In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
[Redacted]
[Redacted]

JANE DOE,	*	
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Petitioner,	*	
	*	
v.	*	Hepatitis B vaccine followed almost two years later by MS; causation?
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SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

Petitioner filed a petition dated July 16, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine she received on December 1, 1995, January 2, 1996, and March 5, 1996 caused an unspecified adverse reaction.

Petitioner filed proof of receiving hepatitis B vaccine on December 1, 1995, January 2, 1996, and April 4, 1996. Med. recs. at Ex. 8, pp. 1, 2, and 3. In her VAERS form, which petitioner filled out herself on June 11, 1999, she wrote that the onset of her symptoms was July 3, 1997. Med. recs. at Ex. 9, p. 3. Under the section asking for a description of adverse events, petitioner notes that on March 31, 1998, she was partially deaf in her left ear, had numbness in

[1] Because of the nature of some of these medical records, the undersigned has redacted the Order to Show Cause. See Vaccine Rule 18.

her hands and feet, had tingling and shocking sensations down her legs, an unsteady gait, vertigo, bladder trouble, depression, memory loss, visual disturbances, and labile mood. On April 7, 1998, she was diagnosed as having multiple sclerosis (MS).

By September 8, 1999, two months after she filed her petition, petitioner filled out a VAERS form for follow-up information and changed the onset date of her symptoms from July 3, 1997 to January 2, 1996. She wrote that was when she had marked and noticeable depression. Med. recs. at Ex, 9, p. 2.

FACTS

Petitioner was born on January 20, 1980.

On November 19, 1993, petitioner saw her pediatrician, complaining of migraine-type headaches once a month, two weeks before she menstruated. She had nausea, vomiting, and visual disturbance. On Tuesday, her sense of smell was messed up because of the migraine. It helped to sleep. Her mother and possibly her father's great-grandmother had migraines. Her mother had a positive TB test. Med. recs. at Ex. 26, p. 18.

On February 14, 1994, petitioner told the pediatrician that she had not had a migraine since [unreadable] the last dose. She also had a question regarding an increase in sweating. This increase in sweating was mainly limited to under her arms and not much anywhere else. She also had trouble with her vision. On examination, she had no abnormalities. Her underarms were wet. She was prescribed medication for migraines. Med. recs. at Ex. 26, p. 17.

On January 30, 1995, petitioner went to St. Joseph Healthcare for a sports physical.

She received hepatitis B vaccine on December 1, 1995, January 2, 1996, and April 4, 1996. Med. recs. at Ex. 8, pp. 1, 2, and 3.

On June 16, 1996, petitioner's mother called the pediatrician for a Phenergan supplement for petitioner who was out of state and having difficulty with nausea due to migraines. Med. recs. at Ex. 26, p. 16.

On June 18, 1996, the prescription was called in. *Id.*

On December 31, 1996, petitioner saw Dr. Christopher L. Bird at St. Joseph Pediatrics and Family Healthcare because she was breaking out before menstruating. She had severe cramps. Cystic acne ran in her family. Her three brothers were on Accutane. She had a migraine and "went blind." Her migraines started at the age of 14-15. Now she had less. Her mother had migraines at age 17 and 18. Med. recs. at Ex. 26, p. 14.

On January 17, 1997, petitioner went to St. Joseph Pediatrics and Family Healthcare for a sports physical for track. She had no problems with social interaction. She was sexually active with condom use. She had no peer pressure. Med. recs. at Ex. 26, p. 13. Petitioner, her mother, and Dr. Bird signed the form. One of the questions was whether petitioner had a medical problem since her last evaluation, which was checked no. Med. recs. at Ex. 26, p. 20.

On July 3, 1997, petitioner went to St. Joseph Healthcare, complaining of facial lesions. She had had a lesion at the right nostril for the past one and one-half months. She was prescribed benzoyl peroxide. Med. recs. at Ex. 26, p. 11.

On September 10, 1997, petitioner went to St. Joseph Healthcare. Her chronic medications were Prozac and birth control. She needed a dermatology referral. She had a history of an acne facial rash. Med. recs. at Ex. 6, p. 5; also Ex. 26, p. 9.

On March 9, 1998, petitioner went to St. Joseph Healthcare, complaining of cramping and bloating. This was not new for her while she was ovulating. At that time, she felt fine. She

had started on oral contraceptives a year ago but stopped taking them when she broke up with her boyfriend. Now she had a new partner, but was using condoms only. Her appetite was good. She denied heartburn. She had no fever or chills. She was alert and cooperative. Med. recs. at Ex. 26, p. 7.

On March 24, 1998, petitioner went to St. Joseph Healthcare, complaining that her left ear was muffled. Med. recs. at Ex. 26, p. 5. She also had ringing in that ear. She had a stuffy nose left over from a bad cold which lasted two weeks with sore throat, cough, and nasal discharge which was brown. This resolved four days previously. Her appetite and elimination were normal. She was on Zoloft. *Id.*

On March 31, 1998, petitioner went to St. Joseph Healthcare, and saw Dr. Christopher L. Bird, complaining of numbness in her right hand (for two days), both feet (for two months--putting onset at February 1998, almost two years after her third hepatitis B vaccination), and buttocks. She had had a cold and now could not hear from her left ear. Two months previously, she was snowboarding and fell on her back and was shocked when her head was brought forward. She was dizzy and had motion sickness and lost her balance but did not fall. The assessment was paresthesias. Petitioner was referred to Dr. Michael Freedman, a neurologist. Med. recs. at Ex. 6, p. 2.

On April 2, 1998, petitioner saw Dr. Freedman because of a two-month history of numbness. This began with a tingling feeling in the bottoms of her feet. Over the past week, she also noted some numbness in her right hand, over the left buttock, and all around her vagina. There was no actual loss of feeling but a tingling sort of paresthesia in those areas. For several weeks, petitioner found that on flexion of her neck, she got an electric-like sensation spreading

down her neck to the low back. For about one and one-half weeks, she had loss of hearing in her left ear. She had no problem with bladder or bowel control. She did not have double vision, vision loss, numbness, tingling, or weakness of the face, trouble speaking or swallowing. Petitioner thought the numbness on the bottoms of her feet were due to a snowboarding injury. About two months ago, she came down hard on her back and the back of her head while snowboarding. The next day, she first experienced numbness on the bottoms of her feet. In the past, she had never had neurologic symptoms before two months ago. Med. recs. at Ex. 4, p. 1.

Under "past medical history," petitioner told Dr. Freedman that she had no chronic medical illnesses. *Id.* On examination, she had normal tone throughout with 5/5 strength throughout. She denied any sensory levels. Even on the right hand and in both feet where felt felt the numb tingling sensation, petitioner seemed to have normal sensation to light touch and pin prick, and joint position sense. *Id.* Her reflexes were 1 to 2+ and symmetrical with downgoing toes. Med. recs. at Ex. 4, p. 2. Although petitioner had a normal neurological examination, Dr. Freedman was concerned about a possible demyelinating disease process. *Id.*

On April 4, 1998, petitioner had an MRI of her brain and cervical spine because of bilateral feet numbness and bilateral hand and groin numbness. Med. recs. at Ex. 3, p. 5. Dr. Stephen G. Babel wrote that petitioner had multiple areas of abnormal signal in both the brain and the cervical spine consistent with a multifocal demyelinative process. She had multiple areas of enhancement consistent with several areas of active demyelination. *Id.* The lesions suggested MS. Med. recs. at Ex. 3, p. 6.

On April 7, 1998, petitioner saw Dr. Freedman again. MRI of the brain and spine and somatosensory evoked potentials from the lower extremity were consistent with a diagnosis of

MS. She also had an elevated hemoglobin, hematocrit, PT/PTT whose etiology was unclear and there was an unclear relation to MS. Med. recs. at Ex. 4, p. 3. Petitioner opted for Avonex therapy. Dr. Lorraine Sanchez suggested petitioner be evaluated rheumatologically. *Id.*

On April 9, 1998, petitioner went to Corrales Chiropractic. Robert A. Lupowitz states that petitioner was examined in that office on April 9, 1998 and petitioner reported that she had been experiencing neurologic disturbances since she was 16 years old, including mood swings and depression. In the past several weeks, her symptoms had intensified, including visual disturbances, difficulty with depth perception, and various transient paresthesias, from her feet to her abdomen, particularly in her forearms and hands. Med. recs. at Ex. 17, p. 8.

On April 16, 1998, petitioner saw Dr. Freedman again. Petitioner was very stressed because of the diagnosis of MS as well as preexisting stresses at school. She denied being suicidal. On examination, petitioner did not seem to be particularly depressed and she moved all four extremities well without any obvious dysmetria. Oligoclonal bands were present on spinal fluid, not seen in serum. Med. recs. at Ex. 4, p. 4. If petitioner were to use Avonex, she would need to be under the care of a psychiatrist because of its potential for precipitating depression. *Id.*

On April 20, 1998, petitioner saw Dr. Freedman. She was reluctant to take any medication to treat MS. She had an abrupt onset of some emotional difficulties about a year previously (1997) and was treated for depression. Petitioner's mother was concerned about the side effects of Avonex and Betaseron treatment precipitating or worsening her underlying depression. Dr. Freedman agreed that was a concern giving petitioner's history. Even Coplymer could cause some emotional lability. Med. recs. at Ex. 4, p. 5.

On May 4, 1998, petitioner saw Dr. Freedman. Her numbness was better. She had lessened tingling in her hands and no numbness in the legs. The prior week, she had some blurring of vision in her left eye. Med. recs. at Ex. 4, p. 6.

On February 9, 1999, petitioner saw R. Renee Richardson, a psychotherapist. In a client information form, petitioner fills out that she had MS symptoms in March 1998 and was diagnosed with MS in April 1998. Med. recs. at Ex. 2, p. 1. She states that she needs medical attention for depression. *Id.* During a clinical summary for outpatient services dated May 11, 1999, Dr. Richardson writes that petitioner's childhood sexual abuse issues were emerging. She also had difficulty accepting and adjusting to her MS. She was expressing her depressive symptoms as well as anger by cutting behaviors. Med. recs. at Ex. 2, p. 3.

On February 12, 1999, Dr. Barbara Koltuska, a Ph.D., wrote a neuropsychological evaluation of petitioner. Med. recs. at Ex. 16, p. 25. Her paternal aunt has MS. Her older brother suffers from depression and is in counseling. Her maternal grandfather, an alcoholic, molested her and her younger brother when she was about four years old. At that time, her family lived in his house. Her younger brother reported the abuse to petitioner's mother who confronted her father, but he denied it. The family moved out of the house and petitioner and her brother were taken into counseling. Petitioner did well for a long time, but at the age of 15 (petitioner was 15 on January 30, 1995), began having serious emotional problems. She became very angry, depressed, and suicidal. She would cut her hands and legs with razors. She was treated with Zoloft and Prozac for six months and went to counseling. She had another severe depression with self-mutilation and suicidal ideation. Two years later, she broke up with her boyfriend and was diagnosed with MS. Med. recs. at Ex. 16, p. 26. Petitioner scored 30/30 on

the mental state exam, revealing grossly intact cognitive functioning. She was oriented to time, place, and person. Petitioner's IQ is in the 90th percentile (high average/superior range). Her IQ testing was done when she was in severe depression. Since her very high score on abstract reasoning and extremely good school performance, her IQ may be higher than reported. Med. recs. at Ex. 16, pp. 28-29. Petitioner's performance on attention and concentration was normal. Med. recs. at Ex. 16, p. 29. She performed in the average/superior range on the memory tests, suggesting no memory impairments. Med. recs. at Ex. 16, p. 30. Her MMPI profile on personality showed that she felt socially and emotionally alienated, rejected, and misunderstood. "There is also some impulsivity, poor social judgment, unstable mood, difficulties in concentration, overactivity and a character disorder in her clinical profile that may be related to early sexual abuse." Med. recs. at Ex. 16, p. 31. Multiple elevations in her profile may suggest borderline personality traits. It is also possible that MS intensified all her earlier emotional problems. Her last episode of self-mutilation was three months ago. *Id.* In conclusion, Dr. Koltuska stated that petitioner suffers from post traumatic stress disorder (PTSD) as a result of sexual abuse as a child, and major depression that may be a result of both PTSD and MS. She was currently functioning within the average/high average range of general intellectual ability. *Id.*

On February 19, 1999, petitioner took a polysomnogram for sleeping disorder. She had upper airway resistance syndrome and periodic limb movement disorder. Dr. Barry J. Krakow recommended that she receive pharmacotherapy for the limb movement disorder and then be evaluated for CPAP titration for upper airway resistance syndrome. Med. recs. at Ex. 7, p. 3.

On March 16, 1999, Dr. Richardson, the psychotherapist, wrote that petitioner was better off with her father. Her mother confronted her with porno a number of times with the family. Med. recs. at Ex. 12, p. 2.

On July 6, 1999, Dr. Richardson diagnosed petitioner recounts how her grandfather sexually abused her. Med. recs. at Ex. 12, p. 3. On July 27, 1999, petitioner reveals more of her worries. Med. recs. at Ex. 12, p. 4.

On July 19, 1999, Dr. Roxanne R. Duran, a licensed psychologist associate, wrote a treatment summary saying she saw petitioner in psychotherapy from May 1997 to April 1998. Petitioner initially presented with severe mood swings and explosive temper tantrums as well as recurring memories of sexual abuse by her maternal grandfather. She reported impulse control problems, obsessive compulsive symptoms, and very low self-esteem. Petitioner was able to get some relief from childhood abuse memories during the course of therapy, but emotional outbursts, anxiety, and depression continued. Dr. Duran referred petitioner to a psychiatrist, Dr. Neil Arnet, for a medication evaluation and petitioner was placed on the anti-depressant Zoloft, which gave her minimal relief but no significant improvement. Dr. Duran diagnosed petitioner with post-traumatic stress disorder and major depression. Med. recs. at Ex. 1, p. 1.

On November 9, 1999, petitioner recounts to Dr. Richardson more of her conflict over her grandfather's sexual abuse, her hatred of him, her guilt for coming out of her room, and her feeling so sad. Med. recs. at Ex. 12, pp. 6, 7.

On July 31, 2003, petitioner saw Dr. Freedman. She no longer felt the need to be on an antidepressant. Dr. Freedman's impression was relapsing, remitting MS. Petitioner was doing well on Copaxone. Med. recs. at Ex. 23, p. 2. The undersigned has not seen Dr. Ford's records.

Other Submitted Materal

Petitioner submitted an affidavit from Krista E. Gibboney, dated November 8, 2003, stating that in 1995 at the end of freshman year (one would assume the end of the school year would be June), petitioner received hepatitis B vaccine and had a drastic change in mood and enthusiasm. She had violent emotional outbursts and would cut her body. She was suicidal. She was fatigued, forgetful, and cold. Ex. 24, p. 1.

Petitioner submitted her mother's affidavit, dated November 14, 2003, in which she states that shortly after receiving hepatitis B vaccine, petitioner had heat intolerance, unusual perspiration, marked fatigue, and drastic personality changes. She told her mother often that she did not feel right, exhibited confusion, memory loss, and violent outbursts, such as punching walls with her fists until her knuckles were bloody. She was less energetic and became depressed and despondent. She was pale. Petitioner saw a psychologist and got worse. She started to self-mutilate. Ex. 25, p. 1. Her symptoms included suicidal tendencies, excessive crying, abdominal pain, blinding migraine headaches, unusual sense of smell and taste, confusion, cognitive impairment, and labile mood swings. "She was diagnosed with MS shortly after her 18th birthday, not long after receiving the Hepatitis B vaccine." Ex. 25, p. 2.

DISCUSSION

Petitioner's first neurological symptoms occurred almost two years after her third hepatitis B vaccination. The depression, migraine, and excessive sweating that petitioner's mother stated occurred after the third hepatitis B vaccination actually occurred before petitioner received hepatitis B vaccine, i.e., in 1993 and 1994. Petitioner's depression is completely understandable considering the horrendous sexual abuse she suffered as a child.

If petitioner insists that her onset of MS occurred one month after her first hepatitis B vaccination (on the day of her second vaccination), she will have to file a report from a medical expert stating that depression is the onset of MS in the absence of neurologic symptoms. Since petitioner was going fairly often to her pediatrician during 1996 for cramps during ovulation, acne, and physical examinations to permit her to be on the track team. One would assume that if she had a total personality change directly after her third hepatitis B vaccination, as petitioner's mother has stated, this would have appeared on one of these medical records. In fact, the opposite appears: she had no difficulty interacting socially.

If petitioner does not file a report from a medical expert that her onset of MS was in January 1996, then the undersigned will continue to assume the onset was in March 1998, 23 months after her third hepatitis B vaccination. The undersigned doubts that petitioner will find an expert to testify that hepatitis B vaccine causes MS two years later.

Petitioner is ORDERED TO SHOW CAUSE by **January 19, 2007** why this case should not be dismissed.

IT IS SO ORDERED.

[Redacted]
DATE

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