In the United States Court of Federal Claims

No. 15-63V

(Filed Under Seal: July 31, 2017)
(Reissued: August 15, 2017)[1]

FINNETTIA GARNER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	Vaccine Act Motion for Review; Hepatitis A and B Vaccination; Parsonage-Turner Syndrome; Althen Burden of Proof Requirements.

Sean F. Greenwood, The Greenwood Law Firm, Houston, Texas, for Petitioner.

Daniel A. Principato, with whom were *Chad A. Readler,* Acting Assistant Attorney General, *C. Salvatore D'Alessio,* Acting Director, *Catharine E. Reeves,* Deputy Director, and *Gabrielle M. Fielding,* Assistant Director, Torts Branch, Civil Division, U.S. Department of Justice, Washington, D.C., for Respondent.

OPINION AND ORDER

WHEELER, Judge.

Petitioner Finnettia Garner initiated this action in January 2015, seeking compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.* ("Vaccine Act"), for injuries allegedly received from a Hepatitis A and B vaccination in December 2011. Ms. Garner claims that the vaccination caused Parsonage-Turner Syndrome ("PTS"), a neurological disorder of the shoulder resulting in significant pain and weakness. The Special Master in this case denied compensation in March 2017.

[1] [1] Pursuant to Rule 18(b) of the Court's Vaccine Rules, this opinion and order was initially filed under seal. As required under the Rules, each party was afforded 14 days from the date of issue, until August 14, 2017, to object to the public disclosure of any information furnished by that party. Neither party submitted any proposed redactions.

Garner v. Sec'y of Health & Human Servs., No.15-63V, 2017 WL 1713184 (Fed. Cl. Spec. Mstr. Mar. 24, 2017) ("Decision"). Petitioner has now filed a Motion for Review with this Court. For the reasons explained below, the Court denies Petitioner's Motion for Review and affirms the decision of the Special Master.

Background

I. Medical History[2]

On December 13, 2011, Ms. Garner received a Twinrix vaccination, which is a combination of the Hepatitis A and B vaccines, together with a typhoid vaccination,[3] in preparation for a trip abroad in connection with her employment. On January 23, 2012, Ms. Garner traveled to Angola. She states in her Affidavit (Dkt. No. 1, Exhibit 1, "Affidavit") accompanying the Petition that on January 27, 2012 (45 days after receipt of the Twinrix vaccination), she experienced severe pain in her right shoulder and arm (the vaccination had been given in her left arm). Ms. Garner reported that the pain lasted ten days, followed by weakness for an unstated period of time. Ms. Garner did not seek medical attention for this condition, explaining that she did not feel comfortable getting medical attention abroad. In April 2012, approximately three months later, and after return to the United States, Ms. Garner had a physical examination where no shoulder issues were found; in fact Ms. Garner did not mention to the doctor any problems related to her shoulder.

On June 15, 2012, Ms. Garner sought treatment for new, significant pain in her left shoulder. X-rays showed a partial dislocation of the left humerus. Dr. Shah, the orthopedic surgeon treating her on June 18, diagnosed "possible" PTS, which is a neurological disorder causing pain and weakness in the shoulder and arm. On June 26, 2012, a physician at TMH Neurological Institute conducted neurological tests of Ms. Garner's left shoulder and arm and found normal readings, although he noted that her "voluntary effort" in contracting the muscles was poor. On July 6, 2012, Ms. Garner returned to Dr. Shah for a follow-up appointment, and she reported to him that her pain had improved by 40 percent, although she showed a limited range of motion in the left shoulder, and she had developed a rash under that arm due to her inability to lift it. Dr. Shah noted that the partial dislocation of her shoulder had improved, and he continued to diagnose possible PTS. Ms. Garner reports in her Affidavit that at this time she was forced to work from home for about three months until the pain subsided in September 2012.

In January 2013, Ms. Garner was involved in a motor vehicle collision and reported left shoulder and neck pain after impact. Her medical records showed no neurological abnormalities and reflected normal x-rays of the neck. Those treatment records make no

[2] All facts relating to Petitioner's medical history are drawn from the Special Master's decision.

[3] The typhoid vaccine is not covered under the Vaccine Act. 42 C.F.R. § 100.3(a).

mention of the December 2011 vaccination or the possible diagnosis of PTS. Ms. Garner states that in March 2013 she experienced a return of the pain and weakness in the left arm which lasted about three weeks; she noted that she did not seek medical attention because the doctors she had seen had not offered any relief.

In December 2013, approximately a year and a half after Ms. Garner's July 6, 2012 visit to Dr. Shah for left shoulder pain, she experienced significant shoulder pain and weakness again, this time on the right side, and returned to see Dr. Shah. She stated in her Affidavit that the doctor commented about the change from the left to the right shoulder, saying that this was unusual, but that PTS could affect both arms.[4] The records show that he diagnosed possible PTS for the right shoulder pain, and noted that her similar symptoms in July 2012 on the left side had been completely resolved. This diagnosis appears to be the most recent medical treatment specifically for shoulder pain. Ms. Garner stated in her Affidavit that her most recent episode of severe shoulder pain occurred on December 18, 2014 on her right side and continued for ten days, while weakness in the right arm and hand continue. There is no record of any medical attention for these most recent complaints.

II. Procedural History

After Ms. Garner's submission of her petition and relevant medical records, Respondent filed a Rule 4(c) Report recommending denial of compensation. Dkt. No. 10. The parties' expert reports were filed by January 2016. Dkt. Nos. 16, 18. After a Status Conference, the Special Master ordered Ms. Garner to file a supplemental expert report to address issues raised in Respondent's expert report, which she submitted in April 2016. Dkt. No. 26. At the status conference held shortly thereafter, the Special Master indicated to the parties that live testimony would not be required, and that Ms. Garner should file her motion for a ruling on the record. The Motion was filed and fully briefed by October 2016. The Special Master's Decision denying compensation was issued in March 2017, and Petitioner filed her Motion for Review on April 21, 2017.

III. Summary of Expert Evidence

A. Petitioner's Expert

Petitioner's expert opinion (Dkt. No. 16) was provided by Dr. Yehuda Shoenfeld, head and founder of The Center for Autoimmune Diseases at Sheba Medical Center in Tel-Aviv, Israel. He also holds the Research Chair for autoimmune diseases at Tel-Aviv University. His work has focused on autoimmune and rheumatic diseases, and he lists many books and papers he has published on these subjects. Dr. Shoenfeld described PTS

[4] The Special Master discussed Petitioner's claim that her PTS appeared in both arms and observed that this could be a possibility with PTS. He thus declined to find that the "migration of symptoms from the right to left arm" would weaken Petitioner's case. Dec. at 24 n.18.

as a "rare disorder" with no definitive tests to confirm its presence. It is characterized by an abrupt onset of shoulder pain followed by weakness and atrophy of the upper arm muscles. Recovery is slow and may require months or years. Dr. Shoenfeld commented that the cause of PTS is unclear but it seems to involve an interaction between genetic predisposition, mechanical vulnerability, and an autoimmune trigger that could come from the vaccines at issue here.

With respect to possible effects of the Hepatitis A ("Hep A") vaccine, Dr. Shoenfeld cited a 2011 study of children after Hep A vaccinations which found a statistically significant number of children with autoantibodies in their blood, signaling an autoimmune response to the vaccine. He also pointed to a case report of a man who developed autoimmune hepatitis after a Hep A vaccination. Turning to the Hepatitis B ("Hep B") vaccine, Dr. Shoenfeld referenced studies that he claimed linked Hep B to several autoimmune diseases such as multiple sclerosis; however PTS was not included in the chart showing possible Hep B autoimmune reactions, and Dr. Shoenfeld pointed out that because the chart was based largely on individual case reports, "the evidence is not strong." He then discussed possible mechanisms such as "molecular mimicry" by which Hep B could cause PTS by inducing the body to have an autoimmune response, although his discussion was based on transverse myelitis ("TM"), an autoimmune disease unrelated to PTS. Regarding the 45-day time elapsed between Petitioner's vaccination and her first report of shoulder problems, Dr. Shoenfeld argued that 45 days was an appropriate time for the vaccine to have induced PTS. To support this position, he provided a chart summarizing time lapsed after vaccination with a variety of vaccines (including Hep B) for cases of TM. The thirteen examples where Hep B was given show time elapsed for diagnosis after vaccination ranging from one week to 27 weeks. Each of the examples was an individual case, and each of the cases dealt with TM and not with PTS.

B. Respondent's Expert

Respondent's expert opinion (Dkt. No. 18) was presented by Dr. Eric Lancaster, a physician on staff at the Center for Autoimmune Neurology at the University of Pennsylvania, as well as an assistant professor of neurology at the same University. He is board certified in neurology with subspecialties in neuromuscular medicine and neuromuscular electrodiagnostic testing, which he stated is critical for proper diagnosis of PTS. His recent publications and research have focused on autoimmune neurological disorders. He has treated five to ten patients with PTS, which is also known as brachial plexitis, referring to an inflammatory injury of the network of nerves in the shoulder. After reviewing Petitioner's medical records, Dr. Lancaster found that the diagnosis of PTS was not supported by the medical records, noting no showing of weakness when pain was not present and also no indication of atrophy, sensory loss or persistent numbness. He also observed that no detailed neurological examinations were done to investigate possible injury to the nerves, and thus identify which nerves might be injured and what abnormalities might have been caused. Assuming Petitioner in fact has PTS, Dr. Lancaster

expressed the opinion that 45 days between vaccination and reaction is too long to associate PTS with the vaccine, citing a 1994 study of the risk of PTS after certain vaccinations (not related to hepatitis), which found the maximum time after vaccination to be four weeks. He also stated that there is no reliable medical evidence that hepatitis vaccines cause PTS, and cited a 2011 Institute of Medicine study which "found no evidence to support the [Hep B] vaccine as cause for PTS."

C. Petitioner's Expert Rebuttal

Dr. Schoenfeld's rebuttal (Dkt. No. 26) filed at the request of the Special Master is limited. He refutes Dr. Lancaster's conclusion that there is insufficient evidence in the medical record to support a diagnosis of PTS by stating that the treating physician's diagnosis and Petitioner's Affidavit reporting her symptoms should be relied on. He then defends his theory that molecular mimicry stemming from the Hep B vaccine could have caused Petitioner's PTS, citing studies that relate to the variety of antigens possibly produced by the Hep B vaccine.

IV. Burden of Proof

Ms. Garner seeks recovery in this case for an "off-Table" injury, that is, an injury caused by a vaccine other than those injuries listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a). In off-Table injuries, claimants must show causation in fact by a preponderance of the evidence. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A); see also Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010). The U.S. Court of Appeals for the Federal Circuit summarized the claimant's evidentiary burden associated with off-Table cases in Althen v. Secretary of Health and Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005), holding that she must establish by preponderant evidence:

(1) a medical theory causally connecting the vaccination and the injury;
(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
(3) a proximate temporal relationship between vaccination and injury.

These factors are now commonly referred to as the three Althen prongs.

V. Special Master's Decision

In denying Petitioner's claim for compensation, the Special Master found that Ms. Garner had failed to carry her burden of proof to establish entitlement to compensation. He analyzed Ms. Garner's medical theory connecting the PTS to the vaccination (Althen prong one) concurrently with the timeframe described between vaccination and injury (Althen prong three). Dec. at 20. In his view, Petitioner's theory that Hep A and/or B

vaccines could cause PTS through a molecular mimicry mechanism has "some reliability," but it breaks down when applied to the events reported by Petitioner. Petitioner claimed vaccine-induced PTS started 45 days from vaccination, but then stopped for five months before flaring up again in June 2012 when PTS was first diagnosed by Dr. Shah. The Special Master found no "medically plausible" explanation for the intermittent start and stop of Petitioner's symptoms. Id. at 21. Also, focusing on the 45-day period between vaccination and first reported shoulder pain, the Special Master found that this was too long a delay for PTS to be attributed to the vaccination. He discussed the chart offered by Dr. Shoenfeld which showed time elapsed for development of vaccine-associated TM and concluded that TM cannot be equated with PTS, which "has not been shown to involve demyelination like TM." He also observed that the chart proposed such a wide range of onset times that it is almost "facially useless." Id. at 22. He found that Respondent's expert, Dr. Lancaster, had persuasively established that PTS would likely occur far sooner. He also noted a study submitted by Petitioner which showed that PTS often has a sudden onset of severe pain, measured in just a few days after the triggering injury or vaccination. Id. With respect to proof of Althen prong two, requiring a showing of a "logical sequence of cause and effect" that the vaccination caused the injury, the Special Master discussed in detail the "paucity of evidence" supporting a diagnosis of PTS in the first place. Although he was reluctant to find "that the evidence absolutely does not support the diagnosis," he found that Petitioner had not shown that an autoimmune process had caused the PTS, when other possible causes (such as the shoulder dislocation) had not been ruled out. He also noted that none of Petitioner's treating physicians had mentioned a link between the PTS and vaccination. Id. at 24-25. The Special Master found that Petitioner had failed to meet her burden of proof for Althen prongs two and three, and thus denied her claim: "The medical record in this case reveals that Petitioner's injury is too far removed from the time of vaccination to plausibly suggest a link between the two, nor has Petitioner presented a persuasive or reliable causation theory that fits the facts." Id. at 25.

Discussion

I. Standard of Review

This Court has jurisdiction to review decisions of the Special Masters in accordance with 42 U.S.C. § 300aa-12(e)(1)-(2). The Special Master's findings of fact receive deferential review under an "arbitrary and capricious" standard, while the Court reviews legal conclusions under the "not in accordance with law" standard and discretionary rulings for an "abuse of discretion." Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). "The arbitrary and capricious standard of review is difficult for [a petitioner] to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact." Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000). "Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including

expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases." Moberly, 592 F.3d at 1325.

II. Motion for Review and Response

Petitioner argues that the Special Master committed error in finding that Petitioner failed to meet her burden of proof to establish Althen prongs two and three. She urges that the Special Master required an impermissible level of scientific certainty in establishing a medically acceptable timeframe for development of her PTS. With respect to proof of causation of the injury, Petitioner argues that more weight should be given to the treating physician records. Petitioner also claims that the Special Master abused his discretion in failing to hold an evidentiary hearing before making his decision on the written record, arguing that the Special Master could not assess Petitioner's credibility in making her claims of injury. Petitioner claims that the absence of her testimony caused the Special Master to "decide points against her." Pet'rs' Mot. for Rev. 18, Dkt. No. 35. In addition, Petitioner filed with the Motion for Review three medical literature exhibits which were not a part of the record below. Dkt. Nos. 34, 38. Petitioner claims that those reports should be considered by the reviewing Court because Petitioner's expert reports had referred to them without actually submitting them.

Respondent counters that the Special Master applied the correct evidentiary standards and rationally explained his conclusions. Regarding causation of the PTS, Respondent maintains that Petitioner did not prove by preponderant evidence that the vaccination was the "but for" cause of the injury, as required by prong two, and that a Special Master can consider evidence of an alternate cause for an injury in assessing the proof. Resp't's Mem. in Resp. to Pet'rs' Mot for Rev. 15, Dkt. No. 40. As to Petitioner's challenge to the decision to rule without a hearing, Respondent points out that Petitioner did not object to this approach in the Special Master's proceeding and in fact filed a motion to rule on the record, and in any event, Special Masters have wide discretion as to whether to hold an evidentiary hearing. Finally, Respondent objects to Petitioner's submission of new medical literature exhibits with the Motion for Review, arguing that this Court should decline to consider them because they were not a part of the record before the Special Master.

Conclusion

With regard to the three medical articles filed by Petitioner which were not a part of the record below, this Court's Vaccine Rule 8(f)(1), found in Appendix B of the Rules of the Court of Federal Claims, prohibits inclusion of any facts or arguments not raised

specifically in the record before the Special Master. For this reason the Court declines to consider the three articles in reaching its decision.

The Court has carefully considered the parties' arguments, the evidence of record, and the Special Master's decision on entitlement, and is satisfied that the Special Master set forth a reasonable basis for his decision. To prove that the vaccination caused the injury (Althen prong two), Petitioner must show "that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of the harm." Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The Special Master reasonably found here that there was insufficient evidence to support Petitioner's claim that the vaccination was the "but for" cause of her PTS. He noted Petitioner's failure to rule out other possible causes of her injury, which Respondent's evidence had suggested could have been caused by the long overseas flight or by her dislocated shoulder. The Special Master also addressed the claimed timeframe in this context because a medically acceptable timeframe "bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis." Id. at 1358. In that regard he reasonably found the 45-day time between vaccination and first claimed injury to be too long to prove causation, relying in part on Respondent's expert's discussion of timeframe in the context of PTS.

Petitioner's argument that the Special Master should have conducted an evidentiary hearing in this case, rather than ruling on the record, is not persuasive. Vaccine Rule 8(d) authorizes a special master to "decide a case on the basis of the written record without an evidentiary hearing." Moreover, Petitioner did not challenge the Special Master's decision to proceed without a hearing when she filed her Motion for a Ruling on the Record. Dkt. No. 28. As to Petitioner's claim that the Special Master "decide[d] points against her" in the absence of live testimony, the Special Master specifically reserved judgment on the veracity of Petitioner's claim of PTS. Dec. at 24. He instead reasonably found that assuming Petitioner had contracted PTS, she had failed to prove that the vaccination caused it under the three-part Althen test.

For these reasons, the Special Master's Decision is AFFIRMED and accordingly, Petitioner's Motion for Review is DENIED. Pursuant to Vaccine Rule 18(b), each party is afforded 14 days from the date of this decision to object to the public disclosure of any information submitted by that party. After that period, this opinion will be released to the public.

IT IS SO ORDERED.

s/ Thomas C. Wheeler
THOMAS C. WHEELER
Judge