In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-777V

Filed: September 7, 2017

HEATHER CARON, *o/b/o and as Next Friend of* A.C., *a Minor*,	*	UNPUBLISHED
Petitioner,	*	Dismissal; Diphtheria-Tetanus-acellular Pertussis ("DTaP"), Polio and Haemophilus Influenza Type B ("IPV/HIB"), Measles-Mumps-Rubella ("MMR"), and Varicella Vaccinations; Chronic Recurrent Multifocal Osteomyelitis ("CRMO"); Insufficient Proof of Causation
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Verne E. Paradie, Jr., Esq., Paradie, Sherman, et al., Lewiston, ME, for petitioner.
Jennifer L. Reynaud, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT[1]

Roth, Special Master:

On July 23, 2015, Heather Caron ("Ms. Caron" or "petitioner") filed a petition for compensation on behalf of her minor child, A.C., under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that the Diphtheria-Tetanus-acellular Pertussis, Polio and Haemophilus Type B ("DTaP-IPV/HIB"), Measles-Mumps-Rubella ("MMR"), and Varicella vaccinations A.C. received on August 2, 2012, caused him to suffer from Chronic

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in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 42 U.S.C. § 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. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Recurrent Multifocal Osteomyelitis ("CRMO"),[3] as well as "chronic episodes of acute otitis media, fever, coughing, leg pain, neck pain, and joint pain, and related symptoms and associated symptoms and deficits." *See* Petition ("Pet."), ECF No. 1.

Petitioner has filed a Motion for Ruling on the Record, ECF No. 39, which also includes a request that the undersigned reconsider the prior ruling in this case determining that the onset of A.C.'s CRMO occurred in January 2013. The request for reconsideration is procedurally improper and has no substantive merit; it is therefore denied. And with respect to the ruling on the record, the undersigned finds that petitioner has failed to carry her burden of showing that the vaccinations A.C. received in August 2012 caused his CRMO. The petition is accordingly dismissed.

I. Medical and Procedural History

A. A.C.'s Health Prior to the Allegedly Causal Vaccinations

A.C. was born on July 18, 2009. The pediatric records indicate that he was born four weeks prematurely, but no prenatal or birth records were filed. A.C. had his first pediatric visit on July 29, 2009, at which time he was noted to be under the care of his aunt and receiving expressed milk due to petitioner having an infection and being hospitalized. He had a history of "weight loss, abnormal," which had improved; he was "d[o]ing well." Pet. Ex. 1 at 3-4.

Between July 29, 2009 and August 2, 2012, when he received the allegedly causal vaccines, A.C. was seen in the pediatrician's office approximately 43 times for various reasons, including congestion, cough, wheezing, ear infections, vomiting, insect bites, and well-child visits. At A.C.'s well-child visits, routine vaccines were administered without adverse event on a modified schedule at his parents' request. *See* Pet. Exs. 1-2.

A.C. was also brought to the hospital on multiple occasions during this time. He was admitted to Maine General Hospital on October 2, 2009 for acute otitis media and upper respiratory infection/pneumonia. Pet. Ex. 1 at 18-21. On November 29, 2009, he was brought to the emergency room at Maine General Hospital for an upper respiratory infection. *Id.* at 34-37. A sweat test was performed at the request of his parents due to concerns that he was constantly sick. The results were normal. *Id.* at 43-50.

On October 18, 2010, A.C. was brought to the emergency room with an ear infection. *Id.* at 92. On September 20, 2011, he was taken to the emergency room for a small cut on his head. *Id.* at 106-07. On November 8, 2011, he was brought to the emergency room for cough and congestion that had lasted for four weeks. At that visit, petitioner stated that since she had been unable to see their primary care physician, she brought A.C. to the emergency room for evaluation. The record for the visit states "[petitioner] is just concerned because [A.C.] has had a

[3] Chronic Recurrent Multifocal Oteomyelitis is an auto-inflammatory bone disease of largely unknown etiology that is "characterized by bone pain and fever with an unpredictable course of exacerbations and spontaneous remissions." Hatem I. El-Shanti, MD & Polly J. Ferguson, *Chronic Recurrent Multifocal Osteomyelitis: A Concise Review and Genetic Update*, 462 Clinical Orthopedics & Related Res. 11 (2007).

persistent cough and nasal discharge. The child himself does not have any complaints. He is quite active as I enter the room. He is up and down off the stretcher and playing with his coloring book and stickers." *Id.* at 108.

In January 2012, A.C.'s care was transferred to a different pediatric practice. On January 31, 2012, A.C.'s new pediatrician noted the following: "pale stool x past month, today was white—had photograph on phone, started after a course of diarrhea that resolved . . . occasional complaints of abdominal pain, 'booboo', has speech delay . . . current cold, rhinorrhea, congestion, wet cough, pulling on ears, fever." Pet. Ex. 2 at 126-28.

On February 3, 2012, A.C. presented to the pediatrician for a follow-up visit, where the following was noted: "[C]omplaining more about abdominal pain 'booboo' in past few days not eating well for 2 weeks, but variable intake whitish-pale stool since 12/25 . . . first cousin had a tumor in intestine that ruptured per parent report, parents are very concerned LFT has slight elevation of AST but otherwise normal. Well appearing child, appropriate for age, no acute distress . . . no rashes . . . LFTs reassuring. Stool studies with negative blood and leukocytes. Fecal fat pending. Parents very concerned given recent complaints of pain and duration of pale stools. Will refer to pedi GI." *Id.* at 129-30. No records from a pediatric gastroenterologist were filed.

On April 26, 2012, A.C. presented to the pediatrician with cold symptoms and a fever. He was diagnosed with an upper respiratory infection. *Id.* at 138-39.

On July 11, 2012, A.C. returned to the pediatrician for "croup" and "reactive airway disease." *Id.* at 140-42. Two weeks later, on July 29, 2012, petitioner brought A.C. back to the pediatrician because he had multiple bug bites. The consultation notes reflect that "[Petitioner] outlined several [of the bites] because he seems to have some big reactions to them." *Id.* at 143.

On August 2, 2012, A.C. visited the pediatrician for a well-child exam where he was noted to be a well child on a gluten free diet. He was meeting all milestones but his speech was only about 50% intelligible. He was being home schooled and needed to catch up on his vaccinations. A.C. received the allegedly causal DTaP, IPV/HIB, MMR and Varicella vaccinations at this visit. *Id.* at 162, 168-71.

B. A.C.'s Health Following the Allegedly Causal Vaccinations

Following the August 2, 2012 visit, A.C. did not return to a medical care provider until December 4, 2012, when he presented for complaints that his right ear had been "closing" for the past few days. He was noted to be afebrile and a well-appearing child in no acute distress. He was diagnosed with ear wax of the right ear. No other complaints were noted. Pet. Ex. 2 at 145-46.

On January 16, 2013, A.C. presented to the pediatrician with leg pain. The medical record notes that petitioner was "concerned about [A.C.'s] [r]ight foot or ankle, seems to be favoring it, [complaining of] pain and when sitting/lying down keeps it flexed up, walking on it abnormally. No known injury, no bruising, no redness, no swelling. Since last Thursday, about

a week now, have tried ice, no other meds." *Id.* at 172. Upon examination, the pediatrician noted a "right foot in flexed position, toes up; walking mostly on medial edge of foot will relax when asked but then flexes again, relaxed when sitting on feet however, [full range of motion], no pain with movement, when distracted no tenderness but when asked points to top of foot that hurts. No edema, no erythema, no ecchymosis." *Id.* A.C.'s foot was wrapped in an ace bandage and petitioner was told to follow up as needed. *Id.* at 173.

On January 19, 2013, petitioner presented A.C. to Mid-Coast Hospital with "20 hours of fever up to 105, has complained of nausea but no vomiting." Pet. Ex. 7 at 292. Petitioner stated that A.C. complained of head pain and had significantly decreased appetite and activity levels. A.C.'s temperature was recorded at 101.8 degrees, and he was noted to be "alert, happy, smiling, interactive and playful, consolable, well hydrated, [and] appears to be pain free." *Id.* at 293. Examination of A.C.'s back, upper extremities, and lower extremities was noted to be normal. A neurological examination was normal with no focal or motor deficits. A.C. moved his extremities equally and had a normal gait. No cause was determined for his fever. *Id.* at 292-94.

On February 8, 2013, A.C. was examined by the pediatrician for fever, cough, congestion, and a runny nose that lasted five days. Both petitioner and A.C.'s sister had upper respiratory infections, but no fever. A.C.'s fever had reached 103 degrees. The pediatrician noted that A.C. was a "well appearing child, appropriate for age, no acute distress." He was diagnosed with viral syndrome and questionable influenza. Petitioner was advised to give A.C. nonsteroidal anti-inflammatory drugs ("NSAIDs"), fluids, and rest. Tamiflu was prescribed. Pet. Ex. 2 at 147-48.

One month later, on March 1, 2013, A.C. was seen again at the pediatrician's office with complaints of stomach pain. Petitioner reported that A.C. had complaints of "belly pain for over an hour, had episode increased pain, crying, around 4 pm; so made [an appointment] now improved, acting like self." A.C. was noted to be a well-appearing child, appropriate for his age and in no acute distress. He was "active in hall and in room, appears comfortable, interactive with exam." A.C.'s abdominal pain appeared to have resolved. *Id.* at 149-50.

Ten days later, on March 11, 2013, A.C. returned to the pediatrician with complaints of pain in his right foot that had lasted for six days. He also was noted as having right knee discomfort, which petitioner believed may be due to A.C.'s abnormal gait. The pediatrician noted the following:

> Foot is held pointing out. 1 month ago had [right] foot pain—lasted 3 days then resolved without treatment. X-ray at that time was negative. No swelling or redness. No fever. No rash . . . PE – R leg and foot with normal exam. No discomfort when moving any area of the leg when he is not bearing [weight] but when trying to walk he points the toes of the [right] foot out and drags the foot along. He point[s] to the medial part of the foot when asked what hurts while he is walking. [Left] knee with normal exam.

Id. at 174.

Five days later, on March 16, 2013, A.C. was examined by an orthopedic specialist at Mid-Coast Medical Group Orthopedic. A.C. was noted to be a three-year-old with over two weeks of right foot pain and abnormal gait with no history of trauma. A.C.'s foot pain had begun to awaken him at night. He had been tested for Lyme disease and inflammatory arthritis, but both tests were negative. Recent x-rays were also normal. The orthopedic specialist believed that A.C. had a "little growth plate fracture, most likely of his distal fibula." He also noted that the limp may be more habit than pathologic. A.C. was encouraged to bear full weight, walk with his foot straight ahead, and use a more normal gait. *Id.* at 122.

On March 23, 2013, A.C. returned to the pediatrician with "fever and neck pain." Petitioner stated that in the prior two weeks, A.C. had begun to complain of pain in his neck when turning his head. He had a fever of 101 degrees the previous night that had since resolved. He had been sleeping more over the past several days. He had not been given Tylenol or ibuprofen for the last two days. He had a runny nose and cough. His foot pain was still present but not as severe as it had been. Upon examination, A.C. was noted to be a "[w]ell appearing child, appropriate for age, no acute distress, happy, playful . . . shotty ant cervical nodes." The pediatrician noted that A.C. was complaining of "pain in a circle around his neck with all movement . . . No cyanosis or deformity noted with normal [range of motion] in all joints still with limp but not as pronounced . . . Arthralgia . . . I'm concerned about the recurrent joint pain that he has been having. Will check labs and plan to refer to rheum." *Id.* at 184-85.

On March 26, 2013, A.C. returned to the orthopedist for follow up. He was still walking in external rotation and had been complaining of pain in multiple joints, including his shoulders. He reportedly had a very stiff neck the previous week which had not resolved. Petitioner advised that A.C. complained of pain, sat on the couch, and then put himself to sleep. Upon examination, A.C. was noted to have decreased motion of the cervical spine. He had full ankle and subtaler motion and was non-tender. It was recommended that A.C. see a rheumatologist. Pet. Ex. 2 at 123.

On April 2, 2013, A.C. was presented to Rheumatology Associates. His parents provided the following history: A.C. was doing well until January 2013 when he started complaining about pain in the right foot and ankle and began to limp. There was no obvious injury or illness, and his x-rays were normal. His symptoms persisted into February. He had some warmth and redness on the dorsal aspect of the right midfoot, but there was no obvious swelling. Treatment mostly consisted of ibuprofen and Tylenol. He experienced prolonged stiffness following inactivity, and was very stiff in the morning. His level of activity had diminished considerably—he walked with a limp and was unable to run. A.C. had sporadic low grade temperatures of around 100 degrees. In the past month, he had also begun complaining of neck pain and right knee and right hand pain. Laboratory tests were noted to be mostly negative, except for a mildly elevated inflammatory marker. Pet. Ex. 4 at 233.

The next day, on April 3, 2013, petitioner brought A.C. to Mid-Coast Hospital stating that he had fevers of up to 101 degrees every day for the past two weeks. Petitioner told the physicians that the rheumatologist had told her that fevers of up to 101 degrees could be a symptom of rheumatoid arthritis. She said that A.C.'s temperature reached 103.7 that day. "Per mother, patient has been having generalized pain for the last month with a ? diagnosis of RA.

After arrival, patient states is better until he moves around and then complains again of pain 'all over' especially knees, ankles, legs and neck." The medical record states that A.C. experienced a "gradual onset of symptoms, [d]ate and time of onset was for a while especially over the last month, [s]ymptoms are worsening." A physical examination revealed that A.C.'s back and ranges of motion in his upper and lower extremities were all normal, but that he was tender at the knees and ankles. The medical record states that A.C. was "[f]eeling better and walking in hallway, ready for discharge." A.C. was discharged with a diagnosis of rheumatoid arthritis and fever of uncertain cause. Pet. Ex. 7, at 295-98.

The following day, on April 4, 2013, A.C. was hospitalized at Barbara Bush Hospital for headache, polyarthralgia, fever, and weight loss. Upon presentation, it was noted that "[t]hese symptoms had been present for several months but had worsened in the past few week[s] to the point where he could not stand. Labs were remarkable for anemia (Hb 9.8) elevated inflammatory markers (CRP 14, ESR 40) and elevated alkaline phosphatase 1524." Pet. Ex. 3 at 223. Extensive testing was performed. A lumbar puncture demonstrated normal cerebrospinal fluid ("CSF"). *Id.* at 224. A.C.'s discharge diagnosis was polyostotic fibrous dysplasia[4] and hypophosphatemia.[5] *Id.* at 223-28. Dr. Daniel Hale at Barbara Bush Hospital summarized A.C.'s medical history as follows:

> The patient is a 3 y.o. male without a significant past medical history who presents with fever and joint pain. Mom reports that in January, he had right foot pain with limping. Seen by PCP [primary care physician] and x-ray looked fine. Treated with an ace bandage. Symptoms resolved within 1 week. Then in March, he complained of BL foot pain and left knee pain. Seen by ortho. More x rays no fracture. PCP referred to rheumatology. Last 5 week[s], his pain has progressively worsened and he was staying up at night crying. Now, he is complaining of R butt or hip pain, R knee, feet, hand pain. Not wanting to pick up things with hands. No swelling or redness of joints. They feel warm to mom. Fever for the past 2 weeks, 99-101 almost every day. Worse at night. Past 3 days, his fever has been getting higher up to 103. Last night, mom took him to Midcoast [emergency room] for fever and neck pain. Not extending his head to look up. Decreased [range of motion] turning head. Not wanting to bear weight unless given pain medications. Pain is improved with Tylenol with codeine. Mom tried giving him Motrin and Tylenol.

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[4] Polyostotic fibrous dysplasia is a "non-inherited developmental anomaly of bone in which normal bone marrow is replaced by fibro-osseous tissues." The disease may be localized to a single bone (monostotic) or multiple bones (polyostotic). *Fibrous Dysplasia Pathology*, Medscape (last updated Jan. 5, 2015), http://emedicine.medscape.com/article/1998464-overview.

[5] Hypophosphatemia is "an abnormally decreased amount of phosphates in the blood; manifestations include hemolysis, lassitude, weakness, and convulsions." *Dorland's Illustrated Medical Dictionary* 904 (Saunders eds., 32nd ed. 2012) (*Dorland's*). It is typically diagnosed at a serum phosphate level of less than 2.5 mg/dL. *Hypophosphatemia*, Medscape (last updated Jul. 26, 2016), http://emedicine.medscape.com/article/242280-overview.

Pet. Ex. 12 at 398-99.

The pediatric hematologist at Barbara Bush Hospital obtained a similar history from petitioner. "In January of 2013 [complaining of] intermittent pain in foot. Pain self resolved. Pain reoccurred and seen by orthopedics. Per report plain films obtained and [within normal limits]. Initially low grade fevers but over the last 2-3 weeks increase fever. Now refusing to walk secondary to pain. Unable to flex neck secondary to pain." *Id.* at 409.

The pediatric infectious disease consult at Barbara Bush Hospital noted that "[t]he history was obtained from mother. [A.C.] is a 3 y.o. male who presented yesterday with 3-4 months of joint pain and intermittent fevers. [A.C.] was in his typical state of health until mid January when he began to have pain of his right foot and ankle . . . one month later in mid February, [A.C.] again began to have pain of the same foot, with some redness and swelling of the dorsum of that foot. He also began to complain of neck pain . . . and in early April was referred to rheumatology due to continued foot and neck pain. He also began to complain of pain in his left knee." *Id.* at 414.

In the months that followed, "bone biopsies were reviewed at multiple institutions and the consensus has been consistent with Chronic Recurrent Multifocal Osteomyelitis." Pet. Ex. 4 at 236. The most recent medical record filed for A.C. is a June 1, 2015, visit with his rheumatologist, who noted that A.C.'s CRMO was in remission, though he continued have stiffness in the morning and complaints of left knee pain. An MRI of the left knee did not show any osteomyelitis but did show a bony abnormality. A.C. walked with an abnormal gait favoring the left leg. His bone scans did not suggest any osteomyelitis. A.C. was referred back to an orthopedic specialist. *Id.* at 253-54.

C. Procedural History

Petitioner filed her petition and affidavit on July 23, 2015, alleging that the vaccinations A.C. received in August 2012 caused his injuries, and that the onset of those injuries occurred in the fall of 2012. ECF No. 1. This case was originally assigned to Special Master Hamilton-Fieldman.[6] Petitioner filed medical records on July 25, 2015, and a statement of completion on September 3, 2015.[7] ECF Nos. 6, 9.

On September 28, 2015, respondent filed a status report ("Resp. S.R."), indicating that the medical records were complete and requested that a status conference be set to discuss the "significant weaknesses in petitioner's claim, most notably the alleged onset of A.C.'s alleged vaccine-injury." Resp. S.R., ECF No. 10.

[6] This case was reassigned to me on January 14, 2016. *See* Order Reassigning Case, ECF No. 18.

[7] Petitioner filed a Notice of Filing of CD containing the following medical records: Waterville Pediatrics; Mid Coast Medical Group Pediatrics; The Barbara Bush Children's Hospital at MMC; StorySmith Pediatric Clinic; Ramesh Gaindh, M.D. Laboratory; Maine Medical Partners Pediatric Specialty Care; Department of Radiology, MMC; NorDx Maine Health; Mid Coast Hospital Diagnostic Imaging; and Maine Medical Center.

The initial status conference was conducted on October 19, 2015. During the conference, Special Master Hamilton-Fieldman discussed the various issues in this case, including the lack of evidence in the record to support petitioner's allegation that the onset of A.C.'s symptoms occurred in the fall of 2012. The parties were advised that unless petitioner could proceed with an expert willing to opine in favor of a five- to six-month onset period, the special master would make an onset determination prior to assessing causation. Petitioner was ordered to file a status report indicating how she would like to proceed and an affidavit explaining her assertion of an onset in the fall of 2012. Order, ECF No. 11.

On November 16, 2015, petitioner filed several pages from a 2012 calendar (the "date book"), a revised affidavit, and affidavits from Theresa Joseph and Irving Joseph (A.C.'s grandparents) in support of petitioner's claim that the onset of A.C.'s injury occurred in the fall of 2012. *See* ECF Nos. 12-14. Petitioner also filed affidavits from Jennifer Rowe and Jeremy Gordon (petitioner's aunt and uncle) on December 8, 2012. ECF No. 15.

The date book filed by petitioner, which was admittedly constructed almost two years after the events in question, dedicates two pages to each month in 2012 and includes petitioner's handwritten notes about what occurred on each date. *See* Ruling on Onset, ECF No. 36, at 2-3 (citing Transcript, 10.2 - 10.12)). The affidavits by petitioner's family members also recount observations of A.C.'s symptoms in the fall of 2012. However, none of the affidavits was based on an independent recollection of the events. All of the affiants relied upon the date book that had been provided to them by petitioner. *See* Affidavits, ECF Nos. 12, 15.

A status conference was held on December 23, 2015. During the conference, petitioner's affidavits and 2012 date book were discussed, particularly the fact that petitioner's affidavits and date book contradict the medical records documenting that the onset of A.C.'s alleged injury occurred in January 2013. Petitioner's counsel argued that the medical records are not always accurate of what patients tell their doctors. Petitioner was ordered to file a brief on the alleged timing of onset. Order, ECF No. 16.

On January 7, 2016, petitioner filed a Brief Regarding Onset of Symptoms ("Pet. Onset Brief"), admitting that, although "the medical records indicate onset of symptoms as January of 2013, when A.C's parents first sought medical attention for A.C.'s symptoms," the affidavits filed by petitioner are "overwhelmingly more persuasive" than the medical records. Pet. Onset Brief, ECF No. 17, at 2-4. Petitioner requested that the Court find "that onset of A.C's symptoms is consistent with the affidavits provided in this matter, or hold an evidentiary hearing regarding the same." *Id*. at 6.

On January 28, 2016, respondent filed a response to petitioner's Onset Brief. Respondent stated that—based on the existing record, which includes the medical records and affidavits filed by petitioner—petitioner has not shown by preponderant evidence that A.C.'s symptoms began in the fall of 2012. *See* Response to Pet. Onset Brief, ECF No. 20. On June 21, 2016, petitioner filed a supplemental affidavit. ECF No. 28.

An onset hearing was held on July 11, 2016. Petitioner was the only witness to testify at the hearing. Thus, petitioner relied exclusively on her own testimony and affidavits, and the

affidavits of her family and friends, which were all based on the date book, to support her claim of an onset date in the fall of 2012. After the hearing, petitioner was ordered to file a 2013 date book which she testified to having. *See* Post-Hearing Order, ECF No. 31. On August 8, 2016, petitioner filed pages from her 2013 date book; however, petitioner stated that she was unable to locate the date book for January and February of 2013. ECF No. 34.

On December 14, 2016, the undersigned issued a Ruling on Onset, ECF No. 35, finding that the "contemporaneous medical records and histories provided by petitioner to [A.C.'s] medical providers at the time of the events more accurately reflect the onset of A.C's CRMO." The undersigned explained that although "there are situations in which compelling oral testimony may be more persuasive than written records," the testimony and affidavits were not "sufficient to refute the contemporaneous medical records, which firmly support the onset of CRMO in January 2013"—five months after vaccination. *Id*. at 5, 17. Petitioner was ordered to file either an expert report based on the findings contained in the Onset Ruling or a status report indicating how petitioner intended to proceed. *Id*. at 18. If petitioner could not secure an expert report based on the timing of onset as found by the undersigned, she was to file a motion to dismiss, a joint stipulation for dismissal, or a motion for a ruling on the record. *Id*.

On April 13, 2017, petitioner filed a status report indicating that she could not obtain an expert to provide an opinion within the parameters of the Onset Ruling and requested a deadline to file for a Ruling on the Record so that she could have a decision upon which to seek review. *See* Pet. S.R., ECF No. 38. Petitioner was ordered to file a Motion for a Ruling on the Record by May 15, 2017. Scheduling Order, dated Apr. 13, 2017. On May 15, 2017, petitioner filed a "Request for Ruling on the Record", ECF No. 39, once again arguing that "the testimony of A.C.'s parents and the affidavits submitted by independent witnesses regarding the onset of A.C.'s symptoms is sufficient to overcome the rebuttable presumption that the information contained in the medical records is accurate." Petitioner also stated that "had [petitioner] been allowed to seek an expert opinion regarding the cause of the osteomyelitis occurring just weeks after the vaccination, as all of the evidence supports, she would have been fully able to meet her burden" to prove causation.[8] Petitioner requests that the undersigned "issue a decision in favor of [p]etitioner or reconsider the earlier decision regarding onset of A.C.'s symptoms and hold a hearing." *Id.* at 7.

On June 6, 2017, respondent filed a response to petitioner's Request for a Ruling on the Record. *See* ECF No. 40. Respondent stated that—based on the existing record, which includes the medical records, affidavits, and the undersigned's Onset Ruling—entitlement to compensation must be denied. This matter is now ripe for decision.

[8] Petitioner attached two articles to her motion: a 2015 online article about "how vaccines work," *see Vaccines (Immunizations) – Overview*, MedlinePlus (2015), http://medlineplus.gov/ency/article/002024.htm; and a 2005 article claiming that osteomyelitis is a complication of the varicella viral infection, *see* Lars Borgen et al., *Acute Osteomyelitis as a Complication of Varicella*, 46 Acta Radiologica 652 (2005).

II. Discussion

In her "Request for Ruling on the Record," petitioner combines a motion for a ruling on the record with a motion for "reconsider[ation]" of the earlier ruling regarding onset and a demand for a hearing. *See* ECF No. 39, at 1, 7. Each of these requests is discussed below, with the latter discussed first.

A. Motion for Reconsideration

Although titled "Request for Ruling on the Record," petitioner seeks "reconsider[ation]" of the December 14, 2016, Ruling on Onset. ECF No. 39, at 7. This request for reconsideration is procedurally improper and substantively without merit.

The Vaccine Rules provide that "[e]ither party may file a motion for reconsideration of the special master's *decision*" within a prescribed time period. Vaccine Rule 10(e)(1) (emphasis added). But a "decision" subject to reconsideration is a decision on whether the petitioner is entitled to "an award of compensation" and "if so, the amount thereof." Vaccine Rule 10(a). The Ruling on Onset was not a decision but rather, it was a *ruling* following a fact hearing which resolved "discrepancies between A.C.'s medical records and the accounts of petitioner and several witnesses" as a means of "clarify[ing] the onset of A.C.'s symptoms" for the parties going forward. Ruling on Onset, ECF No. 36, at 2. It is thus not a "decision" that is subject to a motion for reconsideration under the Vaccine Rules.

Moreover, even assuming *arguendo* that petitioner's request for reconsideration of the onset ruling were procedurally proper, the request is without basis. When ruling on a motion for reconsideration, a "special master has the discretion to grant or deny the motion, in the interest of justice." Vaccine Rule 10(e)(3). This is a demanding standard that requires the movant to show (a) an intervening change in the controlling law; (b) the availability of evidence that was not previously available; or (c) a manifest injustice that would be prevented by reconsideration. *Hall v. Sec'y of Health & Human Servs.*, 93 Fed. Cl. 239, 251 (2010), *aff'd*, 640 F.3d 1351 (Fed. Cir. 2011); *see Gerard v. Sec'y of Health & Human Servs.*, No. 08-786V, 2014 WL 4293342, at *2 (Fed. Cl. Spec. Mstr. Aug. 8, 2014). Reconsideration is not available simply to "give an unhappy litigant an additional chance to sway the court." *Hall*, 93 Fed. Cl. at 251 (citation omitted); *see also Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1348 (Fed. Cir. 2010) (holding that a special master did not "abuse his discretion in declining to grant reconsideration in view of evidence that was previously available and which did not in fact support petitioners' position on the central issues").

In this case, petitioner has not identified anything that would change the outcome of the Ruling on Onset. Petitioner did not identify any change in controlling law, any newly-available evidence,[9] or proof of any manifest injustice so as to warrant reconsideration. Petitioner instead

[9] As noted above, petitioner attached two articles to her motion. *See supra* note 8. Petitioner does not claim that these articles constitute newly-available evidence that would in any way address the core issue in the Onset Ruling—the onset of A.C.'s CRMO and the discrepancies between the contemporaneous medical records and the witness testimony on that subject.

"contends that [the undersigned] erred in her conclusion" and findings of fact concerning onset, repeating arguments that were expressly considered and rejected in the Ruling on Onset. ECF No. 39 at 4. *Compare, e.g.*, *id.* at 7 ("Petitioner submits that the testimony of A.C.'s parents and the affidavits submitted by independent witnesses regarding the onset of A.C.'s symptoms is sufficient to overcome the rebuttable presumption that the information contained in the medical records is accurate."), *with* Ruling on Onset, ECF No. 36 at 5, 17 (explaining that although "there are situations in which compelling oral testimony may be more persuasive than written records," the testimony and affidavits were not "sufficient to refute the contemporaneous medical records" in this case). Essentially, petitioner's sole argument is that the finding of onset five months after the date of vaccination is too remote for her to secure an expert in this case. As a result, petitioner is unable to prove her case, and thus, petitioner argues that the undersigned's finding as to the onset of A.C.'s alleged symptoms is incorrect.

Ultimately, even if reconsideration were an option, petitioner's discontent with the Ruling on Onset would not satisfy the standard under Vaccine Rule 10(e)(3). Petitioner's request for reconsideration and demand for a hearing is therefore DENIED.

B. Ruling on the Record

With respect to petitioner's request for a ruling on the record, the undersigned finds that petitioner has failed to carry her burden to show that she is entitled to compensation.

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may demonstrate that she suffered an "off-Table" injury. § 11(c)(1)(C)(ii). An "off-Table" claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii)(II). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). But a petitioner cannot satisfy her burden of proof under the Vaccine Act by relying on her testimony "alone, unsubstantiated by medical records or by medical opinion." § 13(a)(1).

In this case, petitioner does not allege an injury listed on the Vaccine Injury Table; thus, petitioner's claim is classified as "off-Table," which requires that she "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320. To satisfy this burden, petitioner must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). Under *Althen*, petitioner must establish by preponderant evidence that the vaccination A.C. received caused his injury "by providing: (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." *Id.* at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53).

"[T]o show causation under the preponderance of the evidence standard," a petitioner "must proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014); *see also Althen*, 418 F.3d at 1278 (explaining that a petitioner's claim must be "supported by 'reputable medical or scientific explanation,' *i.e.*, 'evidence in the form of scientific studies or expert medical testimony'" (citation and alteration omitted)); *Shyface*, 165 F.3d at 1351 ("[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation." (citation and emphasis omitted)).

Following the Ruling on Onset, petitioner was ordered to file an expert report based on the findings of fact contained therein that the onset of A.C.'s CRMO began in January 2013. *See* Ruling on Onset, ECF No 35 at 18. Petitioner failed to provide an expert report to support her claim that the vaccinations A.C. received in August 2012 caused his injuries. Additionally, none of A.C.'s treating physicians related the CRMO to any of the vaccinations he received. Petitioner has not provided any expert opinion showing that any of the vaccinations A.C. received *can* cause CRMO,[10] that the vaccinations *did* cause CRMO in this case, or that a five-month onset of CRMO falls within a medically-acceptable timeframe following the allegedly causal vaccinations. In light of petitioner's failure to provide any expert or medical evidence to support her claim, she cannot sustain her burden of proof on any of the *Althen* prongs.

III. Conclusion

Petitioner's request for reconsideration of the Ruling on Onset is **DENIED**. And upon careful evaluation of all of the evidence submitted in this matter—including the medical records, tests and reports, medical literature as well as the testimony and affidavits—the undersigned concludes that petitioner has not shown by preponderant evidence that she is entitled to compensation under the Vaccine Act. Petitioner has failed to offer sufficient evidence showing that any of the vaccinations A.C. received in August 2012 caused his CRMO. **The petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

[10] In petitioner's request for a ruling on the record, petitioner states that the first article attached to her request shows that "[t]he Varicella vaccination injects the Varicella bacteria into the body," and that the second article attached shows that some "[l]iterature indicates Varicella can also cause osteomyelitis." ECF No. 39, at 3. Varicella, commonly known as chickenpox, is a human herpesvirus, not a bacteria. *Dorland's* 342, 2024. Neither of these articles suggests a causative connection between the Varicella vaccination and CRMO, nor do they provide the requisite "reputable medical or scientific explanation" necessary to support petitioner's claim. *Althen*, 418 F.3d at 1278.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master