

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

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NICOLETTE SANTINO,	*	
	*	No. 10-609V
	*	Special Master Christian J. Moran
Petitioner,	*	
	*	Filed: September 19, 2012
v.	*	Re-filed: October 12, 2012
	*	
SECRETARY OF HEALTH	*	Findings of fact; human
AND HUMAN SERVICES,	*	papillomavirus vaccine;
	*	headaches.
Respondent.	*	

Ronald C. Homer & Meredith Daniels, Conway, Homer & Chin-Caplan, P.C.,
Boston, MA, for petitioner;
Debra A. Filteau Begley, United States Dep't of Justice, Washington, DC, for
respondent.

REVISED FINDINGS OF FACT*

Nicolette Santino alleges that the human papillomavirus (“HPV”) vaccine,
which she received on September 20, 2007 and November 14, 2007, caused her to

* This Findings of Fact was originally filed on September 19, 2012. During
a status conference held on October 11, 2012, petitioner pointed out two
inconsistencies and requested clarification. In this reissued version, the word
“within,” which was in the second sentence of the second full paragraph on page 8,
was removed. Additionally, the dates listed in the same paragraph were changed to
read “October 25-28.” The remainder of the document is unchanged.

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.

suffer chronic headaches. Amended Pet. at 1. Ms. Santino seeks compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa—10 et seq. (2006).

To support her claim for compensation, Ms. Santino filed medical records and an affidavit. The recitation of events in the written testimony generally matches with the events set forth in the medical records. However, the onset and frequency of Ms. Santino’s headaches is not clear from the testimony or the records.

A challenge is that Ms. Santino is complaining about headaches. Although headaches are common and generally understood, the details about Ms. Santino’s headaches may be material. The parties seek findings of fact about the frequency, duration, and severity of Ms. Santino’s headaches. There are no objective tests measuring these details. The only information available derives from Ms. Santino’s experience. She has described her experience to doctors who memorialized her statements and treated her based upon her recollections. In this litigation, Ms. Santino has also described how she experienced headaches, both via written testimony (affidavit) and oral testimony. The details in these various accounts are not entirely consistent.

When special masters are confronted with discrepancies among medical records and affidavits, special masters are encouraged to hold hearings to evaluate the testimony of the affiants. See Campbell v. Sec’y of Health & Human Servs., 69 Fed. Cl. 775, 779-80 (2006).

A hearing was held on November 4, 2011, during which Ms. Santino appeared by videoconferencing as permitted by Vaccine Rule 8(b)(2). Following the hearing, the parties filed a joint motion (“Jt. Mot.”) requesting fact-finding on four specific issues. Aside from the four issues discussed below, the parties agree that the medical records and testimony are not in dispute.¹ Jt. Mot. at 1.

Standard for Finding Facts

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

¹ A status conference was held on September 10, 2012. In this conference the Secretary clarified a discrepancy contained in the motion.

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). Medical records that are created contemporaneously with the events that 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 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 problems to the doctor. Third, having heard about the symptoms, the doctor records what he (or she) was told.

The presumption that contemporaneously created medical records are accurate and complete, however, 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.

In weighing divergent pieces of evidence, contemporaneous written medical records are usually more significant than oral testimony. Cucuras, 993 F.2d at 1528. However, compelling oral testimony may be more persuasive than written records. Campbell, 69 Fed. Cl. at 779 (Fed. Cl. 2006) ("like 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), aff'd, 968 F.2d 1226 (Fed. Cir. 1992).

The relative strength or weakness of the testimony of a fact witness affects whether this testimony is more probative than medical records. An assessment of a fact witness's credibility usually involves consideration of the person's demeanor

while testifying. Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The key time frame in this case occurs between when Ms. Santino received the first dose of the HPV vaccine and when she started to see doctors for her headaches. Unfortunately, because Ms. Santino did not start seeing doctors until after she was experiencing headaches for some time, there are no true contemporaneous records in this case. The most recent record following Ms. Santino’s vaccinations is from December 2007, over two months after she received the first dose of the HPV vaccine.

Parties’ Arguments

The parties presented their positions in a joint motion, filed August 1, 2012. The parties agree on three points. First, the parties agree that Ms. Santino began to experience headaches in late October 2007.² Jt. Mot. at 2-3. Second, the parties agree that when Ms. Santino started having headaches, the headaches were intermittent.³ Third, the parties agree that Ms. Santino’s headaches developed into a constant headache. Jt. Mot. at 3-4. The parties, however, dispute when Ms. Santino’s headaches became constant. Jt. Mot. at 4-6.

Ms. Santino claims that her headaches became constant by November 21, 2008, approximately one week after receipt of the second dose of the HPV vaccine. Jt. Mot. at 4-5 (citing tr. 43 and exhibit 1 at 83). Ms. Santino cites a record from Harvard Vanguard Medical Associates, dated December 9, 2007, which indicates that she “has had a frontal pressure, which has been present constantly for the past

² The Secretary notes that two of Ms. Santino’s records place the onset of her headaches in late November 2007. However, the Secretary acknowledges that these records contradict the vast majority of Ms. Santino’s records that put onset in October 2007. The Secretary contends that these records likely represent a change in the severity of Ms. Santino’s headaches, rather than the onset. Jt. Mot. at 2-3 (citing Exhibit 1 at 80 and exhibit 3 at 3).

³ The Secretary, however, notes that two of Ms. Santino’s treating neurologists noted in later histories that Ms. Santino’s headaches may have been constant from the start. Jt. Mot. at 3-4 (citing Exhibit 1 at 58 (Dr. Mullally) and exhibit 3 at 77 (Dr. Cremone)).

2 weeks.” Jt. Mot. at 5 (citing exhibit 1 at 83). Ms. Santino contends that this record places her headaches as constant in late November 2007.

The Secretary asserts that Ms. Santino’s headaches “most likely became constant one or two weeks after” the initial onset of her headaches.⁴ Jt. Mot. at 4-5 (citing exhibit 1 at 54, 60, 63, 73, 83). To support her position, the Secretary also cites to the December 9, 2007 record from Harvard. The Secretary states that while this record describes a frontal pressure present for the past two weeks, the same record also notes that “initially it [the headache] was intermittent but had been present every day for the past 6 weeks,” placing onset of Ms. Santino’s constant headaches in late October 2007. Jt. Mot. at 5 (citing exhibit 1 at 83).

Findings of Fact

The parties have propounded four questions for which they seek findings of fact. Although the parties are truly in dispute on only one of those issues, all questions are resolved below.

1. When did Ms. Santino develop headaches following her first HPV vaccination on September 20, 2007?

Although the records and testimony do not reflect an exact onset date for Ms. Santino’s headaches, the evidence preponderates in favor of finding that Ms. Santino first experienced headaches in late October 2007. It is likely that the headaches began between October 25-28, 2007.

2. Did Ms. Santino’s headaches begin as intermittent, or were they constant from the start?

A preponderance of the evidence supports finding that Ms. Santino’s headaches were initially intermittent. This finding is supported by the records created closest in time to the beginning of her headaches. Exhibit 1 at 46, 54, 73, 79, 83; exhibit 3 at 70. The parties do not dispute this finding. Jt. Mot. at 3.

⁴ In a status conference held on September 10, 2012, the Secretary clarified that her motion should have read that Ms. Santino’s headaches became constant one to two weeks after the initial onset of her headaches, rather than one to two weeks after receipt of the first dose of the HPV vaccine.

3. If Ms. Santino's headaches were initially intermittent, what was the frequency of her headaches before they became constant?

The parties agree that Ms. Santino's headaches initially followed a pattern of appearing and disappearing every two to three days. These first headaches were intermittent. Jt. Mot. at 4 (citing exhibit 1 at 79, exhibit 3 at 66, exhibit 4 at 4); see also tr. at 39-41.

4. When did Ms. Santino's headaches become constant?

The parties most strenuously dispute this point. Ms. Santino argues that her headaches became constant around November 21, 2007. In contrast, the Secretary argues that Ms. Santino's headaches actually became constant one to two weeks after the initial onset of her headaches.

Here, the more persuasive evidence supports the Secretary's position. Ms. Santino told many medical doctors that she was experiencing a daily headache shortly after her headaches first began. Representative records, presented in chronological order, include:

- Exhibit 1 at 83 (report from Dr. Avery, dated Dec. 9, 2007, stating "Patient describes gradual onset of symptoms beginning 6 weeks prior to arrival. . . . Initially it was intermittent but had been present every day for the past 6 weeks.");⁵
- Exhibit 1 at 79 (report from Dr. Tremblay, dated Dec. 14, 2007, stating that headaches "[s]tarted 7 wks ago. Initially, were episodic, now constant. Initially, frontal, now generalized.");
- Exhibit 1 at 72 (report from Dr. Mullally, dated Dec. 29, 2007, stating "The patient has experienced headaches for the past 8-1/2 weeks. Initially they were intermittent, but for the past 2 months, the pain has been essentially constant");
- Exhibit 1 at 63 (report from Dr. Mullally, dated Jan. 28, 2008, stating "for the past 3 months [her headaches] have been constant");

⁵ Because Ms. Santino relies upon this record, it is discussed in more detail below.

- Exhibit 1 at 60 (report from Dr. Bailit, dated Feb. 14, 2008, stating Ms. Santino “was seen... because of constant headaches... since October.”);
- Exhibit 3 at 77 (report from Dr. Cremone, dated April 3, 2008, stating “she has had a daily headache since October.”);
- Exhibit 4 at 4 (report from Dr. Childs, dated Jan. 14, 2009, stating “She says that the headache went away over a few days but that it returned and again was excruciating. She says that the headaches ‘sort of resolved [’] and then began again, still excruciating. Over approximately 2 weeks the headache became constant, 24 hours a day and severe.”
- Exhibit 2 at 1 (report from Dr. Greenstein, dated June 26, 2009, stating “She states that since October 2007 she has chronic daily headache[s] 24x7, which have never disappeared.”).

The multiplicity of records suggesting that the shift to constant headaches occurred within a week after her headaches first began reinforces each other and enhance their persuasiveness. Additionally, in one record, Ms. Santino specifically told Dr. Mullally that there “was no change in her headache after the second vaccine.” Exhibit 1 at 54 (record dated March 20, 2008).

To be sure, some evidence supports Ms. Santino’s argument that the frequency of her headaches changed around late November 2007. However, the predominant supporting evidence is her own testimony. See, e.g., tr. 14-15, tr. 43-44. Ms. Santino cites only one record in support of this claim. Jt. Mot. at 5 (citing exhibit 1 at 83).

Exhibit 1 at 83 documents Ms. Santino’s first doctor visit to address her headaches. The report, in pertinent part, states:

Patient describes gradual onset of symptoms beginning 6 weeks prior to arrival. She has had a frontal pressure, which has been present constantly for the past 2 weeks. Initially it was intermittent but had been present every day for the past 6 weeks.

Exhibit 1 at 83.

Ms. Santino relies upon the portion of this record that states she has been having frontal pressure for the past two weeks. To Ms. Santino, this statement supports finding that her headaches began being constant about two weeks before December 9, 2007, the date she went to Harvard. Jt. Mot. at 5.

In focusing on the “frontal pressure” part, Ms. Santino overlooks the portion of the report stating that the headaches have been present “every day for the past 6 weeks.” A headache experienced every day is a constant headache. Moreover, given the other records, the reference to frontal pressure probably refers to a change in the location of the headache, rather than a change in frequency. See exhibit 1 at 79 (stating that the headaches were frontal and are now generalized). Thus, the December 9, 2007 record is consistent with a finding that the onset of her constant headaches occurred within one week after her headaches first began.

Additionally, Ms. Santino’s oral testimony was not sufficiently compelling to rebut the presumption that statements given to doctors for the treatment of medical problems are accurate. It is inevitable that the passage of time has affected Ms. Santino’s recollection of the events that took place surrounding her HPV vaccine vaccinations. See Lowrie v. Sec’y of Health & Human Servs., No. 03-1585V, 2005 WL 6117475, at *24 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). While Ms. Santino’s medical records are not truly contemporaneous, they were created closer in time than her testimony. Thus, her medical records are likely to be more accurate.

For all of these reasons, a preponderance of the evidence supports finding that Ms. Santino’s headaches became constant one week after October 25-28, 2007, when Ms. Santino’s headaches initially began.

Conclusion

The parties are ordered to provide these findings of fact to any expert whom they retain to testify. These findings of facts should prevent a situation in which an expert assumes “facts” that may not be supported by a preponderance of the evidence. See Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (stating “The special master concluded that the expert based his opinion on facts not substantiated by the record. As a result, the special master properly rejected the testimony of petitioner’s medical expert.”).

A status conference will be held on **Thursday, October 11, 2012, at 2:00 P.M. Eastern Time.** Ms. Santino should be prepared to propose the next step in this case.

IT IS SO ORDERED.

s/ Christian J. Moran
Christian J. Moran
Special Master