

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

KATHRYN and ELLIS GRAHAM, *
Parents and Next of Kin to *
LATIA GRAHAM, a minor, *
Petitioners, *

No. 10-468V
Special Master Christian J. Moran

v. *

Filed: November 14, 2011
Reissued: January 10, 2012

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *
Respondent. *

Findings of fact; fever

Andrew D. Downing, Rhodes, Hieronymus, et al, Tulsa, OK, for petitioners;
Claudia B. Gangi, United States Dep't of Justice, Washington, D.C., for
respondent.

FINDINGS OF FACT¹

¹ Because this unpublished ruling contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

All decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision is filed, a party has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall delete such material from public access. 42 U.S.C. § 300aa-12(d)(4); Vaccine Rule 18(b).

Mr. and Ms. Graham claim that a combination of the tetanus – diphtheria – acellular pertussis vaccine (Tdap) and the hepatitis A vaccine caused their daughter, LaTia, to suffer toxic epidermal necrolysis (“TENS”). The Grahams seek compensation pursuant to the National Childhood Vaccine Injury Compensation Program. See 42 U.S.C. § 300aa-10 et seq. (2006).

The Grahams have retained one doctor, Richard A. Hastings, who opined the vaccines can cause toxic epidermal necrolysis. Dr. Hastings also asserted that in LaTia’s case, the vaccines did cause TENS. In explaining why he maintains the vaccines caused LaTia’s TENS, Dr. Hastings assumed that LaTia started to experience a low-grade fever 48 hours after being vaccinated. Exhibit 11 (Dr. Hastings’s report) at 1161.

This ruling determines only when LaTia started having a fever after the Tdap and hepatitis A vaccination.²

FACTUAL BACKGROUND AND PROCEDURAL HISTORY

LaTia was born in 1993. Her medical history for her first 13 years appears normal. The Secretary has not suggested that any problems originating in her early life contributed to LaTia’s development of TENS. See Resp’t Rep’t at 11-12.

On February 15, 2007, LaTia visited her pediatrician, Ramesh Mohan. LaTia had a boil on her thigh that was abscessed. Dr. Mohan incised the boil. As a precautionary measure, Dr. Mohan prescribed Septra DS. Exhibit 2 at 4. Septra DS is a combination medication of two antibiotics, sulfamethoxazole and trimethoprim. It is most commonly used to treat bacterial infections. Dorland’s Illustrated Medical Dictionary (31st 2007) at 1719, 1828, 1994. Dr. Mohan also instructed LaTia to return in one week.

Ms. Graham followed Dr. Mohan’s instructions by obtaining the Septra. LaTia began taking Septra on Thursday, February 15, 2007. Tr. 22.

On February 21, 2007, LaTia returned for her follow-up appointment with Dr. Mohan. Dr. Mohan noted that the abscess was almost healed. His records from this appointment do not indicate that LaTia suffered from any health problem such as a fever, weakness, or tiredness. Exhibit 2 at 5.

² The ruling does not address whether the vaccines can cause TENS.

During the February 21, 2007 visit, Dr. Mohan gave LaTia the Tdap and hepatitis A vaccinations. He told Ms. Graham that LaTia might have a fever due to the vaccinations in the next few days. If so, Ms. Graham should give LaTia Tylenol. Exhibit 1 (affidavit of Ms. Graham, dated Jan. 26, 2010) ¶ 5; tr. 32.

Ms. Graham maintains that LaTia started to have a fever on Monday, February 26, 2007. Tr. 32; see also exhibit 35. Whether this assertion is supported by a preponderance of evidence is the question resolved here.

On Thursday, March 1, 2007, LaTia was attending school. In the afternoon, she had a fever and sought assistance from the school nurse. The nurse called Ms. Graham, who picked her daughter up from school early. Tr. 34; see also exhibit 34 (school attendance records) at 1318. Ms. Graham attempted to schedule an appointment with Dr. Mohan that day. However, an appointment was not possible.

Dr. Mohan was able to see LaTia the next day, Friday, March 2, 2007, at approximately 1:30 p.m. Dr. Mohan recorded that LaTia had a “high fever since yesterday.” Dr. Mohan also noted that she had a macular rash around her ears. A blood test showed that LaTia had 779 white blood cells per microliter and a normal range is 5,000 to 10,000. Dr. Mohan sent LaTia to the emergency room at the Oklahoma University Children’s Hospital. Exhibit 2 at 6.

Ms. Graham testified that Dr. Mohan said that he would call the emergency room to alert personnel there about LaTia’s imminent arrival. Tr. 60-61. There is no direct evidence that Dr. Mohan placed this call. In any event, LaTia was seen in the emergency room at 7:30 p.m.

The history from the emergency room states that LaTia “developed fever at school yesterday to 103.7.” LaTia “presented to [primary care physician] today at 1:30 p.m. at that time had rash developing on external ears.” Exhibit 3 at 147.³

LaTia was admitted to Children’s Hospital. One diagnosis was “Stevens-Johnson syndrome [(SJS)] going into Toxic epidermal necrolysis.” Exhibit 3 at

³ The basis for the statement that LaTia’s temperature had reached 103.7 degrees is not absolutely clear. Ms. Graham stated that she did not take LaTia’s temperature using a thermometer. It is possible that Dr. Mohan may have taken LaTia’s temperature but a temperature is not recorded in the notes from Dr. Mohan’s office. Tr. 54; tr.81-82.

129 (dermatologist's report, dated March 3, 2007). The details of LaTia's course at Children's Hospital are not particularly helpful in determining whether LaTia began having a fever on February 26, 2007. Thus, those records are discussed summarily.

The hospitalization records show a rapid spread of the disease. Essentially, nearly all external surface of LaTia's body was affected, even her eyes. Pictures, which were submitted as exhibit 5, show LaTia's horrible condition. The pictures communicate the devastation to LaTia much more effectively than any written summary.

The doctors at Children's Hospital prescribed several medications in an attempt to halt the spread of the TENS and /or SJS. One medication was intravenous immunoglobulin (IVIG). A record indicates that IVIG was ordered on March 3, 2007. Exhibit 3 at 144-46. A gastroenterologist stated that LaTia's disease was most likely related to the use of Septra. Id. at 143. The disease continued to worsen and LaTia was transferred to an intensive care unit at Children's Hospital. Id. at 131-33. LaTia did not stay in the intensive care unit for long. A helicopter transported LaTia from Children's Hospital to Shriner's Hospital in Galveston, Texas on March 5, 2007, because of that facility's expertise in treating burns. At discharge from Children's Hospital, the diagnosis was TENS associated with Septra. Id. at 290-92.

At Shriner's Hospital, a person recorded a history that Latia "took 2 week course of Bactrim DS for [illegible] thigh abscess. At end of the therapy, pt = fever + rash which started on ears." Exhibit 4 at 625. LaTia stayed in Shriner's Hospital from March 5, 2007 to March 22, 2007. Her treatment for those two and a half weeks is largely immaterial to determining the cause of LaTia's disease. After discharge from Shriner's Hospital, LaTia was treated at outpatient clinics.

Despite years of care, LaTia still has not recovered fully. Her parents seek compensation for LaTia through the Vaccine Program. Mr. and Ms. Graham filed a petition on July 21, 2010. They electronically filed LaTia's medical records on August 3, 2010.

To support their claim for compensation, the Grahams rely upon the opinion of Dr. Hastings. Dr. Hastings is board certified in internal medicine and has a Ph.D. in Anatomy. He is the author of seven publications. Exhibit 12 (curriculum vitae of Dr. Hastings).

Dr. Hastings presented a summary of LaTia's course in a January 1, 2011 report, which was filed as exhibit 11. Dr. Hastings states, in part, that after LaTia received the hepatitis A vaccine, "Within approximately 48 hours, the patient did experience an elevated temperature and shortly thereafter did experience the onset of a rash." Exhibit 11 at 6. He also states LaTia's "rapidly developing fever and rash following [the hepatitis A vaccine] was a clear medical indication that the [vaccine] caused her Toxic Epidermal Necrolysis condition." *Id.* at 8. A few pages later, Dr. Hastings states again that the hepatitis A vaccine was given on February 21, 2007 "with the patient experiencing the rapid postvaccination symptom of fever and subsequently rash." *Id.* at 14. Ultimately, Dr. Hastings concludes the hepatitis A vaccine caused LaTia's TENS.⁴

The Secretary obtained a report from E. Richard Stiehm. Dr. Stiehm is board certified in pediatrics, allergy and immunology, and diagnostic laboratory immunology, and has authored 275 articles in peer-reviewed journals. Exhibit E (curriculum vitae of Dr. Stiehm).

Dr. Stiehm stated that LaTia suffered from TENS. As to the cause of LaTia's TENS, Dr. Stiehm opined that "the causative agent was co-trimoxazole started 15 days prior to the onset of the illness and continued for 14 days." Exhibit D at 4.

Additionally, Dr. Stiehm challenged Dr. Hastings's presentation of Latia's medical condition from February 27, 2007 through March 2, 2007. Exhibit D at 5-6. This disagreement between Dr. Hastings and Dr. Stiehm prompted discussions at several status conferences.

In a June 3, 2011 status conference, the Grahams acknowledged that Dr. Hastings had erred in asserting that LaTia developed a rash 48-72 hours after the vaccinations. The Grahams were not certain as to whether a change in Dr. Hastings's understanding of when the fever and rash began would affect his opinion that the vaccine caused LaTia's TENS. Consequently, the Grahams were ordered to confer with Dr. Hastings.

In the next status conference, which was held on July 6, 2011, the Grahams reported that fever is important to Dr. Hastings's opinion. The Grahams further asserted that the basis for Dr. Hastings's assumption that LaTia suffered a fever is

⁴ In a March 1, 2011 report, Dr. Hastings includes the Tdap vaccine as a cause for LaTia's TENS. Exhibit 17.

Ms. Graham's affidavit. Due to the importance of this issue, the parties agreed to conduct a hearing to receive testimony from people knowledgeable about LaTia's health from February 21, 2007 to March 2, 2007.⁵

The hearing was held on October 3, 2011. Ms. Graham testified. Mr. Graham also testified, but his testimony was extremely brief because his own health problems prevented him from observing LaTia during the relevant time. At the end of the hearing, the parties declined the opportunity to file briefs about when LaTia's fever began. Thus, this narrow issue is ready for adjudication.⁶

STANDARDS 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 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).

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 to have 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.3d at 1527. A judge reviewing the special master's decision stated that "In

⁵ The parties also began to schedule a hearing for Dr. Hastings and Dr. Stiehm. This hearing is scheduled for January 12, 2012.

⁶ On October 27, 2011, the Grahams filed a report from Steven Pike, a toxicologist. Dr. Pike, like Dr. Hastings, assumed that LaTia "developed the first signs of Steven-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) four days" after vaccination. Exhibit 39 at 1.

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 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).

Decisions by judges of the Court of Federal Claims have followed Cucuras in affirming findings by special masters that the lack of contemporaneously created medical records can contradict a testimonial assertion that symptoms appeared on a certain date. E.g. Doe v. Sec'y of Health & Human Servs., 95 Fed. Cl. 598, 607-08 (2010); Doe/17 v. Sec'y of Health & Human Servs., 84 Fed. Cl. 691, 711 (2008); Ryman v. Sec'y of Health & Human Servs., 65 Fed. Cl. 35, 41-42 (2005); Snyder v. Sec'y of Health & Human Servs., 36 Fed. Cl. 461, 465 (1996) (stating "The special master apparently reasoned that, if Frank suffered such [developmental] losses immediately following the vaccination, it was more likely than not that this traumatic event, or his parents' mention of it, would have been noted by at least one of the medical record professionals who evaluated Frank during his life to date. Finding Frank's medical history silent on his loss of developmental milestones, the special master questioned petitioner's memory of the events, not her sincerity."), aff'd, 117 F.3d 545, 547-48 (Fed. Cir. 1997).

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 v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 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).

A final point is that special masters consider the record as a whole. 42 U.S.C. § 300aa—13(a). The record in cases in the Vaccine Program always contains medical records created from more than one provider of medical care. Special masters’ consideration of multiple sources promotes fact-finding that is in accord with the weight of all the records.

These criteria are used in the analysis below.

ANALYSIS

During the acute stage of LaTia’s TENS, three medical records discuss the onset of her fever. First, Dr. Mohan’s March 2, 2007 record states “high fever since yesterday.” Exhibit 2 at 6. Second, the admission note for Children’s Hospital states: “Pt developed fever at school yesterday & overnight.” Exhibit 3 at 147. Third, the admission note for Shriner’s Hospital indicates that LaTia’s fever began after a two-week course of Septra. Given that LaTia began taking Septra on February 15, 2007, the Shriner’s Hospital note means that LaTia’s fever could not have begun before February 28, 2007.

Significantly, these three records were created at three different institutions and they are consistent with each other. The multiplicity of sources reinforces the likelihood that the history being recounted is correct. While one history may possibly contain inaccuracies, there is less likelihood that three medical specialists made the same mistake. These three records support a finding that LaTia’s fever began on March 1, 2007.

The evidence weighing against this finding is only Ms. Graham's testimony.⁷ Without a doubt, Ms. Graham testified in accord with her memory. She showed no signs of attempting to present false testimony intentionally.

Despite Ms. Graham's honesty, her testimony does not appear accurate. If it were true that LaTia had actually started having a fever on February 26, 2007, then this beginning would have been mentioned in at least one of LaTia's medical records. The absence of notation is particularly notable in the admission record from Shriner's Hospital. LaTia arrived at the burn unit on March 5, 2007, approximately one week after her disease began. During the preceding days, LaTia nearly died. Her parents undoubtedly reflected upon LaTia's history in an attempt to help her doctors identify the cause of the disease. Yet, after the Grahams flew in a helicopter to a special hospital, they associated the onset of LaTia's fever with the completion of Septra, which occurred on February 28, 2007. In the respect that "treatment hangs in the balance," LaTia's case is comparable to Cucuras, which holds the special master did not err in refraining from accepting testimonial assertions that were not memorialized in a record created contemporaneously.

Conclusion

For these reasons, the assertion that LaTia started having a fever on February 26, 2007 is not accepted. The evidence does not preponderate in favor of that finding. The parties are instructed to provide this fact-finding to Dr. Hastings, Dr. Pike and Dr. Stiehm. The parties should be prepared to discuss whether this finding affects their opinions. The next status conference is scheduled for **Tuesday, November 29, 2011 at 2:30 P.M. Eastern Time.**

IT IS SO ORDERED.

S/ Christian J. Moran

Christian J. Moran
Special Master

⁷ The Grahams have not identified any medical records that indicate that LaTia's fever began earlier than March 1, 2007.