

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-1057V

Filed: December 15, 2016

DWIGHT Zahringer, *
On behalf of B.Z., *

Petitioner, *

v. *

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

Respondent. *

UNPUBLISHED

Ruling on the Record;
Vaccine Act Entitlement; Insufficient Proof
of Causation; Measles-mumps-rubella
("MMR") Vaccine

Lawrence Michel, Kennedy, Berkley, et al., Salina, KS, for petitioner.

Heather Pearlman, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON THE RECORD AND DECISION DISMISSING PETITION¹

Roth, Special Master:

On September 22, 2015, Dwight Zahringer ["petitioner" or "Mr. Zahringer"] timely filed a petition for compensation on behalf of his minor child, B.Z., under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² ["Vaccine Act" or "Program"]. The petition alleges that B.Z. suffers from "developmental delays, with the possibility of an underlying demyelinating condition" caused by the measles-mumps-rubella ("MMR")

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in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 (2012)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, I agree that the identified material fits within the requirements of that provision, I will delete such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

vaccination that he received on September 17, 2012. Petition at ¶¶ 2, 11. The petition further alleges that B.Z.'s injuries persisted for more than six months. *Id.* at ¶ 16.

Having reviewed the medical records, I find that they do not support a finding of entitlement for petitioner. Furthermore, a petitioner cannot succeed based solely on his allegations when they are unsupported by medical records or the opinion of a medical expert. 42 U.S.C. § 300aa-11(a)(1). Petitioner failed to provide the opinion of a medical expert which would support his allegations.

On September 14, 2016, petitioner filed for a Motion for a Decision on the Administrative Record. For the reasons stated herein, I find that the petitioner has failed to establish entitlement to an award, thus, the case is dismissed.

I. Procedural History

Mr. Zahringer initially filed his petition on September 22, 2015, as a *pro se* petitioner. Mr. Zahringer stated that B.Z. received MMR, hepatitis, influenza, and pneumococcal conjugate vaccines on September 17, 2012, but only alleged that the MMR was the cause of B.Z.'s injury. Mr. Zahringer also filed nearly 200 pages of medical records with his petition. Petitioner's Exhibits ["Pet. Ex."] 1-2.

This case was assigned to Chief Special Master Dorsey, who issued the initial order on September 30, 2015. This case was reassigned to me on October 28, 2015. Order Reassigning Case, filed Oct. 28, 2015 [ECF No. 8]. An initial status conference was held on November 12, 2015, with Mr. Zahringer appearing *pro se*. Mr. Zahringer was given 60 days to find an attorney and was provided with a list of attorneys who practice in the Vaccine Program. Order, issued Nov. 13, 2015 [ECF No. 13]. Respondent filed a status report requesting that petitioner file an amended petition specifying which vaccine or vaccines petitioner alleges caused B.Z.'s injury and setting forth when the "first symptom or manifestation" of B.Z.'s alleged injury occurred. Respondent's Status Report ["Res. S.R."], filed Nov. 17, 2015 [ECF No. 11], at 1. Respondent's Status Report also noted that upon review of B.Z.'s medical records, B.Z. had been diagnosed with Autism Spectrum Disorder ["ASD"]. I then issued an order requiring petitioner to file an amended petition by no later than April 11, 2016. Order, issued Nov. 19, 2015 [ECF No. 12].

Lawrence Michel, Esq., entered his appearance as petitioner's counsel via a Notice of Appearance on December 1, 2015. Notice, filed Dec. 1, 2015 [ECF No. 13]. A non-pdf order was issued directing Mr. Michel to file a Motion for Substitution of Counsel ["Motion to Substitute"] by December 11, 2015. Order issued Dec. 4, 2015. Mr. Michel filed the Motion to Substitute in as counsel on December 7, 2015. Motion to Substitute, filed Dec. 7, 2015 [ECF No. 14]

Petitioner filed additional medical records in March of 2016. Pet. Ex. 3-13, filed Mar. 31, 2016 [ECF No. 15-24]. Petitioner then filed a motion for extension of time ["MFET"], in order to review B.Z.'s medical records. MFET, filed Apr. 7, 2016 [ECF No. 25]. This motion was granted; petitioner was ordered to file an amended petition by April 25, 2016. Petitioner then filed a second motion for extension of time ["Second MFET"], requesting additional time to

submit his amended petition. Second MFET, filed Apr. 20, 2016 [ECF No. 26]. This motion was granted, and petitioner was ordered to file an amended petition and an expert report by June 27, 2016. Petitioner filed additional medical records on June 6, 2016. Pet. Ex. 17, filed Jun. 6, 2016 [ECF No. 29]. Petitioner filed a third motion for extension of time [“Third MFET”] to submit an amended petition and an expert report. Third MFET, filed Jun. 27, 2016 [ECF No. 30]. This motion was granted, and petitioner was ordered to file an amended petition and an expert report by July 27, 2016. Petitioner filed a fourth motion for extension of time [“Fourth MFET”] to submit an amended petition and an expert report; he also requested a status conference. Fourth MFET, filed July. 25, 2016 [ECF No. 31]. This motion was granted, and a status conference was scheduled for August 16, 2016.

During the status conference on August 16, 2016, petitioner’s attorney “represented that he has been unable to find an expert willing to opine on his client’s behalf.” Order, issued Aug. 17, 2017, at 1-2. Petitioner was ordered to file a motion to dismiss, a motion for a ruling on the record, or a status report by October 3, 2016. Ultimately, petitioner never filed an amended petition or an expert report. However, petitioner did file this motion for a ruling on the record. Motion, filed Sep. 14, 2016 [ECF No. 33]. Respondent filed a response, stating that petitioner had failed to demonstrate entitlement to compensation. Response, filed Sep. 29, 2016 [ECF No. 35]. Petitioner did not file a reply.

This matter is now ripe for decision.

II. Relevant Medical History

B.Z. was born on September 14, 2011, via C-section at 39 weeks. Pet. Ex. 7 at 21. He had APGARS of 9 and 9. *Id.* at 22. On October 14, 2011, B.Z. received the first Tdap vaccination at a well-baby visit. Pet. Ex. 1 at 130. On November 15, 2011, B.Z. received Dtap, IPV, and Hib vaccines at a well-baby visit. *Id.* at 131. On July 9, 2012, B.Z. had a cough and a runny nose; he was diagnosed with left otitis media and prescribed amoxicillin. *Id.* at 135.

On September 17, 2012, B.Z. received the MMR, varicella, hepatitis A, influenza, and Prevnar vaccines; He passed the Denver well child exam and was noted to be “engageable.” Pet. Ex. 1 at 136. It is the MMR vaccination at this visit that petitioner alleges caused B.Z.’s alleged injury.

On October 22, 2012, B.Z. received an influenza immunization. Pet. Ex. 1 at 137. On November 27, 2012, B.Z. presented to the pediatrician with red, crusty eyes; he was diagnosed with conjunctivitis and prescribed amoxicillin. *Id.* at 136. On December 17, 2012, B.Z. presented to the pediatrician for his 15-month well child examination; he received Hib and DTaP vaccines. B.Z. was noted to walk well and say a few words. He passed the Denver well exam. *Id.* at 139.

On January 7, 2013, B.Z. was presented to the pediatrician with complaints of a cough ongoing for two weeks. Pet. Ex. 1 at 140. There was no fever or rhinorrhea. The impression was “chronic coughs;” B.Z. was diagnosed with reactive airway disease. A chest x-ray was performed the same day; it showed “findings compatible with reactive airway disease. No focal

pneumonia.” Pet. Ex. 7 at 103.

On March 18, 2013, B.Z. was presented to the pediatrician for his 18 month well child exam. Pet. Ex. 1 at 141. It was noted that B.Z. passed the Denver well exam and had a cough. It was recommended that B.Z.’s parents “encourage speech.” *Id.*

B.Z. did not visit any medical provider again until September 18, 2013, when he was presented for his two year old well child exam. Pet. Ex. 1 at 142. B.Z. was noted to “say[s] only a few single words,” “plays w/ sis & others,” and “sleeps well, although...nightmares/terrors have occurred.” *Id.*

B.Z. was presented to the pediatrician on October 3, 2013, with complaints of cough, crusty eyes, and touching his ears. Pet. Ex. 1 at 143. He was diagnosed with conjunctivitis and was prescribed mexeta, amoxicillin and supportive care. *Id.*

On October 23, 2013, B.Z. was evaluated at the Educational Assessment Center at Macomb International School [“Macomb”] “due to concerns regarding [B.Z.’s] communication level.” Pet. Ex. 10 at 8. B.Z. was noted to be taking antibiotics for an ear infection. *Id.* An audiology screening was performed “with results suggesting [that B.Z. had] adequate hearing acuity and appropriate tympanometry.” *Id.* at 10. The impression was that B.Z. “qualifies for special education as a child demonstrating an Early Childhood Developmental Delay.” *Id.* at 11. The recommendation was “placement in the Macomb Infant Preschool Program (MIPP) with therapy geared towards” building B.Z.’s communication skills. *Id.*

On March 31, 2014, the Macomb School District ASD (Autism Spectrum Disorder) Teacher Consultant observed B.Z. in his class at Ojibwa Elementary. Pet. Ex. 11 at 5-6. It was noted that the consult was requested because B.Z. had “difficulty with listening, focus, participation, social engagement, and behavior,” and that the teaching team was “looking for additional outside support for strategies.” The teaching team’s concerns were listed as “limited verbal communication, limited response to his name...limited response to what questions and yes/no, limited engagement with peers during unstructured play time...will try to disrobe, difficulty staying in a group or with an activity. Difficulty initiating a task.” *Id.* at 5. The consultant recommended giving B.Z. additional processing time before prompting him, and increasing visual support aids, such as placing “photos on the mirror in the bathroom for the steps of hand washing.” *Id.* at 6. The consultant noted that B.Z. “currently attends ABA [therapy] 6 days a week” and “currently receives speech therapy 2 times a week before and after school.” *Id.*

B.Z. next was presented to the pediatrician on July 1, 2014, with a bloody nose and a cough. Pet. Ex. 1 at 144. He was referred to an ENT.

On July 8, 2014, B.Z. was presented to Michigan Pediatric ENT Associates, complaining of nosebleeds. It was noted that B.Z. “bleeds mainly from the left side and bleeds a lot.” Pet. Ex. 4 at 4. He was also noted to have a speech delay and “prominent blood vessels on anterior of the nasal septum.” *Id.* Bacitracin was recommended.

B.Z. presented to Henry Ford for speech therapy evaluation on August 4, 2014. He was noted to be “alert and cooperative.” Pet. Ex. 7 at 106. The assessment was “Pt with severely decreased auditory comprehension and expressive language skills.” *Id.* The recommendation was “continue with speech therapy per POC.” *Id.*

B.Z. attended speech therapy at Henry Ford twice weekly until December 16, 2014. See Pet. Ex. 7 at 106-127. B.Z.’s discharge summary noted that he “is demonstrating a severe impairment with auditory comprehension skills and ability to use verbal words to communicate.” *Id.* at 127. The reason for discharge was listed as “Pt is taking a break from speech therapy at this time in order to focus upon ABA therapy.” *Id.* at 128. The speech therapist recommended “continuation of speech therapy when his schedule permits.” *Id.*

B.Z. next was presented to the pediatrician on September 19, 2014, for his three year well child exam. Pet. Ex. 1 at 145. B.Z. was noted to be minimally verbal but had made progress in speech at school. He was eating and sleeping well. It was also noted that B.Z. was “scheduled for ASD eval. soon.” *Id.* Finally, it was noted that B.Z. engaged in hand flapping; this was “attributed to vocalization frustration;” he was also “alert, running around room.” *Id.* The impression was “known speech/lang. delay” and “concerns re: ASD.” The recommendation was “FWD HF [Henry Ford] Autism center eval as sched.” *Id.*

On October 15, 2014, B.Z. was presented to Henry Ford “for speech and language evaluation as part of the multidisciplinary autism assessment.” Pet. Ex. 7 at 114. The impression was that B.Z. met “the criteria for Autism Spectrum Disorder. The etiology of the presenting problem is unknown. The prognosis for improvement is good given the appropriate educational services and intensive interventions.” *Id.* at 116. Recommendations included “applied behavioral analysis therapy,” “private speech and language evaluation/treatment,” and “continue with educational placement.” *Id.*

A pediatric occupational therapy evaluation was conducted on November 10, 2014. Pet. Ex. 3 at 73. The impression was that B.Z. had “a diagnosis of unspecified disorder of the central nervous system.” *Id.* at 71. The recommendation was “intense outpatient occupational therapy services.” *Id.*

On November 14, 2014, B.Z. was presented to the Neurology Clinic of Children’s Hospital of Michigan “for a second opinion with regard to his history of developmental delay particularly in speech and recent diagnosis of autism.” Pet. Ex. 2 at 18. The impression was “speech delay, macrocephaly, and autistic features.” *Id.* at 20. A brain MRI was recommended, as well as genetic testing for Fragile X syndrome. *Id.*

No further medical records have been provided.

II. Discussion.

Under the Vaccine Act, petitioner may prevail on his claim by proving a “Table” injury, in which causation is presumed or, alternatively, by proving an “off-Table” injury, in which he identifies a causal link between the vaccine and the injury alleged. Because B.Z. does not meet

the criteria outlined in the Vaccine Injury Table, 42 C.F.R. § 100.3 (2009), petitioner must produce preponderant evidence that a covered vaccine is responsible for B.Z.'s injuries.

A. Legal Standard.

An "off-Table" claim requires that a petitioner establish by preponderant evidence that a covered vaccine caused or significantly aggravated the injury claimed. § 11(c)(1)(C)(ii)(II). Petitioner need not show that the vaccinations were the sole cause, or even the predominant cause, of her condition; showing that the vaccinations were a "substantial factor" and a "but for" cause of her injury are sufficient for recovery. *Shyface v. Sec'y of Health and Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); *see also Pafford v. Sec'y, of Health and Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (petitioner must establish that a vaccination was a substantial factor and that harm would not have occurred in the absence of the vaccination).

The Federal Circuit has set forth three factors petitioners must satisfy to prove causation in off-Table cases. *See Althen v. Sec'y of Health and Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). *Althen* requires that petitioners provide: "(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." 418 F.3d 1274, 1278 (Fed. Cir. 2005). All three *Althen* factors must be satisfied to prevail on an off-Table claim.

The medical theory provided must be a reputable one, although it need only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49. The Supreme Court's opinion in *Daubert v. Merrel Dow Pharmaceuticals, Inc.*, likewise requires that courts determine expert opinions to be reliable before they may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Daubert*, 509 U.S. 579, 590 (1993) (citation omitted). The Federal Circuit has stated that a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly ex rel. Moberly v. Sec'y of Health and Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010).

B. Evaluating Petitioner's Claim.

Under the Vaccine Act, a petitioner may not be awarded compensation based solely on petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physicians. § 300aa-13(a)(1). In this case, because the medical records are insufficient to establish entitlement to compensation, a medical opinion must be offered in support.

B.Z.'s medical records fail to offer any connection between his receipt of the MMR vaccine on September 17, 2012 and later developmental disability, nor do they indicate that he suffered any reaction, injury or illness following his vaccines on September 17, 2012. At his next doctor's visit on October 22, 2012, B.Z. received an influenza vaccine. Pet. Ex. 1 at 137. Thereafter, on December 17, 2012, he was noted to be a well 15 month old and received the Hib and DTaP vaccines. *Id.* at 139. In March of 2013, the first note was made that the parents should

“encourage speech,” yet B.Z. passed the Denver well examination on that date. *Id.* at 141. At his two year old well child visit on September 18, 2013, he was noted to say “only a few words,” “plays w/sis & others,” and “sleeps well, although... nightmares/terrors have occurred.” *Id.* at 142. Though he was examined at the Educational Assessment Center at Macomb International School in October of 2013 for communication concerns, it was not until March of 2014 that he was noted to have “difficulty with listening, focus, participation, social engagement, and behavior,” and that the teaching team was “looking for additional outside support for strategies.” Pet Ex. 1 at 5, Pet. Ex. 11 at 5. Autism spectrum disorder was not a consideration until September of 2014, two years after B.Z. received the MMR vaccine. Pet. Ex. 1 at 145.

On October 15, 2014, when B.Z. presented to Henry Ford “for speech and language evaluation as part of the multidisciplinary autism assessment,” it was noted that the etiology of the presenting problem was unknown. Pet. Ex. 7 at 114. No medical expert report was filed.

Ultimately, petitioner has failed to provide either a sufficient medical opinion or plausible medical theory in support of his claim that the MMR vaccine caused or significantly contributed to B.Z.’s developmental delay or Autism Spectrum disorder. Having failed to establish any of the *Althen* factors by preponderant evidence, petitioner has not demonstrated that he is entitled to compensation.

III. Conclusion.

Constrained by the requirements as set forth in *Althen*, I find that the petitioner herein has failed to produce preponderant evidence that the MMR vaccine is responsible for B.Z.’s condition, and has thus failed to demonstrate entitlement to compensation. **His petition is therefore dismissed. The clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

s/Mindy Michaels Roth
Mindy Michaels Roth
Special Master