

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: February 29, 2008)

No. 01-304V

_____)	
SALVATORE FORMICA,)	UNPUBLISHED
)	
Petitioner,)	Motion for Judgment on
)	the Record; Alleged
v.)	Injuries Include Tinnitus,
)	Fatigue, and Connective
SECRETARY OF THE DEPARTMENT OF)	Tissue Disorder; Medical
HEALTH AND HUMAN SERVICES,)	Records Fail to Support
)	Claim; No Offered Expert
Respondent.)	Opinion
)	
_____)	

Salvatore Formica, pro se for petitioner.

Katherine C. Esposito, with whom were Peter D. Keisler, Assistant Attorney General, Timothy P. Garren, Director, Mark W. Rogers, Deputy Director, and Gabrielle M. Fielding, Assistant Director, United States Department of Justice, Torts Branch, Civil Division, Washington, DC, for respondent.

DECISION¹

¹ The undersigned issues this final decision pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Absent the filing of a motion for review of this decision within thirty days, the Clerk of Court shall enter judgment in accordance with this decision.

Additionally, pursuant to 42 U.S.C. § 300aa-12(d)(4), Rule 18(b)(2) of the Vaccine Rules of this Court, and the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), this decision will be made available to the public unless a party objects, within fourteen days, to the disclosure of: (1) any “trade secret or commercial or financial information which is privileged and confidential;” or (2) any information contained in “medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.”

On May 17, 2001, petitioner Salvatore Formica, through counsel, filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the Vaccine Program).² Petitioner claims that he sustained injuries as a result of the hepatitis B (“Hep B”) vaccine he received on June 28, 1999.³ Petition ¶ 3. The petition does not describe the nature of Mr. Formica’s injury. See generally Petition.

In a status conference held on May 22, 2007, Mr. Formica clarified the nature of the injury for which he was seeking Program compensation, stating that after his third hepatitis B vaccine, he suffered “dizziness, tinnitus [ringing in the ear], and fatigue.” Order 5/31/07 at 1. Subsequently, in Mr. Formica’s communication to the court by facsimile dated September 4, 2007,⁴ he asserted that his medical records show that he suffered “an unspecified connective tissue disorder” which did not exist prior to the administration of the hepatitis B vaccination. Order 9/7/07 at 2. In evaluating petitioner’s motion for judgment on the record, the undersigned considers petitioner’s characterization of his injury in the context of his filed medical records.

Also filed on May 21, 2007, together with the petition, on Mr. Formica’s behalf, were: (1) a vaccination record from Partners Healthcare, see Petitioner’s Exhibit (P’s Ex.) 1; (2) medical records from Massachusetts General Hospital (MGH), see P’s Ex. 2; (3) medical records from New England Medical Center, see P’s Ex. 3; (4) medical records from Brookline, Ear, Nose and Throat, see P’s Ex. 4; (5) medical records from Massachusetts Eye and Ear Infirmary, see P’s Ex. 5; (6) medical records from MGH Beacon Hill Primary Care, see P’s Ex. 6; (7) Mr. Formica’s affidavit, see P’s Ex. 7; and (8) Mr. Formica’s statement regarding no prior civil action, see P’s Ex. 8. Additional medical records were filed on November 27, 2001, June 17, 2003, June 24, 2004, October 6, 2006, and on September 28, 2007.

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. § 300aa-10-§ 300aa-34 (West 1991 & Supp. 2002) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

³ The supporting medical records and all subsequent filings support the fact that the date of the vaccine administration was June 18, 1999, rather than June 28, 1999, as reflected in the petition.

⁴ The undersigned deemed this communication a motion for judgment on the record and filed it into the record of this case by leave of court on September 7, 2007.

Respondent filed a Rule 4(c) Report (R's Rept.) on May 9, 2006. In the Rule 4(c) Report, respondent asserted that this case was not appropriate for compensation under the Vaccine Act. Respondent stated that "petitioner ha[d] yet to offer a reputable medical or scientific theory [through either an expert or a treating physician,] causally connecting the vaccine to any alleged injury." R's Rept. at 7.

Mr. Formica has been proceeding pro se since December 7, 2006, when the undersigned granted petitioner's counsel's motion to withdraw. Prior to counsel's withdrawal, petitioner had been afforded a five-month period of time within which to file an expert opinion. After counsel's withdrawal, petitioner was afforded an additional period of nine months within which to obtain an expert and to file an opinion of causation. At the conclusion of the nine-month time period within which petitioner was directed to obtain counsel and to obtain an expert willing to testify about vaccine-related causation, petitioner requested by facsimile communication with the court on September 4, 2007, that the undersigned decide his claim on the filed records. This facsimile communication was deemed a motion for judgment on the record by the undersigned and was filed by leave of court on September 7, 2007. Motion for Judgment on the Record (P's Mot.). In his communication with the court, Mr. Formica asserted:

I believe that my medical records will provide a logical sequence of cause and effect related to the administration of the Hepatitis B vaccine received on June 18, 1999. The medical records will show that the first onset of symptoms began on June 21, 1999 just three days after the Hepatitis B vaccine. Prior to the administration of the vaccine the petitioner was a healthy male without any health problems. The medical records of Dr. Donna Felsenstein will show that an unspecified connective tissue disorder exists in the petitioner and also the medical records of Dr. Nancy Shadick will indi[cate] the same findings. These conditions didn't exist prior to the administration of the hepatitis B vaccine which is indicated by the petitioner's prior medical history.

P's Mot. at 1. Mr. Formica has not filed an expert opinion.

Petitioner's motion for judgment on the record is now ripe for decision.

I. DISCUSSION

A. The Factual Record

Employed as a biomedical technician at Massachusetts General Hospital (MGH),

petitioner received his first hepatitis B vaccine in 1996, and subsequently developed transient burning, pruritis, and redness of the ears, which resolved after treatment with Benadryl. P's Ex. 2 at 2. Mr. Formica received a second hepatitis B vaccine on May 19, 1999, with no reported side effects. Id. Mr. Formica received the third in the series of hepatitis B vaccines on June 18, 1999. See P's Ex. 11.

Mr. Formica claims to have been generally healthy prior to the receipt of his third hepatitis B vaccination on June 18, 1999. Id. His medical records, however, show that his past medical history was significant for a work-related injury that caused arm and chest pain, which began in April 1992 and lasted for several years. Id. P's Ex. 2 at 1-2.

On June 22, 1999, nearly a month after the second hepatitis B vaccination and four days after his third hepatitis B vaccination, Mr. Formica visited a doctor at MGH, complaining that on the previous day, he had begun to feel lightheaded and jittery, and that he was having palpitations. Id. His examination revealed a temperature of 100 degrees, tachycardia with a pulse of 118,⁵ and blood pressure of 144/80. Id. The records from this visit reflect under the heading "problems" that Mr. Formica presented with tachycardia. The records also reflect the examining physician's note to rule out "hyperthyroidism, [as a] possible s[ide] effect [of] HepB vaccine." P's Ex. 2 at 2. Additional clinical notes include: "[Hep B] p[ackage] insert lists palpitations and agitation . . . so reaction a possibility." Id. (emphasis added).

On July 20, 1999, petitioner was admitted to the MGH emergency room complaining again of lightheadedness, dizziness, palpitations, and jitteriness. Id. at 6. His examination revealed blood pressure ranging from 150/80 to 173/101, a pulse of 131, sinus tachycardia, normal serum electrolytes, blood glucose, and blood count, and a negative drug screen. Id. at 5-14. His diagnosis was anxiety. Id. at 8.

Mr. Formica saw Dr. Lichtenstein, a primary care physician, for the first time on August 6, 1999. P's Ex. 6 at 8. Dr. Lichtenstein noted that petitioner had panic or anxiety attacks on June 22, 1999 and again on July 20, 1999. Id.

Nearly two months later, on October 12, 1999, petitioner was seen at the medical walk-in unit at MGH for a two-day history of tinnitus in the right ear, pressure behind the ear, and nasal congestion. P's Ex. 2 at 15. His examination, which included an

⁵ Tachycardia is "excessive rapidity is the action of the heart; the term is usually applied to a heart rate above 100 beats per minute in an adult." Dorland's Illustrated Medical Dictionary 1850 (30th ed. 2003).

audiogram was normal, and the administered tests for tempomandibular joint syndrome⁶ were negative. Id.; P's Ex. 6 at 7. Later that month, on October 25, 1999, Dr. Lichtenstein diagnosed petitioner with labyrinthitis⁷ and prescribed meclizine to address the condition. P's Ex. 6 at 7.

Petitioner visited Dr. Suzuki, an ear, nose, and throat specialist, on November 22, 1999. P's Ex. 4 at 1-2. Dr. Suzuki noted a five-month history of vertigo, and a six-week history of tinnitus, with additional symptoms of dysequilibrium and fatigue. Id. at 2. Audiometric tests revealed a low and high frequency sensorineural hearing impairment in both ears. Id. Dr. Suzuki suspected a post-viral infection, and initiated therapy with acyclovir. Id.

A MRI brain scan performed nearly eight weeks later, on January 6, 2000, was normal. P's Ex. 2 at 38. On January 26, 2000, petitioner visited the walk-in unit at MGH with complaints of epigastric pain for four days, blurry vision, and jitteriness. Id. at 19. His examination revealed tachycardia with a pulse of 126, a temperature of 100.2 degrees, and no sign of infection. Id. Mr. Formica visited Dr. Lichtenstein again on January 28, 2000, and that examination revealed a mild tremor of the hands, normal thyroid, and a regular pulse. P's Ex. 6 at 5. Again on February 1, 2000, Mr. Formica presented to the emergency room at MGH with a complaint of tachycardia. P's Ex. 2 at 22. He had dizziness, hypertension with a blood pressure measurement of 164/103, but no erratic heart beat (arrhythmia). Id. at 24-28. Mr. Formica's pulse and blood pressure returned to normal after several hours. Id.

Mr. Formica had another episode on February 6, 2000, and on February 16, 2000. P's Ex. 6 at 2-3. Dr. Lichtenstein subsequently noted that petitioner was having episodes every four to five days. Id. Dr. Lichtenstein also reported that Mr. Formica's twenty-four hour urine study, complete blood count, chemistries and sedimentation rate were normal. Id. at 2. An examining rheumatologist did not consider Mr. Formica's positive speckled

⁶ Tempomandibular joint syndrome is also called Costen's syndrome and is "a complex of symptoms including partial deafness, stuffiness in the ears, tinnitus, clicking or snapping of the tempomandibular joint, dizziness, headache, and burning pain in the ear, throat, tongue, and nose." Dorland's at 1814.

⁷ Labyrinthitis is an "inflammation of the labyrinth (internal ear); it may be accompanied by hearing loss or vertigo." Dorland's at 988.

antinuclear antibody (ANA) of 160 to be significant.⁸ P's Ex. 2 at 39-40. On February 16, 2000, Mr. Formica began taking Labetalol, a beta blocker, to prevent his tachycardia and hypertension. P's Ex. 6 at 2.

On March 1, 2000, petitioner again visited Dr. Suzuki, who noted that petitioner had residual tinnitus with intermittent vertigo and an occasional swollen lip. P's Ex. 4 at 6. Petitioner had a normal audiogram and was treated for viral labyrinthitis with Valtrex, an antiviral drug. Id. A Lyme test was negative. P's Ex. 6 at 15.

On April 27, 2000, Mr. Formica visited Dr. James MacLean, who noted chronic rhinitis with dizziness and a positive skin reaction to dust mites. P's Ex. 2 at 43-44. On May 3, 2000, petitioner had a normal brainstem auditory evoked response test.⁹ Id. at 41. A treadmill stress test performed on July 14, 2000, was negative for ischemia.¹⁰ Id. at 53. On August 29, 2000, Mr. Formica underwent a polysomnograph which showed severely disturbed sleep. P's Ex. 3 at 24.

On May 25, 2000, Stephen W. Parker, M.D., wrote an otoneurological evaluation after his examination of Mr. Formica. Dr. Parker reported that "[t]he vestibular test findings are consistent with a well compensated, but severely damaged left inner ear because of the markedly reduced to absent left caloric response with normal rotational tests. The etiology of this damage is uncertain. These symptoms began several weeks after an MMR vaccination and several days after the second dose of a hepatitis B vaccine. I am uncertain of any etiological relationship between the vaccines and the current symptoms. The most common cause of dizziness would be a viral infection of the inner ear. Petitioner's 9/28/07 Filing at 38.

⁸ ANAs are "used to diagnose systemic lupus erythematosus (SLE) and other autoimmune diseases. These antibodies are primarily used to screen for SLE." Mosby's Manual of Diagnostic and Laboratory Tests at 91 (3rd ed. 2006). If the ANA test is positive, other antibody studies must be done to corroborate the diagnosis. Id.

⁹ A brainstem auditory evoked response test is an evoked potential study that is indicated for patients who have a suspected sensory deficit but are unable to indicate or are unreliable in indicating recognition of a stimulus. Auditory brainstem-evoked potentials (ABEPs) "are usually stimulated by clicking sounds to evaluate the central auditory pathways of the brainstem. Either ear can be evoked to detect lesions in the brainstem that involve the auditory pathway without affecting hearing." Mosby's Manual of Diagnostic and Laboratory Tests, at 584-85.

¹⁰ Ischemia is the "deficiency of blood in a part, usually due to functional constriction or actual obstruction of a blood vessel." Dorland's Illustrated Medical Dictionary at 954.

On September 25, 2000, Mr. Formica presented on referral to Donna Felsenstein, M.D., complaining of fatigue and dizziness. Dr. Felsenstein examined Mr. Formica and noted that his symptoms were “unlikely related to the hep B vaccine.” Id. at 18. Between 2000 and 2004, Mr. Formica sought medical treatment for various ailments, including but not limited to fatigue, a sleep disorder, weight gain, chronic fatigue syndrome, and a connective tissue disorder. See generally P’s Ex. 14.

Also included among the filed records for Mr. Formica is a letter from Nancy A. Shadick, M.D., a rheumatologist. Dr. Shadick wrote:

I was Mr. Formica’s rheumatologist in 2002, when he presented with a 2 ½ years of fatigue, arthralgias in the hands, tinnitus, and dizziness after a second Hepatitis B vaccine shot. He had a low positive ANA test and responded to low dose prednisone suggesting that this may have been due to an undifferentiated tissue disorder.

Order of 6/8/2007 at 4 (attaching, and filing by leave of court, letter from Dr. Shadick dated 5/31/07).

In an order following the status conference held on June 11, 2007, in this case, the undersigned noted that “Dr. Shadick [had] not address[ed] a biological mechanism connecting petitioner’s received vaccination with his injury, and inquired whether Dr. Shadick was going to provide oral testimony on petitioner’s behalf.” Order of 6/11/07 at 1. In a later status conference held on July 10, 2007, Mr. Formica reported back to the undersigned that Dr. Shadick was uncomfortable providing an expert opinion of causation on his behalf. Order of 7/18/07 at 1. Without an expert opinion, petitioner relies on the filed records to support his claim

B. Legal Standard and Analysis

The Vaccine Act permits a petitioner to prove entitlement to compensation by showing that either: (1) the vaccinee suffered an injury listed on the Vaccine Injury Table within the prescribed time period, commonly referred to as a “Table” case, see § 300aa-14(a); or (2) the vaccinee suffered an injury that is not listed on the Vaccine Injury Table but is caused in fact by the received vaccination, commonly referred to as an “off-Table” case, see § 300aa-11(c)(1)(C)(ii)(I). By either method, a petitioner bears the burden of proving his claim by a preponderance of the evidence. § 300aa-13(a)(1).

In a “Table” case, a petitioner benefits from a presumption of causation. See § 300aa-14(a); 42 C.F.R. § 100.3(a). The record in this case does not support a finding that

a Table injury occurred.

Accordingly, to establish entitlement to Program compensation, petitioner must prove, by a preponderance of the evidence, an “off-Table” claim, specifically, that the hepatitis B vaccination that he received on June 18, 1999, caused his connective tissue disorder or his tinnitus or his fatigue. Petitioner satisfies his burden of proof “by providing: (1) a medical theory causally connecting [his] vaccination and [his] injury; (2) a logical sequence of cause and effect showing that [his] vaccination was the reason for [his] injury; and (3) a showing of a proximate temporal relationship between [his] vaccination and injury.” Althen v. Sec’y of Dept. of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

In this case, Mr. Formica has failed to supply any evidence of a causal connection between his hepatitis B vaccination and his alleged injuries. Although Mr. Formica’s filed medical records support that he has suffered a cluster of symptoms that are at best temporally associated with the administration of his third hepatitis B vaccine, there is no indication in the volume of medical records filed in this case that any of his treating physicians held the opinion that his third hepatitis B vaccination was in fact causally connected to the development of Mr. Formica’s symptoms. Instead, several of petitioner’s treating physicians acknowledged, without more, a temporal association between the receipt of his third hepatitis B Vaccination and the development of his symptoms. Additionally, several of his treating physicians entertained, without more, the possibility of a causal connection. However, the mere possibility of a causal relationship does not satisfy petitioner’s evidentiary burden of preponderant evidence. Neither does evidence of a mere temporal association between the received vaccination and the alleged injury establish causation under the Vaccine Act. The filed records do not support Mr. Formica’s claim, and Mr. Formica has not provided an expert opinion offering a medical theory causally connecting his vaccination to his claimed injury.

The Vaccine Act prohibits a special master from making a finding of entitlement to compensation based on the claims of petitioner alone, without substantiation by medical records or by a medical opinion. See § 300aa-13(a)(1). In this case, petitioner’s claim is not substantiated by either the filed medical records or an offered medical opinion. Under the Vaccine Act, Mr. Formica’s claim must fail.

II. CONCLUSION

The medical records in this case do not establish a causal connection between Mr. Formica’s hepatitis B vaccination and his alleged injury. Mr. Formica has offered no medical opinion causally connecting his vaccination and his condition. Petitioner’s

motion for judgment on the record is **GRANTED**. Because he has failed to establish entitlement to compensation under the Vaccine Act, petitioner's claim is **DISMISSED**. The Clerk of the Court shall **ENTER JUDGMENT** accordingly.

IT IS SO ORDERED.

Patricia E. Campbell-Smith
Special Master