In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

STACY BOULA and WILLIAM BOULA, legal representatives of an infant, STEPHANIE BOULA,	*	No. 13-356V
	*	Special Master Christian J. Moran
Petitioners,	*	Filed: July 17, 2014
v.	*	Findings of fact; onset; connective tissue disorder
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Gary C. Hobbs, Muller, Mannix & Hobbs, PLLC, Glen Falls, NY, for petitioners; Julia McInerny, United States Dep't of Justice, Washington, DC, for respondent.

FINDINGS OF FACT[1]

On May 24, 2013, Stacy and William Boula filed a petition under the National Vaccine Injury Compensation Program (the "Vaccine Act" or "Program"), 42 U.S.C. § 300aa-10 through 34 (2006). In their petition, the Boulas alleged that the human papillomavirus ("HPV") vaccine and/or hepatitis B vaccine caused their daughter, Stephanie, to suffer an autoimmune disorder and associated undifferentiated connective tissue disease. Pet. at ¶¶ 26, 28. The Boulas filed an amended petition on June 5, 2013, which contained similar allegations. Am. Pet.

[1] The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this ruling on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

at ¶¶ 28, 30.[2] To support their claim for compensation, petitioners periodically filed evidence, including medical records (exhibits 1-7, 11-13, 17, 21) and affidavits from Mrs. Boula and Stephanie (exhibits 14, 19-20).

The records are not consistent about the details of Stephanie's illness. There is uncertainty about what symptoms Stephanie experienced and when she had them. Furthermore, during litigation, Mrs. Boula's position changed. Compare exhibit 14 (aff., dated May 20, 2013) (onset indicated as approximately May 20, 2010) with exhibit 20 (aff., dated Nov. 7, 2013) (onset indicated as May 24, 2010).

When special masters are confronted with discrepancies among medical records and affidavits, special masters are encouraged to hold a hearing to evaluate the testimony of the affiants. See Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 779-80 (2006). However, petitioners declined to present oral testimony because they believed that the written materials were sufficient to support their contentions. Respondent did not object to a lack of hearing. Therefore, because neither party requested a hearing, a hearing was not held. See Vaccine Rule 8(d) (the special master may decide a case on the basis on the record).

In lieu of presenting testimony, the parties filed Joint Proposed Findings of Fact. In their filing, the parties asked for findings on two points: (1) the nature of Stephanie's symptoms, and (2) when Stephanie's symptoms began. Joint Proposed Findings of Fact, filed Feb. 10, 2014, at ¶¶ 17-18 ("Proposed Findings"). The parties anticipate how these facts will affect petitioners' claim, reserving the right to retain expert witnesses should the claim proceed. Id. at ¶¶ 17, 19. Following the parties' joint submission, petitioners were requested to obtain additional records from Stephanie's pediatrician, Dr. Mary Anne Kiernan. Petitioners submitted these records on April 17, 2014 (exhibit 21), making the matter ready for adjudication.

[2] Petitioners also alleged that Stephanie's injuries were "caused in fact by the [HPV] vaccine, the MMR Vaccine, and or a component thereof." Pet. at 1; Am. Pet. at 1. However, this appears to be a typographical error; petitioners intended to allege that Stephanie's condition was caused in fact by the HPV and/or hepatitis B vaccines. See Pet. at ¶ 28; Am. Pet. at ¶ 30.

Standard for Finding Facts

Under the Vaccine Act, petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa–11(c)(2).[3] Medical records that are created contemporaneously with the events they describe are presumed to be accurate. Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Not only are medical records presumed to be accurate, they are also presumed to be complete in the sense that the medical records present all the health problems of the patient. Completeness is presumed due to a series of propositions. First, when people are ill, they see a medical professional. Second, when ill people see a doctor, they report all of their health problems to the doctor. Third, having heard about the symptoms, the doctor records what he or she was told.

Appellate authorities have accepted the reasoning supporting a presumption that medical records created contemporaneously with the events being described are accurate and complete. A notable example is Cucuras in which petitioners asserted that their daughter, Nicole, began having seizures within one day of receiving a vaccination, although medical records created around that time suggested that the seizures began at least one week after the vaccination. Cucuras, 993 F.2d at 1527. A judge reviewing the special master's decision stated that "[i]n light of [the parents'] concern for Nicole's treatment . . . it strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of

[3] With the advent of filing via CM/ECF, there should be a short delay between filing petitions and submitting medical records. Vaccine Rule, Supplement, § 8(a)(ii).

seizures a week after they in fact occurred." Cucuras v. Sec'y of Health & Human Servs., 26 Cl. Ct. 537, 543 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993).

However, the presumption that contemporaneously created medical records are accurate and complete is rebuttable. For cases alleging a condition found in the Vaccine Injury Table, special masters may find when a first symptom appeared, despite the lack of a notation in a contemporaneous medical record. 42 U.S.C. § 300aa-13(b)(2). By extension, special masters may engage in similar fact-finding for cases alleging an off-Table injury. In such cases, special masters are expected to consider whether medical records are accurate and complete. To overcome the presumption that written records are accurate, testimony is required to be "consistent, clear, cogent, and compelling." Blutstein v. Sec'y of Health & Human Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998).

In determining the accuracy and completeness of medical records, special masters will consider various explanations for inconsistencies between contemporaneously created medical records and later given testimony. The Court of Federal Claims listed four such explanations. The Court noted that inconsistencies can be explained by: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. La Londe v. Sec'y Health & Human Servs., 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014).

In weighing divergent pieces of evidence, special masters usually find contemporaneously written medical records to be more significant than later-presented testimony.[4] Cucuras, 993 F.2d at 1528. Testimony offered after the events in question is less reliable than contemporaneous reports when the motivation for accurate explication of symptoms is more immediate. Reusser v.

[4] Although the testimony in Cucuras was given orally, the relative value of testimony vis-à-vis contemporaneously created written records does not depend on whether the witness testified orally or in writing. See, e.g., Bast v. Sec'y of Health & Human Servs., 01-565V, 2012 WL 6858040, at *6 (Fed. Cl. Spec. Mstr. Dec. 20, 2012) (the special master found that the doctor's contemporaneously created medical record held more weight than the parents' joint affidavit), mot. for review den'd, 2014 WL 3719188 (Fed. Cl. July 8, 2014).

Sec'y of Health & Human Servs., 28 Fed. Cl. 516, 523 (1993). However, compelling testimony may be more persuasive than written records. Campbell, 69 Fed. Cl. at 779 ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Camery v. Sec'y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998) (this rule "should not be applied inflexibly, because medical records may be incomplete or inaccurate"); Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance") (citation omitted), aff'd, 968 F.2d 1226 (Fed. Cir. 1992).

Summary of Evidence

The submitted evidence is summarized below in two sections: Stephanie's relevant medical records followed by petitioners' three affidavits, two from Mrs. Boula and another from Stephanie.

Medical Records

On March 11, 2010, Stephanie was seen at Long Pond Pediatrics for a well visit. Exhibit 2 at 58. Stephanie did not present with any complaints. Id. Upon examination, Stephanie had "normal growth and development at 15 yrs old." Id. at 58-59. During her visit, Dr. Sarah Leddy administered Stephanie's first HPV vaccination. Id. at 1, 59. On May 20, 2010, Dr. Leddy administered Stephanie's second HPV vaccination with no associated medical exam. Id. at 1. Stephanie received her third hepatitis B vaccination the following day, May 21, 2010, with no record of a medical exam. Id.

On May 24, 2010 at 3:29 P.M., Mrs. Boula called Long Pond Pediatrics and scheduled an appointment for that same day at 4:30 P.M. Exhibit 21 at 2. During that appointment, Stephanie reported that she had a sore throat that "started today" and that the "onset was sudden." Exhibit 2 at 60. Upon examination, Dr. Mary Anne Kiernan noted that Stephanie's tonsils were "moderately erythematous and ulcerated." Id. Dr. Kiernan diagnosed Stephanie with a sore throat commenting that Stephanie probably had an "early Coxsackie infection." Exhibit 2 at 61. Dr. Kiernan ordered a Group A strep culture, but the strep test was normal. Id. at 61, 93. Stephanie was directed to use "Tylenol and/or Motrin as needed for pain." Id. at 61.

By May 31, 2010, Stephanie continued to complain of a sore throat, and her mother took her to the emergency room at Rochester Memorial Hospital. Exhibit 5 at 2. Stephanie was seen by Dr. Geoffrey Everett and reported "[a] sore throat [lasting] for 8 days, blisters to tonsils, had neg throat culture last Mon., still having pain, unable to eat, taking fluids, blisters getting worse, no fever." Id. at 7. Stephanie's reported pain level was a "6 out of 10." Id. at 8. Upon examining Stephanie's ear, nose, and throat, Dr. Everett noted erythema in her posterior pharynx, but that her tonsils were "normal in appearance." Id. at 8. The rapid strep throat test and the Group A strep culture test results were both normal. Id. at 3, 5. Ultimately, Dr. Everett's impression was viral pharyngitis. Id. at 3. The hospital discharged Stephanie with a prescription to help with her pain. Id.

After seven intervening doctors' visits for various problems between September 29, 2010 and December 22, 2010 (exhibit 2 at 62-68; exhibit 4 at 1-4; exhibit 5 at 16-26), on December 28, 2010, Stephanie went to Long Pond Pediatrics complaining of shin pain that had lasted "since September." Exhibit 2 at 69. Additionally, Stephanie reported stomach bloating, headaches, "ringing in ears," and that she was "very tired despite good sleep last night." Id. Dr. Elizabeth O'Brien reviewed Stephanie's lab results, noting that "thyroid labs, cbc, and also esr" were normal, but that "ANA came back positive last night." Id. Upon examination, Stephanie appeared healthy. Id. at 69-70. Dr. O'Brien suspected that Stephanie had an autoimmune disease because she was an "otherwise healthy and active 16 year old who now has a positive ANA." Id. at 70; exhibit 17 at 26. Dr. O'Brien referred Stephanie to a rheumatologist "to help with work up and possible diagnosis." Exhibit 2 at 70.

On January 4, 2011, Stephanie went to see David Siegel, a pediatric rheumatologist. Exhibit 6 at 1. Stephanie reported fatigue and multiple aches and pains "ongoing since this spring." Id. Dr. Siegel noted that Mrs. Boula thought "all of Stephanie's symptoms started after she got her [HPV] shot in March, 2010." Id. Also, Mrs. Boula attributed "the real start of [Stephanie's] symptoms to having had the second [HPV] shot (in May 2010) after which she had 3 weeks of blisters in her throat." Id. Dr. Siegel's assessment found that Stephanie's history and exam findings "[were] not consistent with rheumatologic disease." Id. However, he ordered blood work to "objectively assess whether this is the case." Id. On January 10, 2011, the nurse practitioner called Stephanie's father, explaining that "all the tests were negative with the exception of the ANA, which was the same." Id. at 10.

Mrs. Boula remained concerned about Stephanie's worsening symptoms. See exhibit 3 at 3. Between September 9-14, 2011, she called Dr. Siegel's office multiple times expressing her concern. Exhibit 6 at 9. Mrs. Boula ultimately sought another medical opinion regarding Stephanie's condition. On September 21, 2011, Stephanie went to the Allergy, Immunology, and Rheumatology Department at Rochester General Medical Group for "evaluation of a positive ANA." Exhibit 7 at 1. In the history of present illness, Dr. Ana Arango noted that Stephanie had "some symptoms suspicious for Raynaud's," including having "to wear gloves inside the house." Id.[5] Stephanie's lab workup only yielded a high titer ANA. Dr. Arango's impression was that Stephanie had Raynaud's disease and a possibility of an inflammatory connective tissue disease. Id. at 2. He ordered several labs to assess the possibility of an inflammatory connective tissue disease. Id.

After seven appointments for other ailments between October 2011, and May 2012 (exhibit 5 at 33-44; exhibit 7 at 3-4; exhibit 13 at 5-6, 10-26), on May 30, 2012, Stephanie saw Dr. Arango for a follow-up visit. Exhibit 7 at 5, 7. Dr. Arango indicated that Stephanie had "an undifferentiated connective tissue disease." The Boulas allege the vaccinations in May 2010, caused Stephanie to suffer this condition.

Affidavits

In support of their allegations, the Boulas filed two affidavits from Mrs. Boula, dated May 20, 2013 (exhibit 14), and November 7, 2013 (exhibit 20), and one affidavit from Stephanie Boula, dated November 7, 2013 (exhibit 19). These affidavits are not entirely consistent with one another.

In her first affidavit, Mrs. Boula averred that Stephanie's sore throat started "approximately two days after vaccination." Exhibit 14 at ¶ 9, dated May 20, 2013. Thus, Mrs. Boula's statement presents a problem for determining the onset of Stephanie's sore throat. Stephanie received two vaccinations, one each on consecutive days. Additionally, Mrs. Boula stated that Stephanie's sore throat lasted for two days before she took her to Dr. Kiernan's office. Id. The visit with Dr. Kiernan took place on May 24, 2010. Exhibit 2 at 1.

[5] Raynaud phenomenon is defined as "intermittent bilateral ischemia of the fingers, toes, and sometimes ears and nose, with severe pallor and often paresthesias and pain, usually brought on by cold or emotional stimuli and relived by heat." Dorland's Illustrated Medical Dictionary 1430 (32d ed. 2012).

However, in her second affidavit, Mrs. Boula averred that she was "mistaken when [she] stated in her May 20, 2013 affidavit that '. . . two days after being vaccinated Stephanie began to complain of a sore throat and headache. I took Stephanie to the doctor's two days later when the sore throat had not resolved.'" Exhibit 20 at ¶ 8 (aff., dated Nov. 7, 2013). She further asserted that "[her] May 20, 2013 affidavit was based on my recollection of almost 3 years earlier. I did not have a calendar or diary of events to assist my recollection." Id. at ¶ 9.

Additionally, in Stephanie's affidavit filed concurrently with Mrs. Boula's second affidavit, Stephanie denied experiencing any adverse reaction or symptoms after her first HPV vaccine on March 11, 2010. Exhibit 19 at ¶ 4 (aff. dated Nov. 7, 2013). Stephanie stated that she began experiencing a sore throat on May 24, 2010, worsening throughout the day, and she had a headache. Id. at ¶ 5. Further, Stephanie explained that the medical records from her emergency room visit on May 31, 2010, were incorrect, and that Dr. Kiernan's records on May 24, 2010, accurately reflect her symptoms. Id. at ¶ 7.

Parties' Positions

Despite the discrepancies among the affidavits and medical records, the Boulas assert that the contemporaneous records of Dr. Kiernan from May 24, 2010, indicate that the onset of Stephanie's first symptoms occurred on May 24, 2010. Thus, the Boulas argue that these records are the best evidence of the date of onset of her sore throat. Proposed Findings at ¶ 15.

The Secretary identifies three potential dates for the onset of Stephanie's autoimmune disease. As evidence in support of an onset date in late March 2010, the Secretary cited the medical records from Stephanie's January 4, 2011 visit to the rheumatologist, Dr. Siegel. Resp't's Rep't, filed Aug. 20, 2013, at 14 (Dr. Siegel noted that Mrs. Boula felt that Stephanie's symptoms began two weeks after she received the March 11, 2010 HPV vaccination). In the alternative, the Secretary argued that if the medical record from May 31, 2010, was precisely accurate, "eight days earlier" would place the onset of Stephanie's symptoms on May 23, 2010. Id. Finally, the Secretary cited Mrs. Boula's first affidavit arguing that the onset of Stephanie's symptoms occurred on May 22, 2010. Id. at 14-15

("my daughter's various symptoms and illnesses began within two days of being vaccinated in May, 2010") (citing exhibit 14 at ¶ 15, aff., dated May 20, 2013). [6]

Findings of Fact

Nature of the Symptoms

Although some evidence suggests that Stephanie was having problems in March 2010, the more persuasive information indicates that she was not. In the medical history from Stephanie's January 4, 2011 visit, Dr. Siegel indicated that Stephanie had fatigue and multiple aches and pains, beginning in spring 2010. However, there are no medical records in spring 2010 to support Dr. Siegel's history. See generally exhibit 2. As discussed previously in the summary of the medical records, Stephanie has an extensive medical history documenting Mrs. Boula's persistence in seeking medical treatment for Stephanie. Therefore, if Stephanie were experiencing problems like fatigue, aches, and pains in late March 2010, Mrs. Boula likely would have taken her daughter to a doctor as she did in May 2010 for a sore throat and for Stephanie's other ailments. The absence of any medical record from late March through April 2010, implies that Stephanie was healthy.

Dr. Siegel relied on Mrs. Boula's memory to learn and to document Stephanie's medical history. See exhibit 6 at 1 (stating that "Mom feels," "Mom attributes," and "Mom reports"). It seems likely that given events in her daughter's life, Mrs. Boula did remember Stephanie's chronology accurately. Mrs. Boula appears to have associated the onset of fatigue with the first dose of the HPV vaccination on March 11, 2010, but actually the problems started relatively close to the time of the second dose on May 20, 2010.[7]

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[6] The Secretary further argues that if the first manifestation of the autoimmune tissue disease were in late March 2010, on May 22, 2010, or on May 23, 2010, the petition was not filed within the statute of limitations because the petition was filed on May 24, 2013. The Boulas should have filed their petition no later than late March 2013, May 22, 2013, or May 23, 2013. Proposed Findings at ¶ 14.

[7] Although Mrs. Boula remembered that Stephanie developed a sore throat after an HPV vaccination, temporal associations do not establish causation. Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

Stephanie was experiencing pain in her throat and headaches in May 2010. Although Stephanie complained that she had "blistered tonsils" and "worsening blisters," neither Dr. Kiernan nor the medical staff at Rochester Memorial Hospital indicated that Stephanie's tonsils were blistered. In fact, the notes from the hospital specifically state that Stephanie's tonsils appeared "normal," although her posterior pharynx was erythematous.

When Sore Throat Began

The medical record on May 24, 2013, carries more weight than the May 31, 2013 record. On May 24, 2013, it was easy for Stephanie to indicate whether the sore throat began "today" or "yesterday." Stephanie reported that her sore throat began "today." Exhibit 2 at 60. In contrast, on May 31, 2013, the record of whether the sore throat began seven days or eight days or nine days prior is probably less important to a historian or record-taker. When Stephanie spoke to the Dr. Everett at Rochester Memorial Hospital on May 31, 2010, she could have been estimating when she said "eight days." Therefore, Stephanie's symptoms began on May 24, 2010.

Conclusion

The parties are ordered to provide these Findings of Fact to any expert whom they may retain to offer an opinion in this case. An expert's assumption of any fact that is inconsistent with these Findings of Fact will not be credited. Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed .Cir. 1993) (holding that the special master did not abuse his discretion in refraining from conducting a hearing when the petitioner's expert "based his opinion on facts not substantiated by the record").

A status conference is set for **Wednesday, August 13, 2014, at 2:30 P.M. Eastern Time**. The petitioners should be prepared to discuss the next step in this case.

IT IS SO ORDERED.

S/Christian J. Moran
Christian J. Moran
Special Master