In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-525V
Filed: April 3, 2018
Not to be Published.

KENDALL VUONG, Individually, and for the Minor, K.A.,	*	
Petitioner,	*	
v.	*	Hepatitis B vaccine; chronic recurring urticaria; no expert report; oral motion to dismiss
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Joseph L. Krueger, New York, NY, for petitioner.
Justine E. Walters, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On April 14, 2017, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that the third dose of hepatitis B vaccine that her son K.A. received on September 16, 2014 caused him chronic recurrent urticaria. Pet. Preamble. She states his recurrent urticaria occurred four times in 2015, twice in 2016, and once in 2017. Pet. at ¶ 6. She also asserts these lesions resulted in secondary visual compromise. Id. at 7. Although not alleged in the petition, petitioner asserts in her affidavit that K.S.'s first rash and painful welts occurred within several minutes of his hepatitis B vaccination on September 16, 2014. Pet. Affid. at 1. Petitioner also asserts that since November 2016, K.A. has spiked

[1] Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). Vaccine Rule 18(b) states that 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 constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall redact such material from public access.

significantly high fevers occurring once or twice a month not associated with skin lesions, lasting about 24 hours. Id. This assertion is not in the petition. This complaint is also not in the medical records.

On September 27, 2017, respondent filed a Rule 4(c) Report in opposition to petitioner's allegations. Respondent notes that the last episode of K.A.'s noted in the medical records was on October 10, 2014 associated with an infectious illness. Resp't's Rep., at 8.

On October 12, 2017, the undersigned issued an Order for petitioner to file an expert report by January 31, 2018.

On January 29, 2018, petitioner filed a motion for an extension of time until March 2, 2018 within which to file an expert report, which the undersigned granted.

On February 27, 2018, petitioner filed a motion for an extension of time until March 16, 2018 within which to file an expert report, which the undersigned granted.

On March 15, 2018, petitioner filed a motion for an extension of time until March 30, 2018 within which to file an expert report, which the undersigned granted.

On March 30, 2018, petitioner filed a motion for an extension of time until April 6, 2018 within which to file an expert report, which the undersigned granted. However, before that motion, petitioner contacted the undersigned's law clerk to request a status conference.

On April 3, 2018, the undersigned held a telephonic status conference with counsel during which petitioner's counsel stated that he could not obtain an expert report to substantiate petitioner's allegations and petitioner had given him permission to move orally for dismissal. The undersigned issued a non-PDF Order cancelling the April 6, 2018 deadline to file an expert report and told counsel she would dismiss this case.

The undersigned **DISMISSES** this case for failure to prove a prima facie case of causation in fact.

Medical Records

Records predating hepatitis B vaccination #3

On December 13, 2013, K.A. received his first hepatitis vaccination. Med. recs. Ex. 2, at 16.

On December 17, 2013, K.S. went to the pediatrician. Id. at 7. He had been throwing up since the previous night. He was not keeping food down. He would burp and then throw up. K.A.'s mother ate some ethnic food over the weekend. The pediatrician diagnosed him with gastroesophageal reflux, gave K.A.'s mother reflux precautions, and told her to watch her diet

and avoid spicy foods. Id.

Two days later, on December 19, 2013, K.A. returned to the pediatrician. Id. K.A.'s left eye had an increase in tearing and yellow mucus. The pediatrician diagnosed K.A. with dacryocystitis[2] and prescribed nasolacrimal massage. The pediatrician also did a core check. He prescribed Vaseline to the diaper area.

On February 11, 2014, K.A. received his second hepatitis B vaccination. Med. recs. Ex. 2, at 16.

Records postdating hepatitis B vaccination #3

On September 16, 2014, in the morning, K.A. received his third hepatitis B vaccination. Id.

On September 16, 2014, in the afternoon, K.A.'s pediatrician recorded that K.A.'s parents came with K.A. for the pediatrician to look at a "rash" (the pediatrician put the word in quotation marks) that developed. Id. at 6. The parents were concerned that K.A. was having a reaction to his hepatitis B vaccination that morning. When the pediatrician examined K.A.'s right thigh, which had received the vaccine, he noted it was clean, dry, and intact (the pediatrician used the acronym "C/D/I"). K.A.'s right cheek was mildly red, but the pediatrician did not note any other rashes. Id. The pediatrician told K.A.'s mother and father that a "shot reaction was not really likely and that the child should be fine." Id.

At 4:30 p.m. on September 17, 2014, petitioner phoned K.A.'s pediatrician and spoke to Stefani. Id. Petitioner said that K.A.'s rash came and went. Petitioner wanted K.A. to have allergy testing. The pediatrician wrote a prescription for her to pick up in the morning on September 18, 2014. Id.

On September 30, 2014, K.A.'s mother called the pediatrician. Id. at 10. Since K.A.'s allergy testing was negative, she was concerned that hepatitis B vaccine caused K.A.'s rash even though he had two prior hepatitis B vaccinations without any rash. She said he had a rash/red patch on his face and arm every time he woke from a nap for about three days after he received the third hepatitis B vaccination. It would self-resolve and go away in about 30 to 40 minutes. The site of the vaccination was also red and warm. The pediatrician explained to petitioner that a local reaction was not an allergic reaction and that K.A.'s rash did not sound anything like a rash due to allergy, especially after K.A. had received two prior doses of hepatitis B vaccine. Petitioner had filed a vaccine reaction form online and wanted the lot number and expiration date, which the pediatrician gave to her. The pediatrician also said that the rash had vanished when he saw K.A. and that he did not have any reason to file a vaccine adverse reaction form because he did not see K.A. have any rash. He also explained that K.A.'s allergy testing was negative, but that they are not 100% accurate for demonstrating allergies in children who truly

[2] Dacryocystitis is "inflammation of the lacrimal sac." Dorland's Illustrated Medical Dictionary 469 (32nd ed. 2012) [hereinafter Dorland's]. "Lacrima" means "tears." Id. at 996.

have hives and atopic dermatitis. Id.

On October 10, 2014, K.A. returned to the pediatrician with a rash and a fever up to 102 degrees the day before. Id. at 9. He threw up Tylenol and his mother gave him a lukewarm bath. He broke out in a rash which looked like hives. He did not have any known medical allergies ("NKMA"). K.A. had hepatitis B vaccination on September 16, 2014 and then had intermittent hives for three days, which went away and came back. They were itchy. The doctor questioned the etiology of the hives. Id.

On December 1, 2014, petitioner took K.A. to a new pediatrician, Dr. Raoul Del Mar. Med. recs. Ex. 5, at 43. K.A. had cough and colds for seven days, but no fever, vomiting, diarrhea, or other symptoms. Id. at 42. Dr. Del Mar notes K.A. did not have a rash. Dr. Del Mar diagnosed K.A. with the common cold (acute nasopharyngitis). Id.

On December 16, 2014, K.A. saw Dr. Del Mar for a well-child check up. Id. at 40. Petitioner had no concerns. Dr. Del Mar notes K.A. did not have a rash. K.A. received MMR and varicella vaccines. Id. at 41.

On January 9, 2015, K.A. saw Dr. Del Mar with a cough and cold for six days, but no fever, vomiting, diarrhea or other symptoms. Id. at 38. Dr. Del Mar notes K.A. did not have a rash. Dr. Del Mar diagnosed K.A. with the common cold (acute nasopharyngitis). Id.

On February 23, 2015, K.A. saw Dr. Del Mar with an intermittent barking cough for two weeks with occasional post-tussive cough, clear bilateral rhinorrhea, and low-grade fever four days ago but none since then, but no vomiting, diarrhea, or other symptoms. Id. at 36. Dr. Del Mar notes K.A. did not have a rash. Dr. Del Mar diagnosed K.A. with the common cold (acute nasopharyngitis). Id.

On March 17, 2015, K.A. saw Dr. Del Mar for his 15-month well-child check up. Id. at 33. Petitioner had no concerns. Dr. Del Mar notes K.A. did not have a rash. Id. K.A. received DTaP, HiB, Prevnar 13, and hepatitis A vaccines. Id. at 34.

On June 23, 2015, K.A. saw Dr. Del Mar for his 18-month well-child check up. Id. at 31. Petitioner had no concerns. Dr. Del Mar notes K.A.'s skin was normal. Id.

On August 13, 2015, K.A. saw Dr. Del Mar for a cough and cold for ten days with no fever, vomiting, diarrhea or other symptoms. He did not have any eye irritation. Dr. Del Mar notes K.A. did not have a rash. Dr. Del Mar diagnosed K.A. with the common cold (acute nasopharyngitis). Id.

On August 28, 2015, K.A. saw Dr. Del Mar for fussiness the prior night. Id. at 27. He had had a cough and colds for seven days, but no vomiting, diarrhea, or other symptoms. He did have a fever. Dr. Del Mar notes K.A. did not have a rash. Id. Dr. Del Mar diagnosed K.A. with otitis media (ear infection). Id. at 28. He prescribed Amoxicillin. Id.

On September 9, 2015, K.A. saw Dr. Del Mar for a follow up. Id. at 23. K.A. finished his antibiotic for acute otitis media four days previously, and the prior night had vomiting and diarrhea with decreased appetite but no fever. Dr. Del Mar notes that K.A. did not have a rash. Dr. Del Mar diagnosed K.A. with viral gastroenteritis. Id. He prescribed hydration with pedialyte. Id. at 24.

On October 26, 2015, K.A. saw Dr. Del Mar with an upper respiratory infection. Id. at 16. He had cough and colds for one day, but no fever, vomiting, diarrhea or other symptoms. Dr. Del Mar notes that K.A. did not have a rash. Dr. Del Mar diagnosed K.A. with an unspecified viral infection. Id.

On November 4, 2015, K.A. saw Dr. Del Mar because he had fallen and hit his head. Id. at 14. Two hours previously, K.A. was standing on a Fisher Price musical table which was about a foot off the ground. K.A. fell off and hit the back of his head on the door frame. He did not lose consciousness. He did not vomit, jerk, or seize. K.A. had a 2 cm x 1 cm soft lump on the back of his head which was slightly red. He ate and acted normally now. Dr. Del Mar diagnosed K.A. with a contusion of his scalp. Id.

On February 11, 2016, K.A. saw Dr. Del Mar because of a possible strep throat. Id. at 11. K.A. had a temperature of 101.3 degrees. His sister had strep throat and K.A. was using her toothbrush. Dr. Del Mar noted that K.A. did not have a rash. His throat and tonsils were hyperemic (congested). Dr. Del Mar diagnosed K.A. with unspecified acute pharyngitis and prescribed amoxicillin. Id.

On June 26, 2016, petitioner went to urgent care at Sutter Health and saw Dr. Rei J. Young. Med. recs. Ex. 9, at 1. Petitioner stated K.A. had possible hives for two days and complained of mouth pain for two days. The rash was "a new problem." Id. The current episode started the day before. The rash was diffuse and itchy. K.A. had been exposed to nothing. K.A. did not have a history of allergies, asthma, or eczema. He did not have a significant past medical history. Id. On physical examination, K.A. appeared well-developed and well nourished. Id. at 2. His eyes were normal. Id.

On January 3, 2017, K.A. went to a third pediatrician, Dr. Daniel E. McCrimons, for a one-week old cough, fever, nasal congestion and rhinitis. Med. recs. Ex. 6, at 8. Under allergies, he notes previous history of hives and swelling after vaccine administration. Id. This notation was based on petitioner's history to him. On physical examination, K.A. did not have a cough. Id. at 9. His extremities were normal. Dr. McCrimons diagnosed K.A. with a viral infection and acute bronchitis. Id.

On February 23, 2017, K.A. returned to Dr. McCrimons for a well-child check up. Id. at 11. For allergies, Dr. McCrimons writes "allergic reaction post immunizations for six episodes." Id. at 12. This is the history petitioner gave him since these supposed six episodes did not occur while Dr. McCrimons was K.A.'s pediatrician. Physical examination showed nothing was

abnormal. Id. at 13.

On April 10, 2017, petitioner and K.A. saw Dr. Michael J. McCormick, an allergist. Med. recs. Ex. 8, at 4. Petitioner gave a history of K.A.'s starting to get hives and localized swelling after getting a hepatitis B vaccination on September 16, 2014. She stated the hives had been getting progressively worse. Sun exposure worsened them. The hives lasted about four days to a week. The hives did not itch and could appear all over K.A.'s body. Petitioner said she did not know what would trigger them. When K.A. had a fever, he would usually get hives. Petitioner also said that K.A. had a reaction to Dtap vaccine he received on March 17, 2015 when his eyes swelled shut and he had hives two hours later. Petitioner said K.A. could eat any food without trouble. Sometimes, K.A. would get hives with a cold and other times he would not get hives, but they mostly occurred when he had an infection. Occasionally, when K.A. had hives, he had no appetite and had diarrhea. Petitioner said K.A. also coughed when he ran around even though he had no hives. A bee stung K.A. the prior summer but K.A. did not have trouble or symptoms. Petitioner wrote a list for Dr. McCormick of K.A.'s fevers: 102.6 degrees on November 12, 2016, 102 degrees on December 20, 2016, 104 degrees on January 4, 2017, 103 degrees on January 17, 2017, 102 degrees on February 25, 2017, and 102.4 degrees on April 4, 2017. Id. K.A.'s last episode of hives was on June 25, 2016. Id. at 5. K.A. did not complain of joint pain. Petitioner wanted to know if K.A. has an autoimmune disease. Id. On physical examination, Dr. McCormick found K.A. had abnormal tubinates[3] bilaterally. Id. at 6. Dr. McCormick's diagnosis was unspecified urticaria. Id. at 7. He told petitioner, "I do not have experience treating children with urticaria after vaccinations." Id. Dr. McCormick did not schedule K.A. for a return visit. Id.

On June 11, 2017, petitioner, her husband, and K.A. went to Sutter Health where K.A. saw PA Roberta Allen with the complaint of periumbilical abdominal pain, probably due to abdominal muscle strain. Id. at 3. K.A. had a new inflatable toy which K.A. was punching when he picked it up and threw it. He complained of abdominal pain, gradually worsening. He said "ow" when he stood up. This happened about one to two hours previously. In range of systems, PA Allen notes "healthy toddler; no underlying health conditions." Id. Under allergies, PA Allen notes "no known allergies." On physical examination, K.A.'s skin was warm, dry, with good color and turgor. Id.

Additional Material

Following Dr. McCrimons' records dated February 23, 2017 are pages of photographs which petitioner has labelled. On page 15 are two photos of rashes petitioner has dated October 10, 2014. That is consistent with the pediatrician's records.

On page 16 of Exhibit 6 are two photos of rashes dated February 2016, stating swelling of face and right eye, fever, sweating, and no appetite. Dr. Del Mar was K.A.'s pediatrician in February 2016. He notes in his February 11, 2016 record that K.A. had a possible strep throat

[3] A turbinate is "any of the nasal conchae." Dorland's at 1991. A concha is a structure that "resembles a sea shell in shape." Id. at 400.

with a temperature of 101.3 degrees after using his sister's toothbrush while she had strep throat. Med. recs. Ex. 5, at 11. The undersigned fails to see how K.A.'s symptoms of congested throat and tonsils are related to a hepatitis B vaccination he received 17 months before. Moreover, Dr. Del Mar notes that K.A. did not have a rash.

On page 18 of Exhibit 6 are three photos of K.A., which petitioner writes were taken on June 25, 2016, and describes as severe hives. K.A. visited Dr. Young on June 26, 2016 who noted rash, that it was a new problem, and noted possible hives for two days.

On page 19 of Exhibit 6, petitioner lists one-day fevers occurring on November 12, December 20, January 4, and January 17, without listing a year. K.A. frequently had colds. He has an older sister who at one point had strep throat.

Petitioner says in her affidavit (Exhibit 1, at 1) that K.A.'s post-hepatitis B #3 vaccine rash lasted for about one week. K.A.'s first pediatrician stated the rash was intermittent and lasted three days, based on petitioner's history to him.

Petitioner states in a supplemental affidavit (filed on August 7, 2017 without an exhibit number) that she reported K.A.'s skin lesions and rashes to Dr. Del Mar during several visits but he failed to record what she said in K.A.'s medical record. Pet. Supple. Affid. at ¶ 11. She further states that Dr. Del Mar's staff told her he would no longer see K.A. because he did not want to give her a vaccination exemption for the state and did not want to deal with the required reporting associated with that exemption. Id. at ¶ 12. Petitioner states she did not continue to take K.A. to doctors each time his rashes recurred because his doctors told her on previous visits that there was nothing more they could do for the rashes. "I felt it was hopeless to make repeated, special visits for the rashes when I was explicitly told seeking medical care was futile." Id. at ¶ 15. Petitioner states that she has tried to obtain the services of a dermatologist or immunologist for K.A.'s recurring rash, but after she told various doctors and medical staff the purpose of her visit was for a recurring rash that a vaccination caused, "all of these specialists have refused [to] take on K.A. as a patient or even schedule an initial appointment." Id. at ¶ 16. Petitioner said that she was currently considering moving from California to another state in hope of finding doctors who will treat K.A. and his condition. Id. at ¶ 17.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove 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 showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause of and effect showing that the vaccination was

> the reason for the injury [,]" the logical sequence being supported by a "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for hepatitis B vaccine, K.A. would not have chronic recurrent urticarial (assuming he has that condition), but also that hepatitis B vaccine was a substantial factor in causing his chronic recurrent urticarial (assuming he has that condition). Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Vaccine Act, 42 U.S.C. § 300aa-13(a)(1), prohibits the undersigned from ruling for petitioner based solely on her allegations unsubstantiated by medical records or medical opinion. The medical records do not support petitioner's allegations.

The Federal Circuit in Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006), emphasized that the special masters are to evaluate seriously the opinions of petitioner's treating doctors since "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." See also Broekelschen v. Sec'y of HHS, 618 F.3d 1339, 1347 (Fed. Cir. 2010); Andreu v. Sec'y of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009). None of K.A.'s treating physicians supports petitioner's allegation that K.A. had a vaccine injury lasting more than six months.

The Vaccine Act requires that if someone has a vaccine reaction, it must last more than six months. 42 U.S.C. § 300aa-11(c)(1)(D)(i). Even if petitioner were to prove that the third hepatitis B vaccination caused K.A.'s initial intermittent rashes and a rash one month later, petitioner would still not prevail because of the absence of evidence that K.A.'s alleged vaccine reaction lasted more than six months.

Petitioner has not filed a medical expert opinion in support of her allegations even though the undersigned gave petitioner from October 12, 2017 until April 3, 2018 (almost six months) to do so.

Petitioner orally moved for a ruling on the record during a telephonic status conference on April 3, 2018.

The undersigned **GRANTS** petitioner's motion and **DISMISSES** this petition.

CONCLUSION

The petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment herewith.[4]

IT IS SO ORDERED.

Dated: April 3, 2018

/s/ Laura D. Millman
Laura D. Millman
Special Master

[4] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.