In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-729V
Filed: April 11, 2011

JARROD RICKARD and JENNIFER THOMPSON, legal representatives of A minor child, ALLIE ANN RICKARD, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED Summary Judgment; Entitlement; Cause in fact; Althen; DTaP; IPV; Hib; PCV

Travis L. Holtrey, Caslin, Cecil & Holtrey, Owensboro, KY, for Petitioners.
Althea W. Davis, U.S. Dep't of Justice, Washington, DC, for Respondent.

LORD, Special Master.

DECISION[1]

I. INTRODUCTION AND SUMMARY

Petitioners Jarrod Rickard and Jennifer Thompson (Petitioners) filed this case under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. § 300aa-10 et seq., on behalf of their daughter, Allie Rickard (Allie).[2] Petitioners alleged that vaccinations Allie received on December 29, 2008, caused her to suffer an encephalopathy and seizure disorder. Respondent has moved for summary judgment on the ground that, when viewing the facts in the light most favorable to Petitioners, Petitioners have presented insufficient evidence on any of the three, required elements of causation. See Vaccine Rule 8(d); Althen v. Sec'y of Dep't of Health &

[1] The undersigned intends to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rule 18(b). Otherwise, the entire ruling will be available to the public. Id.

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. § 300aa-10 et seq. (2006). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Petitioners were afforded opportunities to supplement the record but declined to do so.

Vaccine Rule 8(d) provides: "The special master may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgment, in which event the procedures set forth in RCFC 56 will apply." Under RCFC 56, summary judgment is appropriate where there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law.

Summary judgment is granted here because the record as a whole does not permit a reasonable finder of fact to award compensation to Petitioners. Considering all the evidence, including the opinion of Petitioners' expert, and making all inferences in favor of Petitioners, there are no genuine issues of material fact concerning the legal requirements for establishing entitlement to compensation. Petitioners' evidence, including the medical records and the letter from Allie's treating physician, is insufficient to satisfy the three elements necessary to establish causation-in-fact under Althen. In addition, Petitioners' evidence does not show that Allie suffered an injury set forth in the Vaccine Injury Table. See § 11(c)(1)(C); 42 C.F.R. §100.3(b)(2) (Vaccine Injury Table).[3] Accordingly, Respondent is entitled to judgment as a matter of law.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Procedural Background

Petitioners filed their original petition on October 27, 2009. In response, Respondent filed a Rule 4(c) Report stating that the medical records were insufficient to prove causation and that Petitioners had not offered the opinion of a medical expert to present "a reputable medical or scientific theory" supporting vaccine causation. Rule 4(c) Report at 11.

Following a status conference on March 5, 2010, Petitioners were ordered to file an expert report on or before June 4, 2010; Respondent was ordered to file her expert report on or before September 2, 2010. Order, Mar. 8, 2010. [4]

On June 3, 2010, Petitioners' filed a document entitled "Supplemental Petition and Disclosure of Expert." The Supplemental Petition identified Vinay Puri, M.D., a pediatric neurologist who treated Allie at the University of Louisville Kosair Children's Hospital, as

[3] Petitioners have not alleged a Table Injury, but that possibility has been examined in an effort to determine whether there is any theory on which their claim could succeed.

[4] Vaccine Rule 6 authorizes a special master to convene informal status conferences on a periodic basis. The special master will determine the format for taking evidence based on the specific circumstances of each case. Vaccine Rule 8(a). Section 12(d)(3)(B) of the Vaccine Act, states in pertinent part that in conducting a proceeding on a petition, a special master --

> (i) may require such evidence as may be reasonable and necessary,
> (ii) may require the submission of such information as may be reasonable and necessary,
> (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,
> (iv) shall afford all interested persons an opportunity to submit relevant written information [relating to matters involving the petition], and
> (v) may conduct such hearings as may be reasonable and necessary.

Petitioners' expert, and referred to Petitioners' Exhibits 18 to 20 as "supporting [Dr. Puri's] position on terminating further vaccinations using the Pertussis vaccine." Suppl. Pet. at 2. One of those exhibits was a letter from Dr. Puri describing Allie's vaccinations and seizures. See Petr.'s Ex. 19.

Along with the Supplemental Petition, Petitioners filed additional medical records and information concerning Allie's treatment, including the Supplemental Affidavit of Allie's mother, Jennifer Thompson (Suppl. Aff.), to "clarify" her earlier Affidavit "concerning the initial symptoms leading up to Allie's hospitalization on January 20, 2009." Thompson Suppl. Aff at ¶3 (May 5, 2010) (Petr.'s Ex. 21).

On October 6, 2010, Petitioners filed a "Notice of Submission of Case," in which they stated they would "not be further supplementing the previous opinions of the treating physician and expert, Dr. Puri, nor will Petitioners file any additional medical proof or other evidence." Notice of Submission at 1. The notice stated further that "this case is ripe for a determination by [the special master] in order that this claim may proceed to a proper adjudication." Id.

During a status conference on October 22, 2010, the Notice of Submission and the sufficiency of the evidence on causation was discussed with the parties. Counsel for Petitioners reiterated that no additional information would be forthcoming from Dr. Puri. I indicated agreement with the Secretary that the evidence appeared to be insufficient to establish entitlement to compensation. Accordingly, Respondent was ordered to file a motion for summary judgment on or before November 22, 2010, with Petitioners to file a response within 30 days and Respondent to file a reply, if any, 15 days thereafter. Order, Oct. 22, 2010.

B. Medical History

The pertinent facts are basically undisputed. See Petr.'s Resp. to Mot. Summ. J. ("Summ. J. Resp.") at 2 (Dec. 21, 2010) ("Petitioners for the most part agree with the 'Summary of Facts' as provided in Respondent's Motion"). With certain emendations concerning the onset of Allie's seizures (which are not pertinent to this decision granting summary judgment for Respondent), Petitioners "adopted" the Respondent's factual summary. Id.

Allie was born on July 29, 2008, and her newborn screening tests were normal. Petr.'s Ex. 2 at 15; Petr.'s Ex. 3 at 11-15. She received a Hepatitis B (Hep B) vaccination on July 30, 2008. Petr.'s Ex. 3 at 12, 16.

On October 6, 2008, Allie had a checkup at Pediatric Partners, where she received her first Diphtheria-Tetanus-acellular Pertussis (DTaP), pneumococcal conjugate (PCV) (Prevnar), inactivated poliovirus (IPV), and haemophilus influenzae type-B (HIB) vaccinations along with her second Hep B vaccination. Summ. J. Resp. at 2; Petr.'s Ex. 4 at 50.

On December 29, 2008, Allie, age five months, was seen for a routine checkup at Pediatric Partners. Petr.'s Ex. 4 at 49. She was reportedly laughing, rolling front to back, following 180 degrees, and reaching for toys. Id. At that visit, she received her second DTaP, IPV, HIB, and PCV vaccinations. Id. at 49-50. Petitioner alleged that one or a combination of these vaccinations caused her injury.

According to Jennifer Thompson's affidavit, "On January 4, 2009, my family and I noticed an unusual mild shaking of Allie's right hand while tapping her fingers, accompanied by what appeared to be a brief unusual staring of her eyes. This was the first appearance of what

we would consider different behavior that we observed during her waking hours to this time." Thompson Aff. at ¶6. In her Supplemental Affidavit, Ms. Thompson clarified that Allie's symptoms were observed "a couple of times before Sunday, January 4, 2009, when we were at a family gathering." Suppl. Aff. at ¶4. The symptoms observed "consisted of very rapid finger tapping and jerking of her hand. . . . There was also some twitching that accompanied the symptoms, along with brief unusual staring of her eyes." Id. Ms. Thompson reported calling the office of Allie's primary care physician, Dr. John Houston, on January 12, 2009, and was instructed that "There was no alarm and only minor concern . . . ." Id. at ¶5.[5]

The Supplemental Affidavit continued, "There were future occurrences, although I can't give an exact number or frequency." Id. at ¶6. Allie's family noted that these symptoms were "consistently continuing and mildly increasing in frequency." It was only after consulting Dr. Puri, however, that they understood the importance of the symptoms "as early neurological signs." Id. Ms. Thompson further recounted that on January 30, 2009, Allie was admitted to the emergency room "as a result of violent seizure-type activity which included vigorous shaking of her right arm, tapping of her fingers and abnormal movement of her head and eyes, and her head dropped to the table." Id. at ¶7.

As documented in the medical records, on January 30, 2009, Allie was taken to the emergency room for complaints of seizure activity that had begun twenty minutes before her arrival there. Petr.'s Ex. 7 at 17, 28. Allie's mother reported "episodes of jerking . . . loss of eye contact x 20 second more frequent over past month." Id. at 19.[6] The nursing admission assessment noted that the "guardian/patient statement of problem" as "seizure" and indicated that Allie "has had approx 10 in month but has not been seen." Id. at 28. A slight fever (99.8) was noted. Id. at 28.

Allie was admitted to a short stay unit for observation with a diagnosis of "convulsive disorder." Id. at 5, 18. According to the medical records, Allie was not postictal, was eating well, and had no fever. Id. at 5. Her doctor observed Allie jerking her right arm while remaining aware and alert. Id. at 5. A CT scan revealed no acute intracranial process, but an EEG was abnormal, "suggesting underlying tendency for seizures." Id. at 25-26. An MRI in six months was advised. Id. at 6. Allie was discharged the same day without anti-seizure medication, pending recurrence and the results of the EEG. Id. at 5-6.

On February 3, 2009, Allie was seen in the emergency room of Kosair Children's Hospital with a complaint of seizures involving her whole body. Petr.'s Ex. 8 at 48-49. The admission records stated that Allie had her first seizure on January 4, 2009, and her next seizure on January 30, 2009. Id. at 2.[7] While hospitalized, she was started on anticonvulsant

[5] For the purpose of deciding this motion for summary judgment, I accept as true the facts alleged in Ms. Thompson's Supplemental Affidavit.

[6] During the hospital admission, Allie's parents reported that she had been experiencing "this kind of twitching of the arms for a while since she was almost 2-months old." Petr.'s Ex. 7 at 5. Because the episode on January 30, 2009, was "prolonged" and "more intense," Petitioners decided to seek medical attention. According the same record, Allie had been "doing this since she was 5-weeks-old but more often . . . since the last couple of days." Id.

[7] Significant discrepancies appear in the various accounts of the onset of Allie's seizures. The exact timing and description of the seizures are not at issue with respect to this decision, however. Even accepting the facts as alleged by Petitioners in their Response and drawing all permissible inferences in

therapy (Keppra). Id. at 5. An EEG that day was normal. Id. at 6. An MRI taken on February 4, 2009, was normal, except for some positional plagiocephaly and non-specific sinus and mastoid disease, due either to inflammation or congestion. Id. at 8.[8] Allie was discharged on February 4, 2009, with instructions to continue taking Keppra and to follow up with pediatric neurologist Darren Farber, D.O. Id. at 16.

On February 13, 2009, Allie saw Dr. Farber. See Petr.'s Ex. 9 at 39. Dr. Farber's records noted the onset of seizure on January 4, 2009, and stated that by February 3, 2009, Allie had experienced 10 seizures. Id. at 39. Her seizures continued despite adjustments of her anticonvulsant medication. Id. Dr. Faber noted diagnoses of (1) focal epilepsy with complex partial seizure on the right side; (2) macrocephaly with prominence of subarachnoid spaces; and (3) mild hemiparesis noted on the right side. Id. at 41.

On March 4, 2009, due to increasing seizure frequency and intensity, Allie was taken to the emergency room where she was treated by Dr. Puri. Petr.'s Ex. 10 at 2. She had an extensive metabolic workup and a lumbar puncture, among other laboratory studies. Id. at 10, 13, 34. Allie's medication was adjusted, and she was discharged on March 6, 2009. Id. at 34.

Allie was seen by Dr. Puri on April 7, 2009. Petr.'s Ex. 9 at 27. At that visit, Dr. Puri diagnosed Allie with "a mild cerebral hypotonia, the etiology of which is not defined," refractory epilepsy, and global developmental delay. Id. at 28.

On May 12, 2009, Dr. Puri saw Allie for daily episodes of repetitive "head dropping" occurring over a two minute time period. Id. at 17. Dr. Puri's notes from that visit, under "Diagnoses/Discussion," stated that Allie suffered from "refractory epilepsy of unknown etiology." Id. at 19. Allie's seizures had become more generalized atonic myoclonic seizures. Id. Dr. Puri again noted that the etiology of Allie's seizures was unknown and recorded that she might be suffering from Rasmussen's encephalitis or infantile spasms. Id.[9]

Allie was admitted to Kosair for a scheduled observation on May 18, 2009. Petr.'s Ex. 13 at 9; Petr.'s Ex. 9 at 19. The history of her illness was described as, "Initial seizure after Tdap vaccine at age 5 months, hand tapping." Petr.'s Ex. 13 at 9. The same document noted that Allie had no immunizations "after 4 months." Id. She was treated with IV steroids and Zantac. Id. at 12. A video EEG was abnormal, but it showed no features of hypsarrhythmia. Id. at 8.[10] A brain MRI without contrast was normal, except for continuing postural plagiocephaly. Id. at 4-5, 12. The EEG and MRI were described as inconclusive, and doctors were to continue following her. Id. at 12. Allie was to continue with her Keppra. Id.

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their favor, I do not find evidence in the record to prove a Table injury or actual causation under Althen. In other words, the discrepant facts are immaterial.

[8] Plagiocephaly is an asymmetric condition of the head, resulting from irregular closure of the cranial sutures. Dorland's Illustrated Medical Dictionary (31st ed. 2007) at 1473. Mastoid disease, or mastoiditis, is the inflammation around the mastoid bone near the ear, sometimes a result of otitis media (ear infection). Id. at 1128, 1543.

[9] Rasmussen's encephalitis is a rare form of chronic encephalitis characterized by "intractable focal epilepsy in association with a progressive hemiparesis." Allan H. Ropper & Martin A. Samuels, Adams and Victor's Principles of Neurology, 323 (9th ed. 2009).

[10] Hypsarrythmia is a brain wave abnormality, characterized by random high voltage spikes, that is commonly associated with infantile spasms. Dorland's at 921, 1713.

On June 29, 2009, Allie visited Dr. Puri as a follow up after her hospitalization. In response to her treatment with IV steroids, Allie initially had one seizure per day for a week and then was seizure free. Petr.'s Ex. 9 at 5. She continued to improve and was weaned from anti-seizure medication, but abnormal eye movements were reported. Id. If she continued to experience eye deviations or seizure activity, treatment with steroids was planned. Id. at 7. Allie was to return for a follow-up visit to Dr. Puri in three months. Id. at 8.

A physical therapy note, dated July 6, 2009, stated that Allie had been seizure-free for about seven weeks but suffered persistent motor delays requiring continued physical therapy. Petr.'s Ex. 11 at 12-14.

Allie had a well-child checkup on July 13, 2009. Her pediatrician assessed her with a three-month delay in development. Petr.'s Ex. 4 at 5. The record of that visit noted, "no vacc per L'ville [Louisville?] doc for now." Id.

On August 31, 2009, Dr. Puri saw Allie for her follow-up visit. Dr. Puri noted that Allie's development was improving. Petr.'s Ex. 17 at 4. He listed her diagnoses as global developmental delay, steroid-responsive epileptic encephalopathy, and mild sensory integration disorder. Id. at 5. Allie saw Dr. Puri again on March 8, 2010. Id. at 1. Dr. Puri instructed that Allie should not receive any pertussis vaccinations. Petr.'s Ex. 18.

C. Dr. Puri's Letter

Petitioners filed a letter from Dr. Puri to Petitioners' counsel dated April 23, 2010. The letter was "in response to [Petitioners' attorney's] question dated 3/9/2010," Petr.'s Ex. 19, but the question does not appear in the record. The substantive content of the letter reads:

> Allie Rickard is a now about 1-year-9-month-old who was last seen in my office in March 2010.
>
> My understanding is that Allie started having seizures on January 4, 2009. She had received a series of vaccinations on 12/29/2008. It would appear that there was some sort of a temporal relationship between the vaccinations including a pertussis vaccination and her seizures. There is a possibility that the series of vaccinations that she had could have unmasked her underlying propensity towards seizures also.
>
> In March of 2009 when I recommended to Jennifer Thompson (mother) and Jarrod Rickard (father) that Allie not receive pertussis vaccination in the future, it was based on my standard practice that in infants with severe epilepsies I prefer that they not get pertussis vaccination.
>
> If I can offer any further clarification in this regard, do not hesitate to contact me.

Petr.'s Ex. 19.

D. Petitioners' Claims

Apart from the emendations concerning onset and the Supplemental Affidavit submitted by Ms. Thompson, the Supplemental Petition contained no new allegations. In their original

Petition, Petitioners claimed that Allie received the following vaccines on December 29, 2008: DTaP, IPV, HIB, and PCV. Pet. at 1. Six days later, on January 4, 2009, Allie began suffering "multiple and escalating seizure type symptoms, including right side jerking lasting generally from a few seconds to one and a half (1.5) minutes," which were "caused in fact" by the vaccinations. Id.[11]

The Petition alleged that Allie "had her first seizure type symptom, demonstrated by mild right hand shaking and finger tapping movements, accompanied by unusual eye and head movements" on January 4, 2009. Id. at 2. On January 30, 2009, Allie was admitted to the emergency room for "vigorous seizure type symptoms." Id. Allie continued with regular treatments and evaluation for ongoing seizures. Id.

Petitioners contended that Allie had an encephalopathy and a seizure disorder that were caused-in-fact by the vaccinations she received on December 29, 2008. Id. "The best indication of this correlation is evidenced by Dr. John Houston's note from Dr. Vinay Puri advising there shall be 'no vaccinations per L-ville doc for now,'" the Petition stated. Id. (citing Petr.'s Ex. 4 at 5). Petitioners also contended that Allie's developmental delay was a sequela of her brain injury and ongoing seizures. Pet. at 2.

E. Motion for Summary Judgment and Response

1. Respondent's Motion for Summary Judgment

In her Motion for Summary Judgment, the Secretary argued that Petitioners must prove causation-in-fact, because Petitioners alleged the onset of Allie's injuries was six days after the vaccinations in question -- too long after vaccination to satisfy the requirements of the Vaccine Injury Table. Respt.'s Mot. Summ. J. at 9-10 & 10 n.4. Thus, no compensation would be available under the vaccine injury Table.[12]

The Secretary maintained further that Allie's medical records do not support Petitioners' claim of causation-in-fact because Dr. Puri's opinion falls short of meeting the substantive legal requirements under Althen. Respt.'s Mot. Summ. J. at 10. The Secretary asserted, "Dr. Puri relies solely on a purported temporal association to impute causation, but fails to establish what

[11] As noted above, the Supplemental Petition alleged that Allie's symptoms were first documented on January 4, 2009, but had been observed earlier. See supra. Again, the exact date of onset is not material to this decision.

[12] The only Table injury for which compensation could be available in Allie's case is encephalopathy resulting within 72 hours of DTaP vaccination. See Respt.'s Mot. Summ. J. at 10 n.4; see also 42 C.F.R. §100.3(b)(2) (defining encephalopathy). As noted above, there is a question concerning the date of onset of Allie's neurological symptoms. Even assuming, as I do for the purposes of deciding this motion, that the early seizure symptoms described -- e.g., finger tapping, hand jerking, twitching, "brief" staring -- began within 72 hours after vaccination, Petitioners would be unable to establish a Table encephalopathy. Under the Secretary's Qualifications and Aids to Interpretation ("QAI") for children less than 18 months of age (like Allie), an acute encephalopathy is evidenced by a "significantly decreased level of consciousness" persisting for more than 24 hours and which cannot be attributed to a postictal state. § 100.3(b)(2)(i)(A). The evidence in the record would not, as a matter of law, sustain a finding that Allie suffered symptoms of an acute encephalopathy, as defined by the Secretary, within 72 hours after her December 2008 vaccinations. See Raj v. Sec'y of Dep't of Health & Human Servs., No. 96-294V, 2001 WL 963984, *6 (Fed. Cl. Spec. Mstr. July 31, 2001) (finding that seizures and hospitalization were not enough to meet Table definition of encephalopathy).

the appropriate temporal association is . . . ." Id. at 10-11. The Secretary noted that Dr. Puri did not offer any opinion concerning the allegation of a vaccine-induced encephalopathy, and did not "offer a medical theory or logical sequence of cause and effect linking Allie's symptoms to her seizure disorder." Id. The Secretary characterized as "conjecture" Dr. Puri's statement that Allie's vaccination may have "unmasked" her underlying seizure disorder, saying it was not supported by a sound and reliable medical or scientific explanation. Id.

2. Petitioners' Response in Opposition

In their Response to Motion for Summary Judgment, Petitioners recounted that their original Petition was filed on October 27, 2009, and at a status conference on March 5, 2010, Petitioners were asked to provide additional medical records that had been requested by the Secretary, and also to "supplement the petition with supported expert witness opinion." Summ. J. Resp. at 1. The requested documents were filed on June 3, 2010, but Petitioners sought and were granted an enlargement to supplement "the opinions of expert witness and treating physician, Dr. Puri." Id. On October 6, 2010, Petitioners filed a "notice of submission advising no further proof would be filed in support of petitioners' claim." Id. at 1-2. Petitioners agreed to have the matter decided on a motion for summary judgment. See id. at 2; Order, Oct. 22, 2010.

As stated above, Petitioners essentially agreed with the "Summary of Facts" presented in Respondent's Motion. In their argument, they stated that Vaccine Rule 8 does not permit fact finding on a motion for summary judgment. Summ. J. Resp. at 2 (citing Jay v. Sec'y Dep't of Health & Human Servs., 998 F.2d 979, 982-83 (Fed. Cir. 1992)). Petitioners further stated that "all justifiable inferences are to be drawn in the favor of the non-movant." Summ. J. Resp. at 2.

Petitioners asserted that no "certain diagnosis" ever has been reached in Allie's case. Id. at 3. "[T]he lack of any certain diagnosis seems to substantiate the fact that there is a causal relationship between the vaccinations of December 29, 2008 and the seizure disorder suffered by Allie." Id.

Petitioners agreed that the three-part Althen test was applicable here. Id. Petitioners argued that if all inferences were drawn in Petitioners' favor, summary judgment would be precluded because: (1) Dr. Puri "order[ed] all further pertussis vaccinations be withheld;" (2) Dr. Puri "believe[d] the vaccinations possibly unmasked an underlying propensity to seizures;" and (3) Dr. Puri "state[d] unequivocally that it appear[ed] there [was] a temporal relationship between the vaccinations and the seizures." Id. According to Petitioners:

> [T]his evidence rises above mere speculation and satisfies the burden necessary to avoid a summary judgment and further entitles the petitioner to a determination of the facts of the case and her entitlement to compensation under the National Vaccine Injury Compensation Program.

Id.[13]

[13] Petitioners appear to misapprehend the procedures governing summary judgment. The proper question on summary judgment is "not whether there is literally no evidence but whether there is any upon which a fact finder could properly proceed to find a verdict for the party producing it, upon whom the onus of proof is imposed." Anderson v. Liberty Lobby, Inc., 447 U.S. 242, 251 (1986). Petitioners must present evidence at this stage of the proceedings that is sufficient to permit a decision in their favor. See RCFC 56(e)(2); discussion infra.

In concluding their argument, Petitioners asked and answered a series of rhetorical questions. They pointed to the three prongs of Althen and asserted that prong 1 was satisfied by Dr. Puri's opinion "that the vaccinations possibly unmasked an underlying propensity to seizure activity;" prong 2 was satisfied by Dr. Puri's "professional and expert decision to discontinue all future pertussis vaccinations because logic told him there was a cause and effect relationship here;" and prong 3 was satisfied because "Dr. Puri state[d] unequivocally that it appear[ed] there [was] a temporal relationship between the vaccinations and the seizures." Summ. J. Resp. at 4. Petitioners maintained that they "should survive summary judgment and be given the opportunity to present the resulting damages for consideration of compensation."[14]

III. DISCUSSION

A. Summary Judgment

Summary judgment "is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules . . . which are designed 'to secure the just, speedy and inexpensive determination of every action.'" Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986) (citations omitted). "One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses." Id. at 323-24. These goals are consistent with the purposes of the Vaccine Act. § 12(d)(2) (Rules should provide for expeditious and informal proceedings and provide for limitations on discovery). Indeed, Congress specifically mandated that the Vaccine Rules "include the opportunity for summary judgment." § 12(d)(2)(C).

Vaccine Rule 8 instructs the special master to use the procedures set forth in RCFC 56 in evaluating a motion for summary judgment. RCFC 56(c) provides:

> (1) In General. A motion for summary judgment should be granted if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.

Further, RCFC 56(e)(2) provides:

> Opposing Party's Obligation to Respond. When a motion for summary judgment is properly made and supported, an opposing party may not rely merely on allegations or denials in its own pleading; rather its response must -- by affidavits or otherwise provided in this rule -- set out specific facts showing a genuine issue for trial.

These rules comport with federal law concerning summary judgment. See Jay, 998 F.2d at 983 ("in vaccine cases, as in other cases, summary judgment is summary judgment").

When ruling on summary judgment, "'The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.'" Jay, 998 F.2d at 982 (quoting Anderson v. Liberty Lobby, Inc., 447 U.S. 242, 255 (1986)); see also Crown Operations Int'l,

[14] Petitioners seemed to contend that they should be awarded judgment as a matter of law on the issue of entitlement. No cross-motion for summary judgment was filed, however. Accordingly, that issue is not before me.

Ltd. v. Solutia, Inc., 289 F.3d 1367, 1375 (Fed. Cir. 2002) (patent case). The inquiry is whether the evidence presents a sufficient disagreement of fact to require submission to the factfinder or whether it is "'so one-sided that one party must prevail as a matter of law.'" Jay, 998 F.2d at 982 (quoting Anderson, 447 U.S. at 255). "There is no genuine issue of material fact where the evidence present is insufficient to permit a reasonable factfinder to find in favor of the nonmoving party. Jay, 998 F.2d at 982; see also Crown, 289 F.3d at 1375 (same).

A party opposing summary judgment may not rest on the pleadings alone. Once the moving party has discharged its burden by showing "that there is an absence of evidence to support" the case, the nonmoving party must then "go beyond the pleadings and . . . designate 'specific facts showing that there is a genuine issue for trial.'" Celotex, 477 U.S. at 324-25 (quoting Fed. R. Civ. P. 56(e)); accord, e.g., Anderson, 477 U.S. at 257 ("the plaintiff must present affirmative evidence in order to defeat a properly supported motion for summary judgment"). In the absence of such facts, summary judgment may be entered "so long as the losing party was on notice that she had to come forward with all of her evidence." Celotex, 477 U.S. at 326.

B. Substantive Requirements for Proving Causation-in-Fact

"[T]he determination of whether a given factual dispute requires submission to a jury must be guided by the substantive evidentiary standards that apply to the case." Anderson, 477 U.S. at 255. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." Id. at 248. "[I]t is the substantive law's identification of which facts are critical and which facts are irrelevant that governs." Id.

The substantive law governing causation-in-fact under the Vaccine Act requires Petitioners to prove three elements: (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 proximate temporal relationship between vaccination and injury. Althen, 418 F.3d at 1278. These substantive requirements guide the decision whether to grant summary judgment.

Further, the Vaccine Act states that compensation shall be awarded if the special master or court finds "on the record as a whole" that "the petitioner has demonstrated by a preponderance of the evidence" the matters required to establishment entitlement. § 13(a)(1)(A). "The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Id. Thus, to grant summary judgment for the Respondent, I must examine "as a whole" the medical records and the medical opinion submitted by Dr. Puri to determine whether there is evidence which, if believed, would permit a reasonable fact finder to conclude that the elements of causation were proven here, by a preponderance of the evidence.[15] In this case, Petitioners have not come

[15] Since a petition for compensation under the Vaccine Act case is not "a run-of-the-mill civil case," see Anderson, 477 U.S. at 252, but one in which "close calls" go to the petitioner, I also bear in mind the case law establishing that special masters are to be generous in deciding vaccine injury cases. If this decision were a "close" one, I would deny the motion and allow the case to proceed to hearing. See Capizzano v. Sec'y of Dep't of Health & Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006).

forward with evidence sufficient to create a genuine issue of material fact for hearing. § 13(a)(1)(A); RCFC 56(e)(2).[16]

C. Analysis

Review of the medical record discloses no medical or scientific theory concerning possible vaccine causation. Accordingly, Petitioners must establish such a theory through the opinion of their expert and Allie's treating neurologist, Dr. Puri.

Dr. Puri's letter does not actually state an opinion concerning vaccine causation. The letter therefore presents two distinct issues. The first is whether the letter constitutes an expert opinion supporting Petitioners' allegations of vaccine causation, as required by § 13(a)(1)(A). Assuming it does, the second issue is whether the letter contains enough evidence to permit Petitioners' case to proceed in light of the Althen criteria.

As to the first issue, Dr. Puri's letter does not present an opinion that Allie suffered a vaccine injury. Dr. Puri stated that there appeared to be "some sort of a temporal relationship" and that there was "a possibility that the series of vaccinations the she had could have unmasked her underlying propensity towards seizures also." Petr.'s Ex. 19. Although the letter was fashioned as a "response" to a question from counsel, the question asked by counsel was not recorded. If Dr. Puri was asked if he would provide an opinion that vaccinations in fact caused Allie's injury, that is not reflected in his letter. The letter on its face does not indicate that Dr. Puri did believe vaccinations caused Allie's condition. The very guarded statements actually made by Dr. Puri indicate the contrary. Thus, quite apart from the Althen criteria, the corroboration of Petitioners' allegations required by § 13(a)(1)(A) is missing.

Accordingly, I could grant Respondent's motion based on a complete failure of proof to support Petitioners' allegations. I do not decide the motion solely on that basis, however, because the case is even clearer that Dr. Puri's letter fails to satisfy the three Althen criteria.[17]

Althen Prong 1

Proof of actual causation "'must be supported by a sound and reliable medical or scientific explanation'" that pertains specifically to the petitioner's case. Moberly v. Sec'y of Dep't of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (citing and quoting Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)).

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[16] The insufficiency of the evidence was pointed out to Petitioners on several occasions, and they were afforded ample opportunity to supplement the record.

[17] As noted above, the medical records from Allie's hospital admission on January 31, 2009, stated that, "According to the parents the patient was having this kind of twitching of the arms for a while since she was almost 2-months-old." See Petr.'s Ex. 4 at 44. This record would date the onset of her seizures some two months before the vaccinations in question and preclude a finding of direct causation. See Shalala v. Whitecotton, 514 U.S. 268, 274 (1995) (interpreting the statutory requirements for proving a Table Injury). Petitioners have not alleged significant aggravation of a pre-existing disorder. See § 11(c)(1)(C)(ii)(I). Even if significant aggravation were alleged, the evidence would not suffice to prove the causation elements under that theory. See Loving v. Sec'y of Dep't of Health & Human Servs., 86 Fed. Cl. 135, 144 (2009) (petitioners must prove the significant aggravation was caused by vaccination, under the Althen test). Because the Petition fails under either theory, it is unnecessary to resolve the factual question as to date of onset.

Under Althen prong 1, a petitioner must set forth a biologically plausible theory explaining how the vaccine received by the petitioner could cause the injury complained of. See, e.g., Andreu v. Sec'y of Dep't of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009). This requirement has been interpreted as "can the vaccine(s) at issue cause the type of injury alleged?" Pafford v. Sec'y of Dep't of Health & Human Servs., 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Evidence should be viewed by the preponderance of the evidence standard and "not through the lens of the laboratorian." Andreu, 569 F.3d at 1380. Although the theory of causation need not be corroborated by medical literature or epidemiological evidence, the theory must be sound, reliable, and reputable -- in other words, the theory need not be scientifically certain, but it must have a scientific basis. See id. at 1379-80.

In evaluating whether a petitioner has presented a legally probable medical theory, "the special master is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly, 592 F.3d at 1324. A special master is not required to rely on a speculative opinion that "'is connected to existing data only by the ipse dixit of the expert.'" Snyder v. Sec'y of Dep't of Health & Human Servs., 88 Fed. Cl. 706, 745 n.66 (2009) (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)).

Petitioners rely on the following statement in Dr. Puri's letter to satisfy prong 1:

> My understanding is that Allie started having seizures on January 4, 2009. She had received a series of vaccinations on 12/29/2008. It would appear that there was some sort of a temporal relationship between the vaccinations including a pertussis vaccination and her seizures. There is a possibility that the series of vaccinations that she had could have unmasked her underlying propensity towards seizures also.

Petr.'s Ex. 19 (emphasis added).

Construed in the light most favorable to Petitioners, Dr. Puri's opinion is that the vaccination may have triggered a seizure in a child who was disposed to have seizures, for an unknown reason. This is not evidence that will defeat the motion for summary judgment. Dr. Puri's letter presented no biological theory of vaccine causation, as required by the case law. Nor did his letter present or refer to any medical or scientific evidence to support the reliability of such a theory. Dr. Puri's ipse dixit is insufficient, as a matter of law, to establish entitlement, under the Vaccine Act as well as Rule 56. "[I]t is well settled that an expert's unsupported conclusion on the ultimate issue [to be determined] is insufficient to raise a genuine issue of material fact." Arthur A. Collins, Inc. v. Northern Telecom Ltd., 216 F.3d 1042, 1046 (Fed. Cir. 2000) (patent case); Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1329 (Fed. Cir. 2001) ("Broad conclusory statements offered by [the non-moving party's] experts are not evidence and are not sufficient to establish a genuine issue of material fact"); see Moberly, 592 F.3d at 1324 (evidence must pertain specifically to petitioner's case).

Nor can it permissibly be inferred from Dr. Puri's letter that evidence exists in the medical records or scientific literature that would put flesh on the bones of his skeletal statements. Inferences must be drawn from facts. See United States v. Ross, 92 U.S. 281, 283-84 (1875). "Whenever circumstantial evidence is relied upon to prove a fact, the circumstances must be proved, and not themselves presumed." Id. at 284. The law will not permit inferences to be drawn upon inferences, but requires "an open, visible connection between the principal and evidentiary facts and the deductions from them, and does not permit a decision to be made on remote inferences." Id.

To be sure, the limit on what is a permissible inference may not always be clear. This case, however, represents the extreme end of the spectrum. Petitioners ask not only that I infer the medical and scientific evidence from which Dr. Puri might derive an opinion concerning vaccine causation, but that I infer the opinion itself. Petitioners' demands far exceed the proper boundaries within which the finder of fact may be permitted to infer facts not proven, even under the Vaccine Act.

Althen prong 2

The second prong of Althen requires a petitioner to prove "'a logical sequence of cause and effect show[ing] that the vaccination was the reason for the injury.'" Andreu, 569 F.3d at 1374 (quoting Althen). The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." Knudsen, 35 F.3d at 548-49. Under prong 2, petitioners are not required to show "epidemiologic studies, rechallenge, the presence of pathologic markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect . . . ." Capizzano v. Sec'y of Dep't of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second Althen factor. Capizzano, 440 F.3d at 1325-26; Andreu, 569 F.3d at 1375-77 (treating physician testimony).

No evidence in the medical records corroborates Petitioners' allegation of a logical cause and effect between Allie's vaccinations and her seizures. No treating professional documented his or her belief in vaccine causation, and no testimony, in the form of an affidavit or otherwise, from a treating professional has been presented (other than Dr. Puri's letter). The only link between vaccination and injury appears in the medical histories taken on a couple of occasions in connection with Allie's hospital admissions and therapy. See Petr.'s Ex. 13 at 9. These histories are based on information provided by Petitioners, and add no evidentiary support to their allegations. See, e.g., Bailey v. Sec'y of Dep't of Health & Human Servs., No. 06-464V, 2008 WL 482359 (Fed. Cl. Spec. Mstr. Jan. 31, 2008) (discounting testimony "reflecting the patient history that petitioner himself provided to his treaters"); see generally, Cedillo v. Sec'y of Dep't of Health & Human Servs., 617 F.3d 1328, 1348 (Fed. Cir. 2010) (upholding special master's discounting of treaters notations because they indicated awareness of a temporal but not a causal relationship).

The statement in Dr. Puri's letter on which Petitioners rely to establish Althen prong 2:

> In March of 2009 when I recommended to Jennifer Thompson (mother) and Jarrod Rickard (father) that Allie not receive pertussis vaccination in the future, it was based on my standard practice that in infants with severe epilepsies I prefer that they not get pertussis vaccination.

Petr.'s Ex. 19 (emphasis added).

Vaccine Program petitioners frequently introduce statements by treating professionals indicating that further vaccinations should be withheld to bolster evidence of a logical cause and effect between vaccination and injury. Depending on the content and context of such statements, they may support an inference that the treaters believed there was a logical link between vaccination and injury. Compare Andreu, 569 F.3d at 1376 (causation supported by treating doctor's explained, "unequivocal" opinion that the vaccination caused the injury); Moberly, 592 F.3d at 1323, 1325 (causation not supported by doctors who noted temporal association but never asserted causation). It is impossible in this instance, however, to draw

such an inference because Dr. Puri negated it in his own statement. As indicated in the underlined portion of his statement above, Dr. Puri explained that his recommendation against further pertussis vaccinations was based on a "standard practice" concerning children with severe epilepsy. Petr.'s Ex. 19. This explanation -- setting forth a practice general to all his patients with severe epilepsy -- does not indicate that Dr. Puri believed in a cause-and-effect connection between Allie's condition and the vaccines administered in December 2008. The inescapable import of his statement is that he customarily recommends against future vaccinations for all his patients who have serious seizures disorders, and contains no probative evidence -- or even any inference -- concerning the cause of the seizure disorder in Allie's case.

In the context of the record as whole, the only permissible reading of Dr. Puri's letter is that he did not believe there was a cause-and-effect connection between vaccination and seizures. His letter states that Allie had an "underlying" condition that gave rise to Allie's "propensity to seizures." See Petr.'s Ex. 19. The letter identifies no cause for the underlying disorder. The absence of an opinion favoring vaccine causation is confirmed by Dr. Puri's treatment notes, which stated that the etiology of Allie's epilepsy was "unknown." Petr.'s Ex. 9 at 19.

In addition to the letter from Dr. Puri, Petitioners relied on the fact that no "certain diagnosis" ever has been reached in Allie's case. "[T]he lack of any certain diagnosis seems to substantiate the fact that there is a causal relationship between the vaccinations of December 29, 2008 and the seizure disorder suffered by Allie." Summ. J. Resp. at 3. This is simply argument by Petitioners through their counsel. Neither Dr. Puri nor any other medical professional indicated, by differential diagnosis or otherwise, that vaccination caused Allie's seizures. See Moberly, 592 F.3d at 1323 (stating that the simplistic elimination of other causes does not result automatically in causation). Based solely on uncertainty as to the diagnosis, a fact finder could not reasonably conclude that vaccination caused Allie's epilepsy.

Althen prong 3

A temporal relationship between receipt of a vaccine and alleged onset of symptoms, without more, is insufficient to establish a causal relationship in a cause-in-fact case. Grant v. Sec'y of Dep't of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). To establish causation, a petitioner must show that the injury occurred within a time frame that is consistent with the theory of causation set forth. Pafford, 451 F.3d at 1358 (no medically acceptable time frame found under theory that vaccine triggered an autoimmune inflammatory disorder); accord, e.g., de Bazan, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (proximate temporal relationship requires onset that is appropriate "given the medical understanding of the disorder's etiology").

Here, no theory of causation-in-fact has been advanced. Accordingly, a fact finder could not conclude that the time frame between vaccination and Allie's seizures was consistent with the theory propounded. Under settled law, this deficiency in itself precludes Petitioners from establishing cause-in-fact.[18]

Petitioners rely on this statement by Dr. Puri:

[18] As noted above, even assuming that Allie suffered symptoms within 72 hours of her vaccination, there is no evidence to support the allegation that she suffered an encephalopathy as defined in the vaccine injury Table.

> It would appear that there was some sort of a temporal relationship between the vaccinations including a pertussis vaccination and [Allie's] seizures.

Petr.'s Ex. 19 (emphasis added). In every case, there is "some sort of a temporal relationship" between vaccination and injury. Dr. Puri's letter provides no support for the proposition that the temporal association was appropriate in this case under a medically or scientifically reliable theory. In the absence of such support, Petitioners cannot satisfy Althen prong 3, as a matter of law.

IV. CONCLUSION

On the record viewed as a whole, Petitioners have not presented evidence sufficient to permit a reasonable fact finder to conclude that this case is supported by a plausible or reliable theory of causation, a logical cause and effect relationship between vaccination and injury, or an appropriate temporal relationship between vaccination and injury. Accordingly, Respondent's Motion for Summary Judgment is **GRANTED**, and the Petition is **DISMISSED**.

IT IS SO ORDERED.

s/ Dee Lord
Dee Lord
Special Master