He states her illness started after her second hepatitis B vaccination and was augmented after her breast injury and the third vaccination. Id. He proceeds to discuss vaccines and autoimmunity in a lengthy dissertation that seems addressed for use in a number of cases. Id. at 8-15. In a general discussion of adjuvants, Dr. Shoenfeld states that silicone acts as an adjuvant to the immune system. Id. at 16-17. He continues:

> In [the] human breast[,] prostheses cause a mild foreign body response that result[s] in the formation of a collage[n]ous capsule around the prosthesis. Many such patients may show evidence of a microscopic granulomatous foreign body reaction upon examination of capsular material at explantation of [the] prosthesis. Furthermore silicone breast implant rupture is very common and can pass unnoticed for many years by both patient and physician. The loss of envelope integrity allows capsular silicone ... to escape into surrounding tissues, regional lymph nodes and the circulatory system. Silicone leakage can be asymptomatic or present with a range o[f] symptoms from mild local inflammation with lymph node enlargement, to gross changes in breast size and silicone leakage to other body parts. Furthermore silicone leak may become a chronic process clinically

> and histological[l]y (e.g. granuloma, calcification etc[.]). The systemic effect of implant ruptures and silicone leak was studied by Vermeulen and Scholte in 2003, and a strong correlation between implants envelope rupture and chronic systemic symptoms as **fatigue, impaired memory, headache, muscle and joint pain** was observed. [citations omitted; emphasis in the original.]

Id. at 18.

In describing the instant action, Dr. Shoenfeld states that petitioner had fatigue, weakness, headaches, and nausea following her second hepatitis B vaccination at the same time that she had breast inflammation with lymph node enlargement. Id. at 20. After her third hepatitis B vaccination, her symptoms worsened and became chronic. Id. He states her symptoms are consistent with chronic pain syndrome. Id. at 21. Dr. Shoenfeld states petitioner's biopsy showing immune cell infiltration, chronic inflammation, and extensive calcification in both breasts in every microscopic field strongly supports a chronic immune process associated with the silicon leak. Id. at 22. She might also have had silicone leakage before the third hepatitis B vaccination when she had breast injury and inflammation. Id. He concludes "it is likely that the silicone from her breast implant served as an immune stimulator-**adjuvant** that has augmented the response to hepatitis B vaccine." Id. (emphasis in original). His opinion is that hepatitis B vaccine caused petitioner's rapid onset of problems possibly augmented by the adjuvancy effect of silicone.

On August 20, 2008, respondent orally moved for an additional 30 days to file Dr. Brenner's supplemental expert report which the undersigned granted in an Order of that date.

On September 19, 2008, respondent filed a Motion for Extension of Time until November 3, 2008 to file a report from a new expert because Dr. Brenner had to withdraw from the case due to illness. On September 23, 2008, the undersigned granted respondent's motion.

On October 9, 2008, respondent filed the expert report of Dr. Lawrence Kagen, a rheumatologist (Ex. C) together with his C.V. (Ex. D). Dr. Kagen comments that petitioner had a long history of urinary tract infection and inflammation years antecedent to vaccination. Ex. C at 2. "Because of persistent recurrent symptom,s [sic] often in the absence of bacteria in the urine, cystoscopies were performed three times between 1993 and 1994." Id. He notes that petitioner's expert Dr. Bellanti admits that the record contains no evidence of an autoimmune reaction to either breast implants or vaccination. Id. at 5. Dr. Kagen said there is no evidence to link petitioner's symptoms to vaccination other than temporal association. Id. at 6. He thinks petitioner's illness was the result of pre-existing conditions, anxiety, and depression. Id. at 7.

On October 14, 2008, petitioner filed an article published in Autoimmunity Reviews that Dr. Shoenfeld co-authored which addresses the instant case (Ex. 36). Discussion was ongoing for months concerning when the parties could obtain Dr. Shoenfeld's testimony since he was in Israel and, through past experience, telephonic transmission of his testimony was difficult to comprehend.

On February 3, 2009, the undersigned set a hearing for May 22, 2009. Delay in setting the hearing was necessitated by Dr. Shoenfeld's schedule. However, it turned out that the videoconferencing supposedly arranged for May 22, 2009 was not actually done and the hearing date had to be postponed.

On May 13, 2009, the undersigned set a hearing for July 28, 2009 with petitioner, Dr. Shoenfeld, and Dr. Kagen as in-person witnesses. The Order stated that all exhibits had to be filed by July 14, 2009.

On July 27, 2009, the day before the hearing, petitioner filed three articles as Exs. 37-39: "Autoimmunity and the environment. Infections and autoimmunity – friends or foes?" by S. Kivity, et al. (Dr. Shoenfeld is a co-author) [there is no indication where this article was published but the undersigned was informed at the hearing that it was published in Trends of Immunology] (Ex. 37); a draft of an article entitled "Adjuvants and autoimmunity" by E. Israeli, et al. (Dr. Shoenfeld is a co-author) (Ex. 38); and another draft of an article entitled "Vaccines and autoimmunity" by N. Agmon-Levin, et al. (Dr. Shoenfeld is a co-author) (Ex. 39).

On July 28, 2009, the hearing was held. Testifying for petitioner were petitioner and Dr. Shoenfeld. Testifying for respondent was Dr. Kagen.

Although the prehearing Order states that exhibits had to be filed by July 14, 2009, at the hearing, petitioner's counsel brought in more exhibits which he filed subsequent to the hearing. The same occurred for respondent.

On July 29, 2009, respondent filed a review by P. Duclos entitled "Anti-Infectives. Safety of immunisation and adverse events following vaccination against hepatitis B," 2 Expert Opin. Drug Saf. 3:225-31 (2003) (Ex. E).

Also on July 29, 2009, petitioner filed Exs. 40-43 consisting of two articles, an editorial, and a timeline created by petitioner's counsel and Dr. Shoenfeld: "Rupture of Silicone Gel Breast Implants and Symptoms of Pain and Fatigue" by R.C.W. Vermeulen and H.R. Scholte, 30 J Rheumatology 2263-67 (2003) (Ex. 40); "Editorial. Where There's Smoke There's Fire: The

Silicone Breast Implant Controversy Continues to Flicker: A New Disease That Needs to Be Defined" by F.B. Vasey, et al., 30 J Rheumatology 2092-94 (2003) (Ex. 41); the timeline (Ex. 42); "Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminium hydroxide in muscle" by R.K. Gherardi, et al., 124 Brain 1821-31 (2001) (Ex. 43).

On August 12, 2009, petitioner filed Exs. 44-45 consisting of an article and a letter: "Identical Twins With Macrophagic Myofasciitis: Genetic Susceptibility and Triggering by Aluminic Vaccine Adjuvants?" by S. Guis, et al., 47 Arthritis & Rheumatism 5:543-45 (2002) (Ex. 44); "Concise Communication. HLA-DRB1*01 and macrophagic myofasciitis" by S. Guis, et al., 46 Arthritis & Rheumatism 9:2535-37 (2002) (Ex. 45).

On August 17, 2009, after respondent requested 30 days to allow Dr. Kagen to review and respond to petitioner's recently-filed exhibits, the undersigned issued an Order giving respondent until September 17, 2009 to file Dr. Kagen's response.

On August 26, 2009, respondent filed a second Ex. E consisting of Dr. Kagen's supplemental expert report. Dr. Kagen says that petitioner's Exs. 36-39 are journal articles dealing with autoimmune syndromes which are not relevant to the instant action since the medical records indicate no evidence of autoimmunity and petitioner has no evidence of autoantibodies. Ex. E, p. 1. In referring to Ex. 40, an article by Vermeulen and Scholte discussing rupture of breast implants made of silicone gel, Dr. Kagen says the article must be approached with care since it consists of women self-reporting responses to a questionnaire without the authors benefitting from examination of the responders or perusal of their medical records. Moreover, the confidence intervals of the averaged results in the article were very wide.

The authors of the article did not give a role for vaccines in causing chronic fatigue or suggest that silicone acts as an adjuvant. Id. at 1-2.

In responding to the editorial comprising Ex. 41, Dr. Kagen says the author bases his opinion on the role of silicone breast implants in a new disease that needs to be defined on his own personal experience and review of the literature which is not complete data. He notes that there is again no mention of vaccines in causing the symptoms. Id. at 2-3. Dr. Kagen does not discuss Ex. 42 which is the timeline. In addressing Ex. 43 on macrophagic myositis lesions, Dr. Kagen states that the rare disorder has an unknown cause in patients receiving aluminum-hydroxide-containing vaccines. Hepatitis B vaccine does not contain aluminum hydroxide. Petitioner does not have macrophagic myositis. Id. at 3. In addressing Exs. 44 and 45 which deal with macrophagic myositis, both articles discuss the possibility that genes play a cause in creating susceptibility to the disorder. In order to diagnose the illness, muscle biopsy is necessary. Petitioner had no muscle biopsy in this case or features necessary for diagnosis of macrophagic myositis. Id. at 4. Dr. Kagen concludes:

> To the extent that there may be validity to a theory of silicone as a causative agent (a theory I have definite reservations about), I think it is much more likely that silicone, rather than the Hep B vaccination, was related to [petitioner]'s symptoms. I do not think there is any evidence to support a theory that the silicone acted in concert with the Hep B vaccination in this case, or that the hepatitis B vaccine acted alone to cause petitioner's symptoms. Therefore, after review of the recently submitted literature, my opinion remains that there [is] no evidence that [petitioner]'s symptoms were caused by her hepatitis B immunization.

Id. at 5.

FACTS

Petitioner was born on March 5, 1952.

On March 27, 1987, petitioner telephoned Dr. John Cowan's office. She had spotting and occasional cramps. She was sure she had an early miscarriage and stated it was her eighth miscarriage. Med. recs. at Ex. 3, p. 67.

On August 22, 1988, petitioner saw Dr. Cowan, a gynecologist. She had not had a menstrual period for two years and was still nursing. She complained of bloating, backaches, headaches, nervousness, mild cramps, pain in the side similar to ovulation pains, and stated she experienced all these symptoms when she was pregnant except she did not have nausea or fatigue which she normally had during pregnancy. On August 8, 1988, her pregnancy test was negative. She requested a repeat test. Med. recs. at Ex. 3, p. 69.

On May 10, 1989, petitioner had bilateral breast augmentation. Med. recs. at Ex. 6, p. 2.

On June 1, 1989, petitioner went to Dr. Donald Giant because of an automobile accident the day before. She had whiplash and neck pain. Med. recs. at Ex. 11, p. 83.

On June 2, 1989, petitioner telephoned Dr. Cowan's office and complained of a bladder infection. Med. recs. at Ex. 3, p. 70.

On June 15, 1989, petitioner saw Dr. Giant complaining of pain radiating down the arms with tingling. Med. recs. at Ex. 11, p. 83.

On December 29, 1989, petitioner telephoned Dr. Cowan's office and stated her hormones had been "unbalanced" since her last delivery three years before. Med. recs. at Ex. 3, p. 71. She complained of her hair falling out, nausea, cramps, chills, and diarrhea. Id.

On January 16, 1990, Dr. Cowan's office telephoned petitioner to advise her that her tests were normal. Id.

On April 30, 1990, petitioner went to Dr. Giant with palpitations. She had recurrence of palpitations through the weekend. Her EKG was normal. Dr. Giant thought she might have mitral valve prolapse syndrome. Med. recs. at Ex. 11, p. 82. She complained her heart was beating hard and then her head felt funny. Med. recs. at Ex. 11, p. 83.

On April 30, 1990, petitioner called Dr. Cowan's office and wanted her pulse rate. She was advised that blood pressure and weight were checked at examinations. Id.

On May 4, 1990, petitioner was tested for mitral valve prolapse. She did not have the condition. Med. recs. at Ex. 11, p. 65.

On March 9, 1991, petitioner called Dr. Cowan's office and complained of a bladder infection. Med. recs. at Ex. 3, p. 72.

On May 9, 1991, petitioner called Dr. Cowan's office and said she has felt pregnant for three weeks. Her husband had a vasectomy in November. She was nursing. She was not having a menstrual period. She felt she had ovulated two times. She had the same signs when she was pregnant but not as severe. She got a false negative pregnancy test until six or seven weeks. On testing, petitioner was not pregnant. Med. recs. at Ex. 3, p. 72.

On May 13, 1991, petitioner called Dr. Cowan's office and said she still felt pregnant. She thought she was about five weeks pregnant. She wanted an ultrasound by the end of May and Dr. Cowan said yes. Med. recs. at Ex. 3, p. 73.

On May 20, 1991, petitioner called Dr. Cowan's office and said the symptoms of pregnancy were getting stronger. She wanted to schedule an ultrasound that week. Id.

On June 4, 1991, petitioner went to Dr. Giant, complaining of cough, headache, and stomach pains. Her blood pressure was 90/70. Med. recs. at Ex. 11, p. 82. She told Dr. Giant

that she was also having blackout spells suggestive of orthostatic hypotension. He diagnosed an upper respiratory infection. Med. recs. at Ex. 11, p. 82.

On June 4, 1991, petitioner called Dr. Cowan's office and said she was still having vertigo, cramping, fatigue, and sore breasts. She had a negative beta and ultrasound. She had been dieting. She had bronchitis and was advised to increase rest and fluids, increase proteins, and eat small frequent meals. Id.

On June 24, 1991, petitioner went to Dr. Giant to review lab results of her thyroid which were all normal. She continued with hair loss. Med. recs. at Ex. 11, p. 82.

On September 19, 1991, petitioner telephoned Dr. Giant's office to complain of back ache, stomach ache, and headache. She did not have fever. Med. recs. at Ex. 11, p. 81.

On November 5, 1991, petitioner went to Dr. Dankaert because of hair loss that began in April 1991. Med. recs. at Ex. 2, p. 4. The diagnosis was postpartum alopecia. She had aunts with thin hair. Id.

On January 30, 1992, petitioner went to Dr. Giant, complaining of dysuria for 24 hours. She had recurrent cystitis. Med. recs. at Ex. 11, p. 81.

On February 25, 1992, petitioner went to Dr. Giant because of recurrent dysuria. Id.

On March 13, 1992, petitioner returned to Dr. Giant to recheck her urinary tract infection. Id.

On April 1, 1992, petitioner filled out an informational form for Dr. Cowan. Med. recs. at Ex. 3, p. 74. She had some vulvar and vaginal discomfort. A urinary tract infection was recently treated. She had cyclical head hair loss. She got subjective pregnancy symptoms that then cleared. She had headache and occasional nausea. Id.

On May 8, 1992, petitioner saw Dr. Cowan, complaining of problems with false pregnancy symptoms, three times in 12 months. Id. She had nausea, fatigue, and headaches. She felt she had the symptoms with ovulation. Her hair fell out. Id.

On November 20, 1992, petitioner saw Dr. Giant with a febrile illness. She had a temperature of 101-102° and body aches, chills, and sweats. She had a dry cough, nausea, and stomach ache. She had a history of recurrent urinary tract infections. Her blood pressure was 100/60. Examination showed injection of the pharynx. She had possible mycoplasma. Med. recs. at Ex. 11, p. 80.

On December 8, 1992, petitioner saw Dr. Giant with chest pain. She had to go home from work the prior week due to chest pains early after starting work. She also had some shortness of breath. Dr. Giant diagnosed slowly resolving bronchopneumonia with secondary pleurisy. Med. recs. at Ex. 11, p. 80.

On April 28, 1993, petitioner telephoned Dr. Giant's office complaining of sinus congestion, headache, and cough. Id.

On October 3, 1993, petitioner filled out an informational form for Dr. Cowan. Med. recs. at Ex. 3, p. 76. She recently had a urinary tract infection and had three to four urinary tract infections a year. Id.

On November 22, 1993, Dr. Nancy M. Hockley of Fort Wayne Urology Corporation wrote a letter to Dr. Giant regarding petitioner. Petitioner gave a long history of recurring urinary tract infections. Petitioner linked her infections to drinking coffee, tea, colas, ethanol, and citrus fruits. She believed that each time she had one of these substances, she became infected. Med. recs. at Ex. 10, p. 32.

On December 1, 1993, petitioner saw Dr. Cowan. She was not feeling well on antibiotics for a urinary tract infection. She had antibiotics two weeks earlier for the same reason. She complained of back and abdominal aching, nausea, head peculiarities, problems in her vagina and urethra, and discharge. Med. recs. at Ex. 3, p. 76.

On December 16, 1993, petitioner saw Dr. Hockley. Med. recs. at Ex. 11, p. 51. She felt her urethra was inflamed. She had some side effects from Septra including nausea, vomiting, and fatigue. A cystoscopy revealed some evidence of urethritis. Id.

On April 22, 1994, petitioner saw a urologist at Fort Wayne Urology Corporation, complaining of having burning frequency, fatigue, headache and possible temperature. Med. recs. at Ex. 10, p. 2.

On June 13, 1994, petitioner telephoned Dr. Giant's office, complaining of sore throat and dry cough. Med. recs. at Ex. 11, p. 80.

On October 10, 1994, petitioner saw Dr. Hockley. Med. recs. at Ex. 11, p. 50. On September 18, 1994, she had the sudden onset of dysuria. She got better but then, on October 4, 1994, her symptoms became severe. She requested a cystoscopy. Cystoscopy was unremarkable. There appeared to be no active bladder infection. Id.

On January 5, 1995, petitioner had her first hepatitis B vaccination. Med. recs. at Ex. 14, p. 1.

On February 17, 1995, petitioner had her second hepatitis B vaccination. Id.

On March 6, 1995, petitioner telephoned Dr. Giant's office. She had a sinus infection, headache, dizziness, and nausea. She was prescribed Keflex and Entex. Med. recs. at Ex. 11, p. 79.

On March 9, 1995, petitioner saw Dr. Giant with cold symptoms. Med. recs. at Ex. 11, p. 78. Petitioner had had cold symptoms for about a month. She had occasional nausea, dizziness, and headache ever since the weekend. She had episodes of almost near syncope when getting up too quickly. She had chills and diarrhea two nights previously, but this resolved. She stated she always felt cold, but during this episode, she felt quite hot. Her blood pressure was 110/70. Ear, nose, and throat exam showed mild tenderness to percussion over the sinuses. Dr. Giant diagnosed petitioner with sinusitis and noted that she had recently started on Keflex and Entex. She had been on them only for three days and was gradually improving. Id.

On April 3, 1995, petitioner filled out an informational form for Dr. Cowan. Med. recs. at Ex. 3, p. 77. She had not felt well for the prior two months with nausea and lightheadedness. She felt this was likely due to stress. Id.

On June 2, 1995, petitioner saw Dr. G. Randolph, the doctor who had performed breast implantation. Med. recs. at Ex. 6, p. 4. She wanted him to evaluate an injury she sustained to her right chest. She had sudden pain when she was involved in a pile up with her family in a wrestling match. Id.

On June 3, 1995, petitioner returned to Dr. Randolph with redness in her right breast that he suspected was an infection. Id.

On June 7, 1995, petitioner returned to Dr. Randolph after seeing Dr. Borenstein over the weekend. The Toradol she was taking upset her stomach. Dr. Borenstein placed her on Keflex. Id.

On July 11, 1995, petitioner went to Parkview Memorial Hospital Emergency Care Center because she was in an automobile accident and had arm and knee pain. Med. recs. at Ex.

11, p. 41. She was discharged with diagnoses of multiple abrasions, knee contusion, and biceps strain. Her past medical history was none. Id. Neurologically, Dr. Jeffrey R. Nickel stated there were no focal, sensory, or motor deficits. Deep tendon reflexes were symmetric at 2+. Her gait was normal. Med. recs. at Ex. 11, p. 42.

On July 21, 1995, petitioner saw Dr. Giant with a left eye infection. She also complained of sore throat and fever. She had mild adenopathy. He diagnosed pharyngitis and persistent conjunctivitis. Med. recs. at Ex. 11, p. 78.

On August 2, 1995, petitioner had her third hepatitis B vaccination. Med. recs. at Ex. 14, p. 1.

On August 18, 1995, petitioner had an x-ray taken because she had an automobile accident on July 11, 1995, and had medial ankle and knee pain. Med. recs. at Ex. 11, p. 39. There was no fracture in the foot although petitioner held the foot in a slight plantar flexion. The left knee showed mild degenerative changes. Id.

On August 25, 1995, petitioner saw Dr. Giant because of ankle and knee pain due to the automobile accident. Med. recs. at Ex. 11, p. 77.

On September 6, 1995, petitioner saw Dr. Hockley. Med. recs. at Ex. 11, p. 38. This was a follow-up of her recurrent urinary tract infections and irritative voiding symptoms. Since the doctor saw her in December, she had done extremely well. She had no voiding symptoms whatsoever unless she drank soda or consumed ethanol. She took Macrodantin for prevention. Dr. Hockley refilled her Macrodantin. Petitioner would often take an antibiotic if she cheated on her diet. Petitioner should pay attention to the foods that irritated her bladder as well as the Ditropan. Id.

On September 26, 1995, petitioner called Dr. Cowan's office and said she saw a urologist for recurrent urinary tract infections. She had vaginal discharges and the urologist asked for her to get a check-up with a gynecologist to see if vaginal infection was causing ureteritis. Her four-year-old daughter was also seeing the urologist for infection. Med. recs. at Ex. 3, p. 78.

On September 29, 1995, petitioner saw Dr. Cowan. She had had urinary tract problems since age 21. Id. On an altered diet, she usually did well. The prior week, she had discharge when she was not feeling well. She felt dizzy and lightheaded, and had urinary irritation. Dr. Cowan's impression was vaginal discharge and urethral irritation. Id.

On October 2, 1995, Dr. Cowan called petitioner to tell her all her cultures were negative. Id.

On October 10, 1995, petitioner saw Dr. Cowen who did a pelvic examination. She was in good health, with a left ovarian tumor on ultrasound. Med. recs. at Ex. 3, p. 79.

On October 10, 1995, petitioner called Dr. Cowan's office to tell them that she forgot to tell Dr. Cowan that she had not felt well for the past four to six weeks with extreme fatigue and lightheadedness. She also had intermittent nausea. Id.

On October 11, 1995, petitioner had a chest x-ray, showing a right breast prosthesis. Med. recs. at Ex. 19, p. 56.

On October 13, 1995, petitioner had a laparoscopy for a left ovarian mass. Dr. Michael Amorini diagnosed her with a normal left ovary and endopelvic adhesions. Med. recs. at Ex. 19, p. 53.

On October 14, 1995, petitioner had an analysis of a left ovary biopsy done. The pathologist, Dr. Blandine Bustamante, stated the tissues showed peritoneal fluid cytology and were negative for malignancy. Med. recs. at Ex. 19, pp. 47, 51.

On October 18, 1995, petitioner called Dr. Cowan's office, stating she felt quite well and resumed normal activity. Med. recs. at Ex. 3, p. 80.

On December 15, 1995, petitioner saw Dr. William B. LaSalle, an orthopedist. Med. recs. at Ex. 11, p. 6. Petitioner had had some problems for several months in her right hip area. When she carried her books, she would have a little occasional twinge. Recently, this had become more pronounced and the pain was radiating down her right leg to the knee. She did not have any problems sleeping. She had no bowel or bladder symptoms. Physical examination showed a very healthy female, walking without a limp. She could heel and toe walk with difficulty. Muscle stretch reflexes were normal. She had excellent range of motion of her low back. She had pain with internal rotation of the right hip and Dr. LaSalle pinpointed the area as the superior/posterior aspect of her trochanter. X-rays were normal. Dr. LaSalle concluded petitioner had trochanteric bursitis. He prescribed Medrol with a follow-up of Advil. Id.

On January 4, 1996, petitioner saw Dr. LaSalle. She was improved. Med. recs. at Ex. 11, p. 7.

On June 13, 1996, petitioner saw Dr. Dankaert with herpes zoster on the right side. She also had an open sore on the nasal apex which might also be herpes, but she had a history of perioral dermatitis and the possibility of acne rosacea. Med. recs. at Ex. 2, p. 3.

On June 18, 1996, petitioner returned to Dr. Dankaert. She was doing well. She did not have any cough or shortness of breath. There were no lesions other than in the dermatomal

distribution on the trunk. She did have acne rosacea lesions. The tip of the nose was improved. Med. recs. at Ex. 2, p. 3.

On September 10, 1996, petitioner saw her doctor, stating she had shingles in the spring of 1996 and, at that time, a positive tuberculosis test. Three weeks later, she had a negative TB test when the shingles were about gone. Med. recs. at Ex. 24, p. 16. She had no problems with her bladder now. She took Prozac. She complained of depression and fatigue, especially one week before her menstrual cycle. Prozac helped. Petitioner just did not feel well. Id.

On September 10, 1996, Dr. Cowan did an ultrasound of petitioner's uterus which proved to be normal. She had a 3 mm endometrial stripe. Med. recs. at Ex. 24, p. 21. She was diagnosed with a small follicle/cyst 9 x 8 mm on the left ovary and fatigue. Med. recs. at Ex. 24, p.22.

On September 26, 1996, petitioner saw Dr. Giant, complaining of fatigue since May 1996. She slept more than eight hours a day and still felt tired. She had been on Prozac 10 mg and took it almost every day. This helped her depression but not her energy level. She denied any unusual aches or pains. She wondered if part of the reason for her extreme lethargy were environmental allergies because she had a very strong family history of this. Her blood pressure was 104/60. Ear, nose, and throat exam showed minimal postnasal drip and slightly reddened eyes. He tried petitioner on a non-sedating antihistamine. Med. recs. at Ex. 11, p. 75.

On November 11, 1996, petitioner saw her doctor, complaining of low grade menstrual pain in the abdomen and back all the time. Her bowels were okay. Med. recs. at Ex. 24, p. 17.

On November 26, 1996, petitioner saw her doctor, complaining of menstrual pain for the entire cycle. Id.

On December 3, 1997, petitioner saw Dr. Dankaert. She had been feeling bad for one week and had a patch on her torso, a papule on her nose, and a past history of shingles. She did not have any fever. Med. recs. at Ex. 2, p. 3. She had a furuncle[9] anterior abdomen that started that day. Med. recs. at Ex. 2, p. 2.

On December 3, 1997, petitioner phoned her doctor to schedule her annual gynecologic examination and complained of fatigue for three years (making onset 1994, before she had her first hepatitis B vaccination). She also complained of periods of feeling blue. Med. recs. at Ex. 24, p. 17.

On December 5, 1997, petitioner saw Dr. Giant, complaining of neck ache, headache, tender ears, tender neck, and increasing fatigue. Med. recs. at Ex. 11, p. 73. She had three near-syncopal spells that resolved when she lay down and elevated her feet. (Petitioner's initial complaint of near syncope was June 4, 1991, four years before she received hepatitis B vaccine.) She had not had chills, fevers, or night sweats. She had no other unusual aches and pains. She stated she had a history of depressions in the fall. Her blood pressure was 92/60 supine and 88/60 sitting. Id.

On December 10, 1997, petitioner had a CT scan done of her right lower quadrant because she complained of pain there. She had a negative abdomen and pelvic CT scan. Med. recs. at Ex. 19, p. 43.

On January 20, 1998, petitioner saw Dr. Giant. Med. recs. at Ex. 11, p. 72. She had persistent fatigue, episodes of low blood sugar with sinking spells, and a history of depression.

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[9] Furuncle is "a painful nodule formed in the skin by circumscribed inflammation of the corium and subcutaneous tissue.... It is caused by staphylococci, which enter through the hair follicles...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 745.

Her blood sugars had run as low as the 40s and 50s at work. She felt quite weak at those times. This resolved with eating. He tried raising her dose of antidepressants to treat her lethargy. She stated her mood improved, but she still felt tired all the time. She looked pale and excessively thin. She had lost some weight. There were no other significant physical findings. Id.

On January 21, 1998, petitioner saw Dr. Mark Tartara. Med. recs. at Ex. 8, p. 10. She complained of three years of fatigue. Dr. Tartara suspected hypothyroidism vs. hypoglycemia. Id. Petitioner was a registered nurse and worked the night shift. Med. recs. at Ex. 8, p. 11. Over the past three to four months, her fatigue had been worse. She could sleep 18 hours a day if allowed. She had a blue mood about one year before and went on Zoloft. This worked initially but she stopped the drug. She felt she had no further problems with blue mood. She had three episodes of feeling she would pass out. This was not associated with palpitations or dizziness. She felt a warm sensation. Her last two episodes occurred at work. Her blood glucose was found to be in the 50s the first time and in the 40s the second time. She did not take any carbohydrate at the time. She lost 10 pounds in the fall, but that was due to less appetite. She had wanted to lose weight. She took one to two ounces of ethanol a week. On examination, she had no muscular pains, strains or weakness. Her strength was not changing. She had no weakness and no paresthesias. She had no gait disturbance. She had no recurrent dizziness. She had no history of syncope. She had been working nights for the past five years. She was going to school at night and got her nursing degree one year previously. Id. She worked 4:00 p.m. to 4:00 a.m. and then went back home to sleep for an hour before getting up to get her children to school. Then she went back to sleep. Lately, she had not been able to stay awake in the morning and had her 18-year-old get the younger children to school and drive herself and her sister to

school. Med. recs. at Ex. 8, p. 12. She had some seasonal rhinitis and some morning forehead congestion. She appeared depressed and a bit worried. She had good insight. She had no joint effusions or erythema. She had adequate range of motion without pain. She had no joint instability. She had normal muscle tone and strength was grossly normal for age. Her deep tendon reflexes were symmetric and not pathologic. Sensation to light touch, pinprick, vibration, and proprioception were normal. She had normal relatedness and affect. Her memory was intact to short and long term functions. There was no suggestion of overt depression, anxiety, or agitation. She was alert and oriented to person, time, and place. Id. Dr. Tartara's impression was that her fatigue and spells of profound fatigue may be related to hypoglycemia. He thought her symptoms were most likely multifactorial related to her change of lifestyle to working as a registered nurse two to three nights weekly in addition to taking care of her children, accompanied by some allergic rhinitis and possibly sinusitis and depression. She might have hypoglycemia. He wanted to rule out hypothyroidism and cortisol deficiency although she had normal electrolytes. Med. recs. at Ex. 8, pp. 112-13.

On January 26, 1998, petitioner saw Dr. William Smits, an allergist. Med. recs. at Ex. 7, p. 28. She had fatigue and was feeling poorly. Her ears had been popping for six weeks and were full. Her eyes itched. She had rhinorrhea and sneezing. The age of onset was 30 years of age. (That would be 15 years earlier.) When she ate, she was nauseated. She stated she was always sick as a child. She complained of dizziness and possible hypoglycemia. She had low blood pressure, heart rate, and body temperature. She saw Dr. O'Brien about 11 years before. She had pneumonia in 1992. Her symptoms were better when she was on an allergy diet years ago. The symptoms had been present for two years. She had trouble in April and felt weak. *Id.*

She was on Zoloft. Med. recs. at Ex. 7, p. 29. She was sensitive to corn, milk, wheat, and refined sugar. Some family members had seasonal allergies. Id. She had chronic urinary tract infections as a child. Med. recs. at Ex. 7, p. 30. Dr. Smits diagnosed allergic rhinitis caused by dust and dander, and hay fever, as well as food allergy and dyspepsia. Med. recs. at Ex. 7, p. 31.

On January 27, 1998, petitioner had a CT scan done of her sinuses. No abnormalities were noted. Med. recs. at Ex. 19, p. 41.

On February 13, 1998, petitioner was examined as part of a pediatric nursing specialist employee health examination. She was in general good health. Med. recs. at Ex. 11, p. 23. In a form that petitioner completed on January 14, 1998, petitioner denied allergies, headaches, injuries, and other serious illness. Med. recs. at Ex. 11, p. 22.

On February 19, 1998, petitioner returned to Dr. Smits for a recheck. She had overwhelming fatigue and weakness. She had headaches, jaw discomfort, and her ears hurt. She finished the Prednisone and had more energy. She did not have headaches while she was on the Prednisone. She was very frustrated. Med. recs. at Ex. 7, p. 25.

On March 20, 1998, petitioner told Dr. Smits that the Claritin-D really helped. She had not felt that good in a while. In the last four to five days, she felt like her old self and she could actually go back to work. Med. recs. at Ex. 7, p. 19.

On April 6, 1998, Dr. Smits, the allergist, wrote a letter to Dr. Giant. Med. recs. at Ex. 7, p. 66. He said he had diagnosed petitioner with allergic rhinitis, asthma, and a history of fatigue. Allergic work-up confirmed sensitivities to trees, weeds, molds, and certain foods. Petitioner was aware that she was allergic to cats but, despite this, she had two pet cats, a pet dog, and one guinea pig. Id. She was on Claritin-D, Allegra, Singulair, and Volmax. Petitioner stated she

felt she had responded well to the current medication and had found energy which she had not had for quite a while. Id. Dr. Smits administered shots to petitioner. Med. recs. at Ex. 7, p. 11.

Also on April 6, 1998, petitioner received the following allergy serums from Dr. Smits: vial A for trees, weeds, roaches, cats, feathers, and corn; vial B for molds. Med. recs. at Ex. 7, p. 58.

On August 25, 1998, Dr. Paul E. Later, a neurologist, wrote a letter to Dr. William Smits that he had recently seen petitioner. Med. recs. at Ex. 5, p. 3. Her primary complaint was severe fatigue. She also complained of dysequilibrium, general malaise, body aches, and joint aches. About three years ago, she had an episode of severe tiredness all the time. In April 1996, she noted shingles on her left flank. In October 1997, she had an episode of syncope at work and had documented low blood sugar in the 40s. In January 1998, she had waves of excessive sleepiness that would last for 20 hours a day, and poor concentration. In June 1998, she had episodes of a hypersensitive patch on her scalp. About two weeks prior to her visit with Dr. Later, petitioner had episodes of dysequilibrium. She did not have diplopia or a sense of band-like tightness of the extremities or thorax. She had chronic bladder control changes without any real changes recently and no incontinence. She had no history of optic neuritis or symptoms of migratory myalgia. Id. She was checked for allergic causes of her symptomatology. *Id.* Petitioner was allergic to many environmental allergens. Med. recs. at Ex. 5, p. 4. Her family history was significant for multiple sclerosis, cardiac disease, miscarriages, and migraines. On physical examination, petitioner was alert and oriented with normal speech and language function. Motor examination was normal. Deep tendon reflexes were 3+ throughout. Fine motor control was normal. Individual muscle strength testing was full. Cerebellar examination

showed normal finger-to-nose and rapid alternating movements. She showed normal light touch and double simultaneous stimulation. Her gait was normal straight, heel, toe, and tandem walk. Id. Dr. Later wondered if petitioner had demyelinating disease and recommended a brain MRI. Id.

On October 5, 1998, petitioner saw Dr. Kenneth A. Smith, a rheumatologist. Med. recs. at Ex. 7, p. 61. He wrote a letter to Dr. Smits, dated October 20, 1998. He evaluated her for arthralgias and myalgias and discussed her three-year history of fatigue, noting her history of disturbed sleep pattern. Dr. Smith thought she had fibromyalgia and not an underlying inflammatory disease process. Her physical examination was normal. Id. Dr. Smith suggested Elavil and other anti-depressants. Med. recs. at Ex. 7, p. 62. He also suggested a regular aerobic exercise program. Stretching and strengthening exercises should be continued. All narcotics and potentially addictive drugs should be avoided. Id.

On October 21, 1998, petitioner filled out an immune dysfunction questionnaire for Dr. Andrew W. Campbell of Houston, TX, who is neither an immunologist nor a neurologist. Med. recs. at Ex. 1 (page number indecipherable). She stated that she had three years of fatigue, one year of attention deficit disorder, one year of memory disturbance, one year of spatial disorientation, one year of frequently saying the wrong word, two years of depression, two years of mood swings, six months of sleep disturbance, one year of dysequilibrium, one year of lightheadedness, one year of severe muscular weakness, two years of decreased libido, one year of muscle and joint aches, six months of weight gain, 25 years of abdominal pain, diarrhea, nausea, intestinal gas or irritable bowel syndrome, three years of rash of herpes simplex or shingles, 12 years of hair loss, 25 years of cold hands and feet, 20 years or longer of multiple

sensitivities to food and other substances, and 10 years of low blood sugars, worsening in the past year.

Also on October 21, 1998, petitioner filled out a personal and family health history for Dr. Campbell. Med. recs. at Ex. 1 (page numbers indecipherable). She marked positive for allergies, anemia, miscarriage, hay fever, TB test followed two weeks later by a negative test, fainting, spells of dizziness, ear pain, shortness of breath climbing a flight of stairs, irregular heartbeat, burning when urinating, loss of control of bladder, blood in urine, trouble holding urine (mostly 1974-94), varicose veins, phlebitis or inflamed leg veins which started in 1990, constant thirst, coldness, sluggishness or fatigue, jumpiness, joint pain, loss of muscle strength, back pain, worry over her job and money, and drinking coffee and alcohol. She had numerous miscarriages before 12 weeks from 1978 to 1985.

On October 26, 1998, Dr. Campbell examined petitioner. Med. recs. at Ex. 1 (page numbers indecipherable). In his examination, he found her deep tendon reflexes normal. He diagnosed her with demyelinating disease.

On November 19, 1998, petitioner saw Dr. Dankaert. She had perioral dermatitis. This occurred twice a year and lasted about six weeks. Med. recs. at Ex. 2, p. 2.

On February 1, 1999, Dr. Campbell diagnosed petitioner with abnormal reflex, CIDP, demyelinating disease, lymphadenopathy, and Raynaud's syndrome. Med. recs. at Ex. 1 (page number indecipherable).

On March 19, 1999, petitioner had a right breast hematoma which Dr. Joseph Mlakar drained. Med. recs. at Ex. 19, p. 37. Petitioner underwent capsulectomies and removal of breast implants with immediate reconstruction a week previously. She presented at that time with

growing swelling of her right breast secondary to hematoma. She was taken to surgery for evacuation. Id.

On March 23, 1999, petitioner had an evacuation of a seroma and excision of a pseudocapsule of the right breast. Med. recs. at Ex. 19, p. 34. Dr. Brian J. Lee stated she had removal of implants, a capsulectomy, and mastopexy approximately two weeks before. Subsequently, she had a hematoma of the right breast which was drained four days previously. That morning the right breast increased in size. She had not had fevers, chills, nausea, vomiting, or any other symptoms. Id.

On March 29, 1999, petitioner saw Dr. Campbell. Med. recs. at Ex. 1 (page number indecipherable). She had completed six IVIG treatments, the last one on March 15 or 18, 1999. On March 9, 1999, petitioner had bilateral implant removal. Two weeks after March 9, 1999, petitioner had two to three days of great energy and normal cognitive function. She felt normal again, especially after IVIG treatment. She was much improved. Her fatigue and weakness improved. Her cognitive function improved after each IVIG treatment and with the implants removed. Sleep was not a problem.

Also on March 29, 1999, Dr. Campbell diagnosed abnormal reflex, CIDP, and immune mechanism disorder. Med. recs. at Ex. 1 (page number indecipherable).

On April 4, 1999, petitioner had biopsies of her breasts. Med. recs. at Ex. 4, p. 4. Dr. Rahim Karjoo, a pathologist, diagnosed fibrous capsule from the right breast showing laminated fibrous tissue, presence of abundant crystalloid material (silicone) in the wall of the capsule, and presence of the silicone beyond the surface capsule in the scar tissue adjacent to the breast. He also diagnosed a laminated fibrous capsule containing a small number of silicone, mostly in the

histiocytes, from the left breast showing fibrosis, scar formation and vascularization of the breast adjacent to the capsule and inflammatory changes of the breast tissue. Med. recs. at Ex. 4, p. 3. Dr. Karjoo commented that this particular case had extensive calcification extensions and leaking of the silicone in both breasts, with the right more prominent with severe calcification. Id.

On April 12, 1999, Dr. Cowan did an ultrasound of petitioner's uterus, showing small fibroids, the largest being 1.3 cm in diameter, intramural in nature. There was a well-demarcated 9 mm endometrial stripe. Petitioner had a small uterine leimyomata (benign tumor).[10] Med. recs. at Ex. 24, p. 19.

On April 13, 1999, petitioner had a biopsy of her endometrium showing a proliferative endometrium with focal mild stromal breakdown changes, negative for hyperplasia, atypia, and malignancy. Med. recs. at Ex. 24, p. 18.

On June 29, 1999, petitioner saw Dr. Campbell. She had had a total of eight IVIG treatments. There were 12 IVIG treatments ordered. She had two IVIG doses ordered April 29, 1999. Med. recs. at Ex. 1 (page number indecipherable). Petitioner said she had fatigue for the past two months. She felt better after six weeks of IVIG. She slept without problem. Her joint/muscle pain resolved since receiving IVIG. Dr. Campbell diagnosed CIDP, fatigue, hepatitis B vaccine reaction, and immune mechanism disorder.

[10] Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1011.

On August 3, 1999, Dr. Campbell diagnosed petitioner with polyclonal gammopathy[11]. Med. recs. at Ex. 1 (page number indecipherable). He stated she had an abnormal nerve conduction test.

On September 16, 1999, petitioner filled out an Immune Dysfunction Questionnaire Update for Dr. Campbell. Med. recs. at Ex. 1 (page number indecipherable). She stated she had, on a scale of severity from 0-10: fatigue (7), attention deficit (7), calculation difficulties (7), memory disturbance (9), frequently saying the wrong word (6), mood swings (2), sleep disturbances (2), headaches (2), numbness or tingling (1), dysequilibrium (3), lightheadedness (8), severe muscular weakness (6), near blackouts (6) intolerance of alcohol (4), decreased libido (4), muscle and joint pains (from 4-5 to 7-8), abdominal pain (3), recurrent flu-like illnesses (5-6), twitching muscles (2), severe nasal or other allergies (5), weight gain (3), night sweats (3), heart palpitations (2), one episode of shingles, uncomfortable urination (4), rashes (5), hair loss (7), frequent canker sores (5-6), cold hands and feet (7), shortness of breath (8), symptoms worsened by extremes in temperature (7), sores that will not heal (7), multiple sensitivities to food, medicine, and other substances (3), and under other symptoms weakness, fatigue, mental decline and lightheadedness. Petitioner denied anxiety and depression.

Also on September 16, 1999, Dr. Campbell examined petitioner. She had normal deep tendon reflexes. Med. recs. at Ex. 1 (page number indecipherable). Petitioner was concerned about her mental status and energy level. She stated that her cognitive function was not what it used to be. She was disoriented while driving for moments and then was able to find her way.

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[11] Gammopathy is "a condition marked by disturbed immunoglobulin synthesis." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 751. "Polyclonal" means "derived from different cells." Dorland's, at 1479.

She experienced less fatigue, but still had fatigue. She functioned at a low level of energy. She slept okay. Her body aches were a lot better. She had limited levels of joint and muscle pain. Dr. Campbell diagnosed CIDP, fatigue, hepatitis B vaccine reaction, and immune mechanism disorder.

On October 1, 1999, Dr. Campbell noted that petitioner had polyclonal gammopathy, an increase in her cholesterol, an increase in her SGOT, abnormal although improved nerve conduction studies, positive myelin basic protein antibodies, and positive ganglioside GM-1, and he diagnosed CIDP. Med. recs. at Ex. 1 (page number indecipherable).

On October 7, 1999, Dr. Campbell diagnosed petitioner with CIDP, fatigue, hepatitis B vaccine reaction, and immune mechanism disorder. Med. recs. at Ex. 1 (page number indecipherable).

On February 8, 2000, petitioner went to a doctor and stated that she had had chronic urinary problems since she was 20 (27 years ago). Med. recs. at Ex. 18, p. 9. She stated that her aunt had chronic bladder problems. Id.

On March 7, 2000, petitioner had a cystoscopy which showed a normal bladder with mild vaginitis. Med. recs. at Ex. 18, p. 8. She had a renal and bladder ultrasound on that date because of chronic cystitis with frequency since age 20. She had normal kidneys and bladder with 98% evacuation of the bladder. Med. recs. at Ex. 18, p. 33.

On September 6, 2000, petitioner had a history of interstitial cystitis and had discomfort. A urinalysis was negative. Med. recs. at Ex. 18, pp. 22, 29.

On March 22, 2001, petitioner saw Darlene Noble, a nurse practitioner, for a gynecological examination. Med. recs. at Ex. 24, p. 9. Petitioner thought she was menopausal.

She did not have hot flashes, but she was more emotionally labile and specifically had depression. NP Noble stated that petitioner's examination was normal. She tried to reassure petitioner that everything she was experiencing as far as cycle change was very normal. Id.

On March 6, 2002, petitioner went to Northeast Indiana Urology with a longstanding history of interstitial cystitis. Med. recs. at Ex. 18, p. 15. The doctor's assessment was pelvic pain, possible interstitial cystitis. Id.

On August 7, 2002, petitioner had a hysterosalpingogram. Dr. Christopher Wing stated petitioner had complete occlusion of the endometrial cavity and/or obstruction at the level of the internal cervix. Med. recs. at Ex. 19, p. 20.

On December 4, 2002, petitioner had a chest x-ray because of coughing and fatigue. She did not have significant cardiopulmonary disease. Med. recs. at Ex. 19, p. 17.

On April 10, 2006, petitioner saw Dr. Madhav H. Bhat, a neurologist. Med. recs. at Ex. 25, p. 20. Petitioner complained of memory disturbance for 10 years, starting in 1995, and fatigue for several months. Despite having short-term memory disturbance and confusion, her performance in the hospital CCU had not declined. She had not made any mistakes. She did not have headaches, nausea, vomiting, or dystaxia. Petitioner said her symptoms came after a hepatitis B vaccination which she had in 1995 when she had fatigue, tiredness, concentration difficulties, and generalized weakness. She saw the neurologist Dr. Later and a local allergist. She saw Dr. Campbell and received IVIG once a week for almost a year for presumed chronic inflammatory demyelinating polyneuropathy. Id. She did not have a neurological evaluation then. She never had proximal or distal leg weakness, arm weakness, or persistent hand or feet paresthesia then. Med. recs. at Ex. 25, p. 21.

In past medical history, Dr. Bhat wrote "questionable diagnosis of CIDP and significant fatigue." Id. Her family history is positive for coronary artery disease. Neurological examination showed an alert, oriented woman who followed simple commands. Her fund of knowledge was adequate. Insight was normal. Repetition of three words was normal with a recall of three out of three objects on the first try. Judgment, similarities, and abstraction were normal. There were no constructional or ideational apraxias. Strength was normal in all extremities. Coordination was normal. Sensory evaluation was normal. Tendon reflexes were normal in all extremities. Plantar reflex was flexor bilaterally. She walked well. She had no difficulties rising from a chair. Romberg sign was absent. Dr. Bhat's impression was that petitioner's subtle short-term memory disturbance and concentration difficulties may be secondary to underlying anxiety and depression. Dr. Bhat did not find clinical evidence of Alzheimer's disease or encephalopathy. The symptoms petitioner reported 10 years earlier are not typical for a diagnosis of CIDP. Id.

On April 19, 2006, petitioner had an EEG done. Dr. Bhat stated it was normal. Med. recs. at Ex. 25, p. 16.

Also on April 19, 2006, petitioner had a brain MRI. Petitioner gave a history of gradual memory loss over several years. Med. recs. at Ex. 25, p. 18. There were multiple scattered T2 signal hyperintensities in the frontal and parietal occipital deep white matter and subcortical white matter. Dr. John R. Kim stated that he did not see any immediate periventricular white matter lesions. These areas were not associated with abnormal restriction or abnormal enhancement. The differential for this finding would include chronic small vessel ischemic/occlusive disease, vasculitis, and less likely demyelination. Id.

On June 28, 2006, petitioner saw Dr. Bhat as a follow-up. Med. recs. at Ex. 25, p. 3. Petitioner continued to have subtle short-term memory disturbance and trouble concentrating at work as well as at home, although she continued to perform activities of daily living skills independently. Petitioner did not have trouble driving or handling her financial duties. She did not have any deterioration of her work performance as a critical nurse. When asked, petitioner denied depression although she admitted to occasional anxiety. Id. Petitioner was fatigued and tired all the time. Dr. Campbell treated her with IV gamma globulin. Her history included a "questionable diagnosis of immune dysfunction and CIDP," and fatigue. Id.

On August 9, 2006, nurse Anita Lough noted that Dr. Bhat reviewed the CSF studies which showed no evidence of demyelinating disease. Med. recs. at Ex. 25, p. 6.

Neurological examination showed an alert, oriented woman who followed simple commands. Petitioner's language function was normal. Id. Motor, sensory, and tendon reflex evaluations were normal. Med. recs. at Ex. 25, p. 4. She walked well. Neuropsychological testing that Dr. Williams performed was within normal limits. The symptoms were attributed to underlying stress. A brain MRI was unremarkable other than a subtle nonspecific white matter signal lesion in the left parieto-occipital head region that was more suggestive of a gliosis[12] than demyelination. Id. A multiple sclerosis panel and cerebrospinal fluid were normal. EEG was normal. Dr. Bhat concluded that a large portion of petitioner's neurological symptoms were

[12] Gliosis is an excess of astroglia. Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 778. Astroglia are astrocytes. Dorland's, at 170. Astrocytes are neuroglial cells of "ectodermal origin, characterized by fibrous, protoplasmic, or plasmatofibrous processes." Dorland's, at 169.

secondary to underlying anxiety and possible depression. After a lengthy discussion with petitioner, Dr. Bhat decided to treat petitioner with Prozac. Id.

Other Submitted Material

Petitioner filed a statement from her sister Elizabeth M. Bode, dated November 26, 2002. Pe. Ex. 20. Although Ms. Bode does not specify which hepatitis B vaccination to which she is referring, she states that before the vaccination, petitioner was like the Energizer bunny. But after the vaccination, she became more and more ill. P. Ex. 20, p. 1. After Dr. Campbell started treating her, Ms. Bode saw small improvements. P. Ex. 20, p. 2.

Petitioner filed a statement from Janet A. Zoll, a registered nurse, dated January 10, 2003, who administered intravenous immunoglobulin to petitioner. P. Ex. 21.

Petitioner filed a statement from Ruth Miley, a registered, nurse, undated, who used to work with petitioner. She stated that petitioner would become very pale and nearly faint. She also mentioned that petitioner had low blood sugar which was not corrected by giving her juice. P. Ex. 22.

Petitioner filed a statement from another sister, Teresa M. Gigli, undated, saying that before her first hepatitis B vaccination in 1995, petitioner was extremely active. Some time in the fall of 1995, petitioner felt faint or lightheaded a lot. This worsened over the winter and spring. In the fall of 1998, petitioner told Ms. Gigli that she had fibromyalgia. Another sister and Ms. Gigli found Dr. Andrew Campbell for petitioner and she began to improve slowly after starting treatment with him. P. Ex. 23.

Petitioner filed as Ex. 36 an article based on her own case entitled “Chronic fatigue syndrome with autoantibodies – The result of an augmented adjuvant effect of hepatitis-B

vaccine and silicone implant" by A-L Nancy and Y. Shoenfeld (petitioner's expert), 8 Autoimmunity Reviews 52-55 (2008). The authors consider petitioner to have chronic fatigue syndrome. They also state that petitioner had demyelination. Silicone is considered an adjuvant to the immune system and may induce adjuvant disease. To the authors' best knowledge, this is the first case of combined (or double) adjuvant effect of vaccine and silicone. Id. at 53, 54.

Petitioner filed as Ex. 37 an article entitled "Infections and Autoimmunity – friends or foes? by S. Kivity, N. Agmon-Levin, M. Blank, and Y. Shoenfeld (petitioner's expert). The volume, title of journal year of publication, and article page numbers were not provided. The authors state that infections can trigger autoimmune reactions.

Petitioner filed as Ex. 38 a 39-page draft of an article which Dr. Shoenfeld states was accepted by the Journal of Lupus entitled "Adjuvants and autoimmunity" by E. Israeli, N. Agmon-Levin, M. Blank, and Y. Shoenfeld. The authors state that silicone as an adjuvant with connective tissues diseases is debatable. Id. at 2.

Petitioner filed as Ex. 39 a 27-page draft of an article which Dr. Shoenfeld stated was accepted by the journal Nature Rheumatology entitled "Vaccines and autoimmunity" by N. Agmon-Levin, Z. Paz, E. Israeli, and Y. Shoenfeld. On page 2, the authors state "Post-vaccination autoimmune phenomena are rare and may appear as a sub-acute o[r] very late event. Therefore, in most instances it is difficult, if not impossible, to ascertain that vaccination caused or precipitated these phenomena." The authors state that the latency period between the initial immune insult and clinical disease could be years. Id. at 5. In these instances, vaccination may be a second exposure to the same antigen followed by a reaction in days. Id. at 6.

Petitioner filed as Ex. 40 an article entitled "Rupture of Silicone Gel Breast Implants and Symptoms of Pain and Fatigue" by R.C.W. Vermeulen and H.R. Scholte, 30 J Rheumatology 2263-67 (2003). The authors conclude that there is a high incidence of rupture of silicone breast implants in women with chronic fatigue symptoms. Id. at 2263. Seventy-six percent of the women with silicone breast implants had ruptured implants which amounted to 81% of the chronic, debilitating fatigue group and 60% of the non-fatigue group. Id. at 2266.

Petitioner filed as Ex. 41 an editorial entitled "Where There's Smoke There's Fire: The Silicone Breast Implant Controversy Continues to Flicker: A New Disease That Needs To Be Defined" by F.B. Vasey, et al., 30 J Rheumatology 2092-94 (2003). The author states that removal of the breast implants resulted in alleviation of fibromyalgia/chronic fatigue-like illness. Id. at 2092.

Petitioner filed as Ex. 42 a timeline of events depicting symptoms and dates. Since only the first page was prepared by Dr. Shoenfeld and the rest by petitioner's counsel, it does not need comment.

Petitioner filed as Ex. 43 an article entitled "Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminium hydroxide in muscle" by R.K. Gherardi, et al., 124 Brain 1821-31 (2001). The authors conclude that individuals contracted macrophagic myofasciitis resulting in diffuse arthromyalgias and fatigue due to intramuscular injections of aluminum hydroxide-containing vaccines. Id. at 1821.

Petitioner filed as Ex. 44 a case report entitled "Identical Twins With Macrophagic Myofasciitis: Genetic Susceptibility and Triggering by Aluminic Vaccine Adjuvants?" by S. Guis, et al., 47 Arthritis & Rheumatism 5:543-45 (2002). The authors report two cases of

macrophagic myofasciitis in twin sisters after receipt of hepatitis B vaccination. They opine that the vaccines' aluminic adjuvant possibly triggered the illness in genetically susceptible recipients. Id. at 543. The 64-year-old sisters complained of arthritic symptoms. Id. at 543-44.

Petitioner filed as Ex. 45 a letter entitled "HLA-DRB1*01 and macrophagic myofasciitis" by S. Guis, et al., 46 Arthritis & Rheumatism 9:2535-37 (2002). The authors support the idea that aluminic immunizations may trigger macrophagic myofasciitis in a particular genetically susceptible recipient. Id. at 2536.

Respondent filed as Ex. C the medical literature to which Dr. Brenner referred in his expert report. The first entry is an article entitled "Special Article. Shattuck Lecture–Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion" by Dr. Marcia Angell, 334 NEJM 23:1513-18 (1996). Dr. Angell said there is no valid proof that silicone gel-filled breast implants cause connective tissue disease. The second entry is a letter entitled "Experience of a Scientific Panel Formed to Advise the Federal Judiciary on Silicone Breast Implants" by B.S. Hulka, et al., 342 NEJM 11:812-15 (2000). The letter describes the legal experiences of the panel. The third entry is an article entitled "Meta-Analyses of the Relation Between Silicone Breast Implants and the Risk of Connective-Tissue Disease," by E.C. Janowski, et al., 342 NEJM 11:781-90 (2000). The authors found no association between breast implants and autoimmune disease. The fourth entry is an article entitled "Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms" by J. Sanchez-Guerrero, et al., 332 NEJM 25:1666-70 (1995). The authors found no association between silicone breast implants and connective-tissue diseases. The fifth entry is an article entitled "Chronic diffuse musculoskeletal pain, fibromyalgia and co-morbid unexplained clinical

conditions" by L.A. Aaron and D. Buchwald, 17 Best Practice & Research Clinical Rheumatology 4:563-74 (2003). The authors state that fibromyalgia frequently overlaps with chronic fatigue syndrome, irritable bowel syndrome, temporomandibular disorders and multiple chemical sensitivities. Id. at 564. The sixth entry is an article entitled "Comorbidity of Fibromyalgia and Psychiatric Disorders" by L.N. Arnold, et al., 67 J Clin Psychiatry 8:1219-25 (2006). The authors found a substantial lifetime psychiatric comorbidity in persons with fibromyalgia. The seventh entry is an article entitled "The Fibromyalgia Bladder Index" by K. Brand, et al., Clin Rheumatol (electronic) 1-7 (2007). The authors state that irritable bladder syndrome are common in individuals with fibromyalgia. Id. at 1. The eighth entry is an article entitled "The Relationship between Fibromyalgia and Interstitial Cystitis" by D.J. Clauw, et al., 31 J psychiat res 1:125-31 (1997). The authors state that interstitial cystitis patients and fibromyalgia patients had significant overlap in symptomatology. Id. at 125.

Respondent filed as Ex. E a review by P. Duclos entitled "Anti-Infectives. Safety of immunisation and adverse events following vaccination against hepatitis B, 2 Expert Opin. Drug Saf. 3:225-231 (2003). Over one billion people have been vaccinated against hepatitis B virus. Ex. E at 225. Duclos states that establishing a causal relationship between many purported adverse events and hepatitis B vaccination is difficult because the events are rare and occur among unvaccinated people and are more likely in older age groups. Id. at 226. Duclos summarizes the findings of a committee that the World Health Organization set up in 1999 to evaluate safety issues and make scientific recommendations. Id. Duclos concludes that the risks of hepatitis B vaccine are theoretical. Id. at 229.

TESTIMONY

Petitioner testified first. Tr. at 9. She and her husband have four children. She also had six miscarriages. Tr. at 11. As a child, she had multiple sore throats and ear infections. After she had a tonsillectomy in fourth grade, she did not get sick much afterwards. Tr. at 13. Throughout her life, she has struggled with urinary tract infections or urinary tract irritation without bacteria in the urine. Tr. at 14. It is extremely common in her family. She has aunts, sisters, and two of her daughters who have chronic urinary problems. Id. Her mother had trouble with urinary tract infections but not as much as two of her sisters and not to the extent that petitioner and her daughters do. Id.

Petitioner got breast implants on May 10, 1989. Tr. at 18. After she breastfed her fourth child in early 1992, the breast implants encapsulated and became hard. Tr. at 20. She decided to get her nursing degree and went back to school part time in January 1992. Tr. at 20-21.

Around the time she went to nursing school, she took a part-time job on the weekends, working two 12-hour shifts, at B.F. Goodrich/Michelin making tires. Tr. at 21. Her shift was midnight to noon. Tr. at 22. It was a very physically demanding job, not usually done by women. Id. She always completed 110 percent of what the quota was. Tr. at 23. Sometimes the tires were very heavy. Id. She would build larger tires for pickup trucks and those tires weighed 60 pounds. She weighed 120 pounds, but she could do it without a problem for 12 hours. Id. She has been athletic most of her life, swimming and bicycling in high school, and working out five days a week. Tr. at 24. Even though she was in her forties, she could make tires. Id.

When petitioner worked 12-hour shifts building tires, she had to build 370 or 380 of them in 12 hours. Tr. at 25. When she built the big tires, she had to build 220 of them in 12 hours.

And she would lift the tires over her head to stack them on a rack. Id. When she worked from midnight to noon, she went home and slept until about dinnertime, got up, prepared dinner, spent time with the family, and went back to work. Tr. at 26. She only had to do it two days in a row. Id.

Then the factory shifted everyone onto one rotating swing shift of 12 hours and she worked three or four days in a row and had three days off. Tr. at 27. She set up her nursing class schedule to accommodate this, but when she started nursing clinicals, she could not do a rotating swing shift and left Goodrich in January 1995. Id.

Besides taking care of her four children, petitioner had six- to eight-hour shifts of clinicals a week and then class time when she was not in clinicals. Tr. at 28. She wanted to finish clinicals in two years. Id. The nursing department strongly encouraged receipt of hepatitis B vaccine because the students came into contact with bodily fluids. Tr. at 29.

Petitioner received her first hepatitis B vaccination on January 5, 1995 without any problems afterward. Id. After her second hepatitis B vaccination on February 17, 1995, she did not feel well through April. She was very tired and had a hard time getting up and going to clinicals. Id. She also had trouble taking care of her children. But by May and June, she had her energy back. Id. She remembers that during the winter, besides being very tired, she felt as if she had a viral illness. Her stomach did not feel quite right. Tr. at 30. The nausea and lightheadedness that occurred two months prior to April 1995 occurred after the second hepatitis B vaccination. Tr. at 31.

She saw Dr. Randolph on June 2, 1995 for an injury to her right chest due to wrestling on the floor with her family. Id. She had pain and redness along one side of her right breast. Id.

On July 11, 1995, she was in an automobile accident and bruised her knee and right arm. Tr. at 32. She was not having any trouble with fatigue at that point or her stomach feeling funny. Id.

On August 2, 1995, petitioner received her third hepatitis B vaccination and, toward the middle of August, she started feeling very tired again and her stomach did not feel right. Id. She had no appetite and felt lightheaded and dizzy. After that point, she never felt good again. Id. On October 10, 1995, Dr. Cowan found a mass on her ovary. Tr. at 33. She had laporascopic surgery and it was not cancer. Tr. at 34.

Petitioner testified that from August 1995 on, she never felt well again and never had the energy level she had before. Tr. at 35. She would have days where she felt a little better but her fatigue got greater. Tr. at 35-36. She was still going to class and taking care of the children, but she was sleeping as much as possible and more than normal. Tr. at 36. In January 1996, she started clinicals again and was fatigued and not feeling well. She was not working out any more. She graduated in December 1996. Tr. at 36-37. Antidepressants made her happier, but did not help her fatigue or energy level. Tr. at 37.

Petitioner took a job at the Women's and Children's unit but only part time because she did not have the energy or strength to work full time. She worked two to three eight-hour shifts a week. Id. In August 1997, she switched to the Pediatric Intensive Care Unit to three 12-hour shifts from 4:00 p.m. to 4:00 a.m. That is when her health took a serious downturn. Tr. at 38. Her thought processes for the 12 hours started to be a challenge. Id. She started to have body aches in her joints and muscles, in addition to the fatigue and feeling ill. Tr. at 39. She struggled to make it through a 12-hour shift. Id. Around 11:00 p.m. or midnight, she was so tired that she would get very pale and pass out or come close to it. The staff would check her blood sugar and

pressure. At one point, her sugar was low. Id. She could not function mentally very well and was exhausted. Id. In late December or early January 1998, she stopped working at Parkview. Tr. at 41.

Dr. Campbell told her she was likely suffering from a demyelinating illness. Tr. at 49. He told her she had chronic inflammatory demyelinating polyneuropathy and started her on IVIG treatments in February 1999 which ended in June 2000. Petitioner believes IVIG saved her life. Tr. at 53. On March 9, 1999, she had the breast implants removed. Tr. at 54. She had inflammation twice in the right breast after surgery, the first due to a hematoma and the second due to a seratoma. Tr. at 55. She felt much better, and in June 2000, went back to work one day a week. Tr. at 56. She finds she can work two or three eight-hour shifts a week and maintain her function and health. Tr. at 56-57.

Petitioner testified that she had frequent urinary problems. Tr. at 67. When she had a urinary tract infection, it would upset her stomach and make her feel tired, but the biggest problems were burning and frequency. She felt ill when she had urinary problems. Id. The drug Pyridium (pain reliever) upset her stomach and nauseated her. Tr. at 68.

She had pneumonia in 1992. Tr. at 68-69. She was in nursing school from January 1992 to January 1995. Tr. at 70. She took summer classes each summer. Tr. at 71. When she was taking nursing prerequisite classes, she was also working four days on and three days off in a 12-hour shift at Goodrich. Tr. at 74. Although she was struggling to stay awake in class after working a lot of hours, she was not struggling with fatigue. Tr. at 76.

Petitioner said she did not have any problems after her first hepatitis B vaccination. Tr. at 79. After the second hepatitis B vaccination, she struggled with fatigue for three months. She

struggled to get out of bed in the morning and was tired after she slept all night. She had more trouble going to nursing class and taking care of her children. She felt ill, did not have much appetite, and was dizzy, as if she had the flu. Tr. at 80. She does not know when it began except it was some time in February and ended in May. She could sleep without a problem and went back to exercising. Id.

Dr. Giant was the first doctor petitioner saw after receiving her second hepatitis B vaccination. Tr. at 81. She told him she had not felt well for about a month. Tr. at 82. She did not have cognitive problems after the second hepatitis B vaccination or even right away after the third hepatitis B vaccination. Tr. at 85-86. The fatigue was much worse after the third vaccination and her symptoms waxed and waned. Tr. at 86. When she reached a point of incapacitation, the mental issues came in. Tr. at 87. The onset was in mid-August. Id. She did not go to a doctor because she did not have a fever, a sore throat, an earache, or vomiting. She assumed her fatigue was due to a virus. Id. When she saw Dr. Giant ion August 25 because of knee and ankle pain from a car accident, she did not tell him about her fatigue because she assumed it would pass. Tr. at 88. In early September, she called her urologist Dr. Hockley to complain of bladder discomfort, nausea, fatigue, and lightheadedness. Tr. at 88-91. When her doctor told her she had an ovarian mass, she remembered there had been something wrong with her since August and she thought it was ovarian cancer. Tr. at 92. After the ovarian cyst was removed, she did not complain to a doctor about fatigue for a year. Tr. at 93.

Petitioner testified that from August 1995 on, she never felt right, and never felt 100 percent again. Tr. at 95. She was not able to get up early, and did not have the energy level. Id. Severe pain and memory issues started in the summer of 1997. Tr. at 99. When she went on

three eight-hour shifts in the pediatric ICU in the fall of 1997, her symptoms picked up and she started calling physicians again because the symptoms were intensifying and she had new pain and memory issues. Tr. at 100. Her blood sugar was low. Tr. at 103.

Dr. Yehuda Shoenfeld, an immunologist, testified next for petitioner. Tr. at 109. He stated that the silicone of her breast plants had an adjuvant effect which combined synergistically with the adjuvant of the second and third hepatitis B vaccinations, causing petitioner chronic fatigue syndrome. Tr. at 141. An adjuvant is a substance that can stimulate the immune system nonspecifically and help it react to other compounds. Tr. at 131. Adjuvants are in vaccines and inlaid in silicone. Tr. at 133. An adjuvant can cause any autoimmune disease by polyclonal activation of the immune system. Tr. at 137.

Dr. Shoenfeld said it was difficult to say whether it was the silicone or the vaccine causing petitioner's problem. Tr. at 139. But the fact is that petitioner had symptoms after the second hepatitis B vaccination which were worse after the third vaccination. This was associated with polyclonal gammopathy which means stimulation of the whole immune system. Id. Plus, IVIG remarkably ameliorated her problem. Id. There is some kind of overlap between the removal of petitioner's breast implants and the IVIG. Tr. at 141.

Dr. Shoenfeld had never seen a case like this before in which there was a combination of adjuvant from the silicone of the breast implant and vaccine. Tr. at 143. He thinks in petitioner's case, there was a combined synergistic effect of the adjuvant of the silicone and the second and third vaccinations. Tr. at 141. If it had just been the effect of the silicone, why did petitioner have a severe aggravation of her symptoms after the third vaccination? Tr. at 143. He opined that both the breast implants and hepatitis B vaccine were substantial factors in causing

petitioner's injury. Tr. at 145. Dr. Shoenfeld called what petitioner has "adjuvant autoimmune condition," for which the trigger was her vaccination. Id.

When petitioner was wrestling with her child on the ground, she had trauma to the capsule enclosing the breast implant with subsequent inflammation. Tr. at 146. However, Dr. Shoenfeld believed that even if petitioner had not had breast implants, hepatitis B is the cause of her condition. Tr. at 147.

Petitioner's breast implants had calcified which happened because she had inflammation. Blood streamed toward the inflammation and calcium was deposited there. Tr. at 149. Petitioner did not have demyelination or chronic inflammatory demyelinating polyneuropathy. Tr. at 150. He thinks Dr. Campbell might have diagnosed CIDP as a ruse to get the insurance company to allow use of IVIG for petitioner. Tr. at 150-51.

The failure of petitioner to complain about a chronic state of fatigue for a year (from December 1996 to December 1997) to her doctors does not affect Dr. Shoenfeld's opinion because it may have been a slow progression. Tr. at 151-52. In cases dealing with adjuvant, onset is more flexible–could be longer or shorter. Tr. at 152. Chronic fatigue syndrome involves autoantibodies. Tr. at 153. Fibromyalgia does not clearly involve autoantibodies. Tr. at 154.

Dr. Shoenfeld stated that petitioner's chronic fatigue began after her second hepatitis B vaccination, but he did not recall when. Tr. at 163. It became very severe after the third hepatitis B vaccine. Tr. at 164. That petitioner did not see doctors to complain of fatigue for two years except for short periods of time did not bother Dr. Shoenfield because fatigue is a very subjective complaint. Id. Dr. Shoenfeld said that what is fatigue for someone else is not fatigue

for a "superwoman" like petitioner. Id. Petitioner and her husband were in financial difficulties and she needed to work to provide for the family which also included four children. Id.

The injury to petitioner's right breast occurred around June 2, 1995. Tr. at 169. Until that time, she had felt better after the second hepatitis B vaccination of February 17, 1995. Id. Two weeks after the second vaccination, petitioner complained about fatigue. Tr. at 171. After the third hepatitis B vaccination, she complained about severe fatigue. Id. Dr. Shoenfeld stated that anyone who has a chronic disease will complain about fatigue, but the fatigue is not the same every day. Tr. at 176.

Dr. Shoenfeld said that petitioner may meet the criteria for chronic fatigue syndrome, but she does not have any neuronal defects now. Tr. at 178. He cannot say if petitioner has fibromyalgia because no one examined her for the 18 pressure points which define fibromyalgia. Tr. at 179. In essence, Dr. Shoenfeld believes petitioner has something that has no diagnostic name. It is the action of the silicone breast implants adjuvant combined with the effect of the hepatitis B vaccine. Id. She had polyclonal general fatigue. Id. Petitioner had severe fatigue, unrefreshing sleep, headaches, myalgia, arthralgia, and the adjuvant syndrome. Tr. at 184. Petitioner does not have chronic fatigue syndrome but she has a syndrome which is characterized by chronic fatigue. Id. This condition has autoimmune flavors because many of the patients have autoantibodies. Tr. at 186. This condition is accepted by the medical community because it has many names and follows silicone implants and vaccinations. Tr. at 188-89. Researchers, but not clinicians, believe that chronic fatigue syndrome is an autoimmune condition. Tr. at 190.

Dr. Shoenfeld co-authored a case report published in Autoimmunity Reviews, a journal of which he is founder and co-editor, entitled "Chronic Fatigue Syndrome With Autoantibodies"

(Ex. 36). Tr. at 194-95. When asked why he titled it "Chronic Fatigue Syndrome with Autoantibodies" when he now testified that petitioner does not have chronic fatigue syndrome, Dr. Shoenfeld answered that chronic fatigue was petitioner's most important manifestation. Tr. at 195-96. This was the prominent syndrome until he defines it as a new syndrome. Tr. at 196.

Dr. Lawrence Kagen, a rheumatologist, testified for respondent. Tr. at 198. His subspecialty is muscles. Tr. at 202. He has seen patients with chronic fatigue as a symptom and fibromyalgia. Tr. at 203. Dr. Kagen summarized petitioner's course as follows: She received hepatitis B vaccine on January 5, 1995, and February 17, 1995. On March 6, 1995, she phoned Dr. Giant, and visited him on March 9, 1995, complaining of a cold, occasional nausea, dizziness, and sinus. She had had the cold for one month. Tr. at 205. He does not believe that hepatitis B vaccine causes upper respiratory illness. Tr. at 206. On August 2, 1995, petitioner received her third hepatitis B vaccination and, on September 21, 1995, spoke to her neurologist, complaining of bladder discomfort, nausea, fatigue, and lightheadedness, dating her symptoms back four to six weeks, or the end of August, beginning of September. Tr. at 208. Dr. Kagen does not believe that hepatitis B vaccine caused petitioner urinary tract problems. Id.

Dr. Kagen recounted that medical records going back to December 1989, including April 1992, May 1992, and December 1993 showed complaints of nausea. Tr. at 209. Petitioner complained of headaches in June 1991. She complained of fatigue in June 1991, May 1992, December 1993, January 1994, and November 1994. Id. On October 10, 1995, petitioner told Dr. Cowan that she had extreme fatigue, lightheadedness, and intermittent nausea. Tr. at 210.

Fatigue is a symptom which can occur in many kinds of diseases. Tr. at 212. Dr. Kagen did not see anything in the record to indicate that petitioner has an autoimmune disease. Tr. at

213. If someone has an autoimmune disease, he or she has to have a specific one. Id. Petitioner had a borderline increase in gammaglobulin when she was receiving gammaglobulin infusions. Tr. at 214. Her rheumatoid factor was normal. Another time, the test was borderline. Id. She had a borderline increase in IgG and she was below normal in IgM and IgA. Tr. at 215. To Dr. Kagen, there was not any marked evidence of the presence of autoantibodies. Tr. at 216. He stated he would not characterize petitioner as having polyclonal gammopathy or hypergammaglobulinemia. Id. In order to make those diagnoses, he would need marked elevations in the levels of gammaglobulin, which petitioner did not have. Id.

Dr. Kagen stated that patients who have abnormalities in their immune systems can have manifestations in two large areas. Tr. at 217. In the first area, they are subject to frequent infections. Petitioner did have frequent urinary tract symptoms, but the cultures did not reveal infection, and when she had a biopsy of the bladder, no infection was seen. Id. In the second area, people have an autoimmune disease, but there is no evidence that petitioner has one. Id.

Dr. Kagen diagnosed petitioner with multiple problems. Tr. at 218. She has had many episodes of urinary symptoms. She has had multiple cystoscopies. She had many procedures related to bladder biopsy. She has symptoms of an inflammatory urinary system. Id. Several physicians diagnosed her with depression which is not surprising since she has been through six pregnancy losses. Id. In addition, she was concerned about cancer and her ovarian tumor fortunately turned out to be benign. Tr. at 219. She was diagnosed with shingles. Id. There was no documentation of the diagnosis of shingles that petitioner's doctor made. Tr. at 220.

Dr. Kagen said that petitioner has had long-lasting fatigue whose onset was several years after hepatitis B immunization. Id. Petitioner had more than one occasion in 1997 of low blood

sugar, said to be in the 40s or 50s, which is strikingly low. Tr. at 221. Petitioner's history of blackouts goes back to 1991. Tr. at 222. Most of petitioner's complaints predate hepatitis B vaccination. Id. Dr. Kagen does not know the cause of petitioner's chronic fatigue which began in 1997, two years after the administration of hepatitis B vaccine. Id.

The undersigned asked Dr. Kagen if he attributed calcification of a breast implant to an abnormal reaction of the body to the substance, and he replied:

> THE WITNESS: Yes. Well, I think there was an injury, and I think an implant filled with saline would be something like a balloon. It could be damaged. The silicone leaked from these implants, and there was a tissue reaction to them, and the tissue reaction was a calcification and also the ingestion of silicone particles by what are referred to as histiocytes. Histiocytes are the cells that ingest foreign materials. So those cells were pulled to that area, they ingested the foreign materials, and they led to a local tissue reaction, which was seen by the pathologist. ... She had redness at that time, so at that time she had findings of inflammation. Now the other part of this is I think that leakage of silicone and local inflammation is unfortunately not that rare in patients that have silicone implants, but I think the coincidence of autoimmunity and that kind of thing is very rare or doesn't occur.

Tr. at 230, 231, 232.

In the paper that Dr. Shoenfeld co-authored about this case, he and his co-author wrote that petitioner had polyclonal gammopathy, high levels of antiadrenal, antistriated muscle, and antismooth muscle, but that is not so. Tr. at 236.

Dr. Kagen's impression of petitioner was that "she has been through hell multiple times and she has survived in a magnificent way. And I think I found her to be forthright, absolutely." Tr. at 246. However, he stated her testimony does not agree with the medical records, plus she admits to memory problems and cognitive problems so it is hard for him to say her testimony is accurate. Tr. at 247. His impression of petitioner is that she is a very brave woman. Id.

Considering her pregnancy losses, an automobile crash, and taking care of her family, Dr. Kagen said there was "not enough that can be said in praise of a person like that." Tr. at 247-48.

Dr. Kagen has multiple diagnoses for petitioner, anxiety being one of them. Tr. at 248. Hepatitis B vaccine is not the cause of her problems which she has surmounted in an admirable fashion. Id. He thinks her urinary tract inflammation (rather than infection since infection was never demonstrated and her cultures were negative), depression, multiple losses of babies, ovarian tumor, shingles, anxiety, and allergies probably all had an impact on her severe fatigue in 1997. Tr. at 249-50. Petitioner's urinary symptom problems began in her 20s and she lived with that for at least 20 years before 1998. Tr. at 250. They caused episodic fatigue. Id. Dr. Kagen stated that even transient fatigue has an impact. Tr. at 251. He stated:

> [T]he major manifestations which we perceive it by have disappeared, but it doesn't mean that it may not have an underlying impact. Whatever happens to us that's negative affects us and affects us over the long haul. And if it happens to you repeatedly, over and over again, that's going to have an impact. So I don't think it's fair to say well, she got better in two days. Why isn't she better now? Why is it going on for such a long period of time? I think it modifies you. It modifies the way you respond.

Id.

Petitioner's silicone breast implants caused her to have surgery. Tr. at 256. The fact that they were inflamed, producing a local reaction, had an impact on her life. Tr. at 256-57.

The undersigned then asked Dr. Shoenfeld if he thought the following scenario showed rechallenge or positive rechallenge: no reaction occurs after the first vaccination; a transient reaction occurs after the second vaccination; a more significant reaction occurs after the third vaccination and the reaction continues. Tr. at 267. Dr. Shoenfeld said yes, it was a boost. Tr. at

267-68. It is immunologically significant because of the increase of antibodies against the immunizing material. Tr. at 268.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(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. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Sec'y 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. Sec'y 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. Id. at 1148.

Petitioner must show not only that but for the vaccine, she would not have had the fatiguing condition, but also that the vaccine was a substantial factor in bringing about her

fatiguing condition. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999) (a baby developed a high fever after receiving DPT vaccine; he was also harboring E. coli infection which can cause fever; testimony showed that both the vaccine and the infection were substantial factors in causing his high fever that led to his death; petitioners prevailed because the vaccine was a substantial factor).

Close calls are to be resolved in favor of petitioners. Capizzano, 1440 F.3d at 1327; Althen, 418 F.3d at 1280. *See generally*, Knudsen v. Sec'y of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994).

In essence, the special master is looking for a medical explanation of a logical sequence of cause and effect (Althen, 418 F.3d at 1278; Grant, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen:

> Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.
>
> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

The Federal Circuit in Knudsen, 35 F.3d at 549, also stated: "The special masters are not 'diagnosing' vaccine-related injuries."

This is an intensely complicated and difficult case. Petitioner has had decades of inflammatory and allergic problems: 20 years of urinary tract inflammation and allergies to numerous substances. These problems run in her family. Moreover, she encountered more inflammation from the saline breast implants which were encased in silicone. The literature supports her expert Dr. Shoenfeld's testimony that inflammation from leaking silicone can be subclinical, i.e., without overt symptoms, yet still be present. Petitioner testified that after her fourth child was born and she was breastfeeding, the implants calcified. Then, after the second hepatitis B vaccination, petitioner injured her right breast and had overt inflammation. After the third hepatitis B vaccination, her symptoms of fatigue continued. Four years later, in 1999, she had the breast implants removed and pathologic analysis showed inflammation from silicone leakage from both breasts (even the left one which had not received injury in 1995) in every slide with histiocytes (macrophages) attempting to deal with the inflammation.

This is a Shyface situation, only with three known factors unrelated to the vaccine: (1) chronic uterine inflammation, (2) chronic allergies, and (3) silicone leakage resulting in histiocyte activation, plus hepatitis B vaccine. Dr. Shoenfeld testified that the silicone leakage boosted petitioner's reaction to her second vaccination. There is a difficulty in that petitioner really did not complain of fatigue from the second and/or third vaccination until practically two years later. She had numerous visits to doctors for sinus, allergic, uterine, and low sugar problems without identifying debilitating fatigue. But recognizing that, as Dr. Shoenfeld stated, petitioner is a "superwoman," and as Dr. Kagen, respondent's expert, stated, she is a magnificent survivor, very brave, absolutely forthright, admirable, and he could not praise her enough, the undersigned believes that petitioner fights off fatigue more than the rest of us can or do.

Everyone in the courtroom was impressed with her, particularly her extraordinary workload building 30- or 60-pound tires for 12-hour shifts. Her nursing school shifts were also interminably long. She performed all this work while taking care of her husband and four children.

Although the undersigned agrees with Dr. Brenner and Dr. Kagen that there is no reliable proof of autoimmunity here because the only proof comes from Dr. Campbell's laboratories and he is notorious for diagnosing every vaccinee with CIDP (Dr. Shoenfeld said perhaps Dr. Campbell's misdiagnoses are a ruse to obtain insurance coverage to administer IVIG to patients), that does not mean that petitioner did not become ill. Not all immune problems are autoimmune. Although petitioner ascribes her improvement to the IVIG, it may well be that the removal of her breast implants in 1999 was a major factor in her improvement. The adjuvant factor about which Dr. Shoenfeld testified coming from the silicone was then gone.

The undersigned accepts Dr. Shoenfeld's testimony that, beginning at least in June 1995 when she injured her right breast, petitioner's chronic inflammation from the leaking silicone in her breast implants played a substantial factor in her worsening fatigue. Dr. Kagen also thought the breast implants played a role in her fatigue (although he did not think the hepatitis B vaccine played any role whatsoever). The undersigned also accepts Dr. Kagen's testimony that the decades that petitioner experienced urinary tract inflammation played a role in her fatigue. He said the chronic inflammation has an impact and modifies the way someone responds. The undersigned accepts Dr. Shoenfeld's testimony that hepatitis B vaccine also caused petitioner's fatigue. Even if petitioner did not have breast implants, Dr. Shoenfeld opined that hepatitis B vaccine caused her fatigue.

The undersigned ruled in Jane Doe/52 v. Sec'y of HHS, No. [redacted], 2009 WL 5206199 (Fed. Cl. Spec. Mstr. Dec. 15, 2009; reissued redacted Jan. 9, 2010), that hepatitis B vaccine can (and in that case did) cause fibromyalgia and chronic fatigue syndrome. Jane Doe/52 did not concern breast implants or silicone adjuvant. However, it did concern an antigenic stimulant other than the hepatitis B vaccine--prior exposure to Epstein Barr virus (EBV)–to which both petitioner's expert and respondent's expert (Dr. Kagen, the same respondent's expert in the instant action) attributed a causal role. To petitioner's expert (who was petitioner's treating immunologist) in Jane Doe/52, hepatitis B vaccine reactivated petitioner's dormant EBV which led to petitioner's chronic fatigue syndrome and fibromyalgia, whereas respondent's expert Dr. Kagen in Jane Doe/52 attributed causation solely to the EBV without any causal role for the vaccine.

Jane Doe/52 and the instant action are similar in that, in both cases, hepatitis B vaccine plus stimulus from another biologic event (in Jane Doe/52, the EBV; in the instant action, leaking silicone plus decades of chronic inflammation) combined to cause chronic fatigue. The undersigned recognizes that Dr. Shoenfeld in the instant action does not diagnose petitioner with either chronic fatigue syndrome or fibromyalgia (whereas petitioner in Jane Doe/52 had both), but petitioner in the instant action did have chronic fatigue symptoms.

Based on the testimony of both experts who testified, the undersigned sees here a vaccinee who with decades of chronic urinary tract inflammation and allergies, experienced calcification of her breast implants after her fourth child was born, received hepatitis B vaccine in January and February 1995, then experienced transient fatigue and more inflammation when she hurt her right breast in June 1995, followed by her third hepatitis B vaccination, when she

experienced more fatigue which does not go away, with a worsening of her breast implant inflammation, necessitating surgery to remove the implants in 1999.

Dr. Shoenfeld testified that there is rechallenge, also called positive rechallenge, in this case because the same symptom of fatigue after the second hepatitis B vaccination occurred after the third hepatitis B vaccination.

Petitioner has proven by preponderant evidence the medical theory that hepatitis B vaccine can be a substantial factor in causing a fatiguing condition when combined with chronic inflammation due to decades of urinary tract and allergic conditions, and chronic leakage from silicone capsules. This is the first Althen prong.

Petitioner has also proven by preponderant evidence that hepatitis B vaccine was a substantial factor in causing her fatiguing condition as there is a logical sequence of cause and effect in her reaction to hepatitis B vaccine because she is historically someone who frequently exhibits inflammation due to stimuli, i.e., her urinary tract inflammation, her allergies, and her histiocytic response to silicone leakage. This is the second Althen prong.

Lastly, petitioner has proven by preponderant evidence that there is a medically appropriate time relationship between her third hepatitis B vaccination in August 1995 and her fatiguing condition (which mirrors the temporal sequence of the transient reaction she had in February to her second hepatitis B vaccination). This is the third Althen prong.

Petitioner has proven causation in fact.

CONCLUSION

Petitioner is entitled to reasonable compensation. The undersigned hopes the parties may reach an amicable settlement. A telephonic status conference will be set soon to discuss how the parties will proceed in resolving damages.

IT IS SO ORDERED.

May 24, 2010
DATE

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