In the United States Court of Federal Claims

No. 15-777V Filed: January 30, 2018 Reissued for Publication: March 19, 2018¹

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OPINION

HORN, J.

On July 23, 2015, Petitioner Heather Caron, parent and next friend of minor, A.C., and on behalf of A.C., filed a timely petition for compensation with the National Vaccine Injury Compensation Program, under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1–300aa-34 (2012) (Vaccine Act). On September 7, 2017, Special Master Mindy Michaels Roth of the United States Court of Federal Claims denied Petitioner's claim for an award of compensation, finding that Petitioner did not show by a preponderance of the evidence that she is entitled to compensation under the Vaccine Act. See Caron v. Sec'y of Health & Human Servs., No. 15-777, 2017 WL 4349189, at *10 (Spec. Mstr. Fed. Cl. Sept. 7, 2017). On September 26, 2017, Petitioner filed a motion for review in this court to review the Special Master's decision denying her claim, pursuant

¹ This opinion was issued under seal on January 30, 2018. The parties did not propose redactions to the January 30, 2018 opinion, and, thus, the court issues the opinion for public distribution.

to Rule 23 of the Vaccine Rules of the United States Court of Federal Claims (Vaccine Rules) (2017). This case comes to the court upon that motion.

FINDINGS OF FACT

The following relevant facts are established by the exhibits of records submitted by Petitioner in this matter and the Special Master's factual findings from her December 14, 2016 Ruling On Onset and her September 7, 2017 Decision Denying Entitlement. See Caron v. Sec'y of Health & Human Servs., 2017 WL 4349189, at *1-5; see also Caron v. Sec'y of Health & Human Servs., No. 15-777, 2016 WL 7664309, at *5-9 (Spec. Mstr. Fed. Cl. Dec. 14, 2016). According to the records before the court, A.C. was born on July 18, 2009, four weeks prematurely. Eleven days after birth, A.C. appeared "alert, well nourished, well hydrated, [and with] no acute distress," and by two months old, A.C. was healthy and well developing.

During his first three years of life, A.C. was seen at the pediatrician's office over forty times for a variety of complaints, such as ear infections, insect bites, congestion and coughing, and for standard well-child visits. According to the records before this court, prior to the visit on which A.C. received the vaccines at issue in the case before this court on August 2, 2012, A.C. received routine vaccines on a delayed schedule with no apparent adverse side-effects.

Among his numerous visits, when he was around ten weeks old, A.C. was admitted to Maine General Medical Center to "rule out sepsis or pneumonia or meningitis." When A.C. was around six months old, he was referred to a pediatric pulmonologist for multiple respiratory issues. On September 20, 2011, when A.C. was two years old, he was taken to the emergency room after falling forward and cutting his forehead with his toy train. Shortly after that visit, on November 8, 2011, Petitioner took A.C. to the emergency room for a cough and sinus congestion. The medical record notes that because Petitioner and A.C. were unable to see the primary care physician, she took A.C. to the emergency room instead. The medical record also states that "[t]he child himself does not have any complaints. He is quite active as I enter the room." On July 29, 2012, Petitioner took A.C. to the pediatrician's office because A.C. had multiple bug bites. The medical record states that "[m]om has outlined several because he seems to have some big reactions to them." There was "[n]o concern for infection," however, and A.C. did not have any fever.

² Initially, Petitioner submitted twelve exhibits, which were hospital and physician records, from A.C.'s various medical visits, beginning from A.C.'s birth through June 2015. Petitioner later filed four more exhibits: copies of her 2012 date book and her 2013 date book, which were hard copies of calendars that Petitioner kept, and two on-line articles as exhibits to her May 15, 2017 Request For a Ruling On The Record, for a total of sixteen exhibits before the Special Master and this court.

On August 2, 2012, a couple of weeks after his third birthday, A.C. visited the pediatrician for a well-child visit. He was noted to be a "[w]ell appearing child, appropriate for age, [with] no acute distress." He was being home schooled and was behind in his immunizations. At this August 2, 2012 visit, A.C. received the allegedly causal diphtheriatetanus-acellular pertussis (DTaP), haemophilus influenza type B (HIB), measlesmumps-rubella (MMR) and Varicella vaccinations.³

On December 4, 2012, approximately four months after A.C. received the August 2, 2012 vaccines at issue in this case, A.C. visited his pediatrician for complaints regarding his right ear. The medical record notes that his right ear was "closing," but that A.C. was acting well and had no fever and made no mention of foot pain. This was A.C.'s first medical visit after receiving his August 2, 2012 vaccines.

On January 16, 2013, A.C. visited the pediatrician's office to address foot pain. The medical record notes:

[Petitioner] concerned about [A.C.'s] R[ight] foot or ankle, seems to be favoring it, c/o [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[.]

The pediatrician also noted: a "R[ight] foot in flexed position, toes up; walking mostly on medial edge of foot . . . no pain with movement, when distracted no tenderness but when

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³ All parties and the Special Master agree that the alleged injurious vaccines were administered on August 2, 2012. Petitioner, defendant, and Special Master Roth each noted in their filings that A.C. received the inactivated polio virus (IPV) vaccine, along with the other alleged injurious vaccines, on August 2, 2012. For example, the petition states that A.C. "received DTap-IPV/Hib, MMR and Varicella vaccinations, . . . on August 2, 2012," Defendant's October 26, 2017 response to Petitioner's Motion For Review states that A.C. "received diphtheria-tetanus-acellular pertussis ('DTap'), inactivated polio ('IPV'), haemophilus Type B ('HIB'), measles-mumps-rubella ('MMR'), and varicella vaccinations" on August 2, 2012. Special Master Roth, in her December 14, 2016 Ruling On Onset and her September 7, 2017 Decision Denying Entitlement, states that A.C. received the DTaP, IPV/HIB, MMR and Varicella vaccines on August 2, 2012. See Caron v. Sec'y of Health & Human Servs., 2016 WL 7664309, at *6 ("A.C. received the allegedly causal DTaP, IPV/HIB, MMR and Varicella vaccines at that visit."); see also Caron v. Sec'y of Health & Human Servs., 2017 WL 4349189, at *2 ("A.C. received the allegedly causal DTaP, IPV/HIB, MMR and Varicella vaccinations at this visit."). Upon review of A.C.'s medical records, however, it appears that A.C. did not receive the IPV vaccine on August 2, 2012. The immunization record for A.C. from MidCoast Pediatrics and the medical chart dated August 2, 2012 that was electronically signed by Dr. Emily Wesolowski at MidCoast Pediatrics, which were filed by Petitioner as part of A.C.'s medical records before the Special Master and this court, however, indicate that A.C. received only the DTaP, the HIB, the MMR, and the Varicella vaccines on August 2, 2012.

asked points to top of foot that hurts. no edema, no erythema, no ecchymosis[.]" A.C.'s foot was wrapped in an ace bandage and Petitioner was told to follow up as needed.

On January 19, 2013, Petitioner took A.C. to Mid Coast Hospital with "20 hours of fever up to 105." The medical record states that A.C. had been complaining of some head pain and nausea and that A.C. had experienced decreased appetite and activity, but also states that during his physical exam, A.C. was "alert, happy, smiling, interactive and playful, consolable, well hydrated, . . . appears pain free." Additionally, an examination of his joints and back were "normal"; A.C. "[m]ove[d] all extremities equally"; there were "no focal motor deficits" and A.C. had a "nml [normal] gait."

As reported in the medical records, A.C.'s joint pain increased and he was seen various times regarding this pain throughout March 2013. For example, the medical record indicates that A.C. had "neck pain when turning head fast . . . [and] not wanting to move [his] neck," and by March 26, 2013, A.C. "[o]ften times . . . complain[ed] of pain so much that he just [sat] on the couch and then put[] himself to bed."

On April 4, 2013, A.C. was admitted to the Barbara Bush Children's Hospital at the Maine Medical Center with symptoms of "headache, polyarthralgia, fever and weight loss." According to the medical record, A.C.'s "symptoms had been present for several months but had worsened in the past few week [sic] to the point where he could not stand." The medical record further notes:

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 with limping. Seen by PCP [primary care physician] and xray 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 [sic], 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 ED [emergency department] for fever and neck pain. Not extending head to look up. Decreased ROM [range of motion] turning head. Not wanting to bear weight unless given pain medications.

During this hospital stay, A.C. underwent extensive testing, including a bone scan, a magnetic resonance imaging (MRI) of his neck, and bone biopsies from his mandible and tibia. On April 13, 2013, A.C. was discharged with an initial diagnosis of polyostotic fibrous dysplasia and hypophosphatemia.⁴

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⁴ Fibrous dysplasia is defined as "a disease of bone marked by thinning of the cortex and replacement of bone marrow by gritty fibrous tissue containing bony spicules, producing

Other medical reports taken during A.C.'s April 2013 hospital stay reflect a similar history of foot pain beginning around January 2013. The pediatric oncologist noted, "[i]n January of 2013 c/o [complaining of] intermittent pain in foot. Pain self resolved. Pain reoccurred And seen by orthopedics." The resident pediatrics specialist noted that "[m]om reports that in January, he had right foot with limping. . . . Symptoms resolved within 1 week." The rheumatologist noted that, "[A.C.] is known to me. I saw him for the 1st time on 4/2 with 2-3 month h/o [history of] arthralgia localized to knees, left foot, and neck." The pediatric infectious disease consult 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."

On April 29, 2013, A.C. had a follow-up visit with the rheumatologist, who noted that A.C.'s illness can "best be described as chronic recurrent multifocal osteomyelitis," although there was an initial belief that A.C. may have had fibrous dysplasia. The rheumatologist also noted that A.C.'s hypophosphatemia had since been corrected with medication. On June 10, 2013, the rheumatologist noted that the medical consensus regarding A.C.'s symptoms is a diagnosis of Chronic Recurrent Multifocal Osteomyelitis (CRMO).⁵ During the ensuing months, A.C. was seen by his rheumatologist and received immunosuppressive therapy to treat his CRMO.

According to the medical records before the court from Rheumatology Associates, P.A., the rheumatology practice that A.C. was visiting in 2015, as of June 1, 2015, A.C.'s CRMO was in remission. At a June 1, 2015 visit, the rheumatologist noted, however, that A.C. continued to have stiffness in the morning and left knee pain. The rheumatologist also noted that x-rays of the left knee were "normal" but A.C.'s MRI did show a bony abnormality.

On July 23, 2015, Petitioner filed a timely petition on behalf of A.C. for compensation with the National Vaccine Injury Compensation Program, pursuant to the Vaccine Act. Petitioner alleged that:

[A.C.] received DTap-IPV/Hib, MMR and Varicella vaccinations, which are all 'Table' vaccinations, on August 2, 2012, and who thereafter suffered from

pain, disability, and gradually increasing deformity." <u>Dorland's Illustrated Medical Dictionary</u> 581 (32nd ed. 2012). Polyostotic fibrous dysplasia is a "later stage of fibrous dysplasia of bone in which several or many bones are involved." <u>Id.</u> Hypophosphatemia is defined as "an abnormally decreased amount of phosphates in the blood," and "manifestations include hemolysis, lassitude, weakness, and convulsions." <u>Id.</u> at 904.

⁵ Osteomyelitis is defined as "inflammation of bone caused by infection, usually by a pyogenic organism, although any infectious agent may be involved. It may remain localized or may spread through the bone to involve the marrow, cortex, cancellous tissue, and periosteum." <u>Dorland's Illustrated Medical Dictionary</u> 1347 (32nd ed. 2012). Multifocal means "arising from or pertaining to many foci." Id. at 1187.

Chronic Multifocal Osteomyelitis, 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, which were caused in fact by the above stated vaccination.

Petitioner filed an affidavit from Petitioner Heather Caron, A.C.'s mother, with the petition and, aside from the civil cover sheet, did not submit any other documentation with the petition.

In her affidavit, Petitioner stated that "[s]oon after the vaccination, A.C. began to experience pain and related symptoms in his foot and ankle, but my husband and I did not immediately seek medical attention because the symptoms did not appear to be significant." She stated that "[h]owever, by January of 2013, A.C.'s symptoms and complaints of pain in his fight [sic] foot and ankle had become far worse." She then stated that "[h]is symptoms persisted into February without an obvious cause, and A.C. began limping." According to Petitioner's affidavit, by April of 2013, A.C. was having "difficulty sleeping and was running a consistent low grade fever." Petitioner then stated that A.C. "was hospitalized for further evaluation at Maine Medical Center in Portland, Maine on April 4, 2013" and was "discharged on April 13, 2013." In June of 2013, according to Petitioner's affidavit, "bone biopsy results indicated chronic recurrent multifocal osteomyelitis." Petitioner then stated that "A.C. has undergone multiple evaluations and treatment for his multifocal osteomyelitis and related symptoms and continues to suffer from the same."

On July 24, 2015, Petitioner's case was assigned to Special Master Lisa Hamilton-Fieldman.⁶ Also on July 24, 2015, Special Master Hamilton-Fieldman issued an order requiring Petitioner "to file a statement of completion when the process of filing medical records is deemed complete" and particularly requested that Petitioner file "prevaccination records starting from three years prior to vaccination." The Special Master "directed [Petitioner] to 42 U.S.C. § 300aa-11(c)(2) which lists what types of records should be filed [to] include pre-injury, physician, and clinic records." ⁷

⁶ This case was originally assigned to Special Master Lisa Hamilton-Fieldman and transferred to Special Master Mindy Michaels Roth on January 14, 2016.

maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (included all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records)[.]

⁷ Pursuant to 42 U.S.C. § 300aa-11(c), entitled "Petition Content", a "petition for compensation under the Program for a vaccine-related injury or death shall contain . . . an affidavit, and supporting documentation," and shall also include:

On July 25, 2015, Petitioner filed a Notice Of Filing Of CD's Containing Medical Records which listed the twelve exhibits of medical records she filed with the clerk of Court. Each exhibit was a compilation of the contemporaneous records from a particular physician's office or hospital that A.C. had visited during approximately the first six years of his life. In total, Petitioner submitted 482 pages of medical records. Thereafter, Petitioner certified to Special Master Hamilton-Fieldman, via a statement of completion that "she believes she has provided the entire medical records associated with Petitioner's petition." In an October 20, 2015 order, Special Master Hamilton-Fieldman stated that during an October 19, 2015 status conference, "the undersigned concurred with Respondent's argument . . . that there is insufficient evidence in the record to support Petitioner's allegation that onset occurred in the fall of 2012." Special Master Hamilton-Fieldman stated that, "[c]ontrary to the assertions in Petitioner's affidavit, multiple treatment providers have documented self-reported onset in January of 2013." Special Master Hamilton-Fieldman then ordered that "Petitioner shall file any additional documentation of the earlier alleged onset" and "an additional affidavit . . . explaining why the medical records unanimously document onset in January 2013."

On November 16, 2015, Petitioner filed a supplemental affidavit in support of her allegation that the onset of A.C.'s symptoms began earlier than January 2013, as documented by the contemporaneous medical records. Petitioner repeated from her initial affidavit that "[s]oon after the vaccination, A.C. began to experience pain and related symptoms in his foot and ankle, but my husband and I did not immediately seek medical attention because the symptoms did not appear to be significant." Petitioner, however, newly alleged that at least on five separate occasions before January 2013, A.C. presented with symptoms, such as, being "very quiet, [and] distant," having "pain in his feet" and a "slightly abnormal gait," being "extremely fatigued," and "running a consistent low-grade fever." Petitioner also alleged in her supplemental affidavit that on or about August 19, 2012, A.C. and Petitioner visited the home of Patricia Bailey, and "Ms. Bailey reported to me that . . . she found A.C. to be very guiet, distant and not interacting with the other children, which was not his normal behavior." Petitioner does not explain in her supplemental affidavit how she knew Ms. Bailey. Petitioner, however, later testified at the July 11, 2016 fact hearing before Special Master Roth that Ms. Bailey was a friend from her church. Petitioner then alleged in her supplemental affidavit that in September 2012, A.C. spent the weekend with Jennifer Rowe and Jeremy Gordon, when his parents were away. Petitioner also does not explain in her supplemental affidavit how she knew Jennifer Rowe and Jeremy Gordon. Petitioner later testified at the July 11, 2016 fact hearing before Special Master Roth they are her aunt and uncle. While A.C. stayed with Jennifer Rowe and Jeremy Gordon, according to Petitioner, A.C. complained of foot pain to them.

⁴² U.S.C. §§300aa-11(c)(1), (2). A petition also should also include "an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability." 42 U.S.C. § 300aa-11(c)(3).

Petitioner further alleged in her supplemental affidavit that in October 2012, Petitioner and A.C. visited the home of Dixy Love O'Neill. Petitioner did not state in her supplemental affidavit how she knew Ms. O'Neill. Petitioner later testified at the July 11, 2016 fact hearing before Special Master Roth that Ms. O'Neill was a friend from church. According to Petitioner, Ms. O'Neill informed Petitioner that "she recalled A.C. complaining about pain in his feet on that occasion and asking to be carried down to see her horses."

In addition, Petitioner alleged in her supplemental affidavit that in November 2012, Irvin and Theresa Joseph visited Petitioner's home. According to Petitioner, Irvin Joseph informed Petitioner that while he was at Petitioner's home, he noticed that "A.C. was walking with a slightly abnormal gait and heard him complain of pain in his feet." According to Petitioner, Theresa Joseph also informed Petitioner that "A.C. and she were sitting on the stairs at the family home, A.C. told her about the 'boo boos' in his feet." Petitioner then alleged that in late December 2012, Petitioner and A.C. visited the Josephs' home, during which time "A.C. was running a consistent low-grade fever." Petitioner did not explain in her supplemental affidavit how she knew the Josephs, but later testified at the July 11, 2016 fact hearing before Special Master Roth that the Josephs were her husband's mother and stepfather, A.C.'s grandparents.

Petitioner also alleged in her supplemental affidavit that "I maintained a date book back in 2012, where I recorded all important dates and events" and that "I can recall all of these dates because I recorded them in my date book." Petitioner filed with Special Master Hamilton-Fieldman a black-and-white copy of the date book she referenced in her supplemental affidavit, which Petitioner labeled as exhibit thirteen. Based on the record before the court, Petitioner's date book consists of ten pages from a 2012 calendar. Each page corresponds to a particular month, spanning from March to December 2012. The date book does not contain pages for the months of January and February 2012. The date book also displays handwritten notes under particular days, such as "Mom Dentist" under July 9, 2012, and "Pats ap. @ 5:40" under July 2, 2012. For example, the date book reflects the following notes for the respective dates that Petitioner discussed in her supplemental affidavit as the times when A.C. allegedly presented with vaccine related symptoms during the fall of 2012:

• for August 19, 2012, the date book entry states, "Dress Up Day/Party" and "Ant Pain in Foot:"

on the calendar in the individual boxes.

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⁸ Although Petitioner states that she "can recall of these dates because I recorded them in my date book," it appears that Petitioner did not actually write in any numerical dates in the date book, which is a pre-printed month at a time form calendar that has individual boxes for each day of the month. The numerical dates pre-printed in the upper left hand corner of each of the individual boxes and Petitioner's brief, hand written notes are visible

- for September 22, 2012, the date book entry states, "½ h," "Pats Fishin [sic] Trip," "Last week cleaning," and "8 miles;" the date book does not have anything noted for September 23, 2012;
- for October 15, 2012, the date book entry states, "1 return," "Dixy's House for Coffee." "Pain Ant Foot," and "1 ½ hrs;"
- for November 17, 2012, the date book entry states, "Pain in Ant Feet," "Pats Mom,"
 "1½ hrs;" and for November 18, "Pats Mom;"
- for the period of December 26 through 29 of 2012, the date book entry displays a line running through the entries for December 26, 27, 28, and 29, and states, "Foot Pain," and "Pats Mom."

Notably, when Petitioner was asked by Petitioner's counsel at the July 11, 2016 fact hearing before Special Master Roth whether she contemporaneously made the handwritten notes in her date book regarding A.C.'s alleged complaints of foot pain, Petitioner stated that she did not. The following colloquy occurred between Petitioner's counsel and Petitioner at the July 11, 2016 fact hearing regarding Petitioner's 2012 date book:

- Q. Did you, in fact, keep a date book back in August of 2012?
- A. Yes.
- Q. And is that a place you would record events that would occur in your life?
- A. Yeah. Just about everything I don't want to forget.
- Q. Okay. And you would -- and you have a copy of that that you've provided to us and we've submitted to the Court?
- A. Yes.
- Q. And just so the Court is clear, I'm showing you, this is the original. Is that right?
- A. Yes.
- Q. And have you at some point in time gone back and written in dates when you remember A.C. complaining about foot pain?
- A. Yes.
- Q. And when did you -- when did you go back and write those in, or actually, let me ask it this way: Did you write his complaints in contemporaneous to

his complaints? In other words, at the same time, or did you go back later and put those in?

A. I went back later and put those in.

Q. And do you remember when it was that you went back and put those in? A. It was when he first started seeing Dr. Holly Brown, and so that was in 2014, I believe.

As Petitioner testified at the July 11, 2016 hearing, Dr. Holly Brown is "a licensed acupuncturist and oriental medical doctor." Petitioner explained that Dr. Brown expressed concern that the vaccinations may have caused A.C.'s issues and told Petitioner to see how far back she could remember A.C. having any complaint at all.

Petitioner's counsel also asked Petitioner the following question regarding the 2012 date book at the July 11, 2016 hearing:

Q. Okay. And, so, there are certain dates where you wrote down on exact dates days that he complained. How is it that you remember two years later the specific dates that he had complained on?

A. Because I could remember those events and what was going on that day.

In addition to her supplemental affidavit, Petitioner filed affidavits from four of the six individuals⁹ she had previously alleged witnessed A.C.'s fall 2012 onset of symptoms in her supplemental affidavit: Jennifer Rowe and Jeremy Gordon, who each stated in their respective affidavits that they had witnessed A.C. experience foot pain in September 2012, and Irvin and Theresa Joseph, who each stated in their respective affidavits that they had witnessed A.C. experience foot pain in November 2012. Based on the affidavits. all four affiants did not independently recall the dates of their observations of A.C., but instead, based the dates they included in their affidavits on the dates Petitioner shared with each of them from her retroactively edited date book. The affidavits for Theresa and Irvin Joseph each state in identical wording that "I can remember the dates, because Heather Caron apparently maintained a date book with dates that she and I would have seen each other and recently shared that date book with me." The affidavits for Jennifer Rowe and Jeremy Gordon also respectively state in identical wording that "I can remember the date, because Heather Caron apparently maintained a date book with

⁹ Based on the record before the court, Petitioner did not provide an affidavit for Ms. O'Neill. Petitioner also did not provide an affidavit for Patricia Bailey despite Petitioner's statement in her Motion For Review that she "provided affidavits from Ms. Bailey and others regarding their observations of A.C." and her statement in her May 15, 2017 Request For Ruling On The Record before Special Master Roth that "[t]he record already contains affidavits from Ms. Bailey and others regarding their observations of A.C."

dates that this overnight would have occurred and recently shared that date book with me."

After Petitioner filed her November 16, 2015 supplemental affidavit and the four affidavits in support of an alleged fall of 2012 onset, Special Master Hamilton-Fieldman continued to have "concerns regarding the reliability of the evidence in support of the earlier alleged [2012] onset" and thus, on December 28, 2015, ordered Petitioner to file a brief "regarding the alleged timing of onset" and the government to file a responsive brief. In particular, Special Master Hamilton-Fieldman noted in her order, dated December 28, 2015, that Petitioner recently filed "affidavits and datebook . . . in support of her allegation that the onset of A.C.'s injury occurred in the fall of 2012." Special Master Hamilton-Fieldman then noted that "to the extent that these records contemporaneously document an early onset, they contradict previously submitted medical records documenting self-reported onset in January of 2013."

The parties subsequently submitted briefs to Special Master Hamilton-Fieldman regarding the alleged timing of the onset of A.C.'s symptoms. In her brief, Petitioner admitted that "the medical records indicate onset of symptoms as January of 2013," yet she argued that the multiple affidavits she had filed in support of her allegation of a fall 2012 onset "are overwhelmingly more persuasive than the medical records regarding the onset of A.C.'s symptoms." Petitioner stated that "should the Court not be persuaded by the affidavits in this matter, Petitioner requests an evidentiary hearing for the Court to resolve the apparent tension between the medical records and the later recorded recollections."

In its response brief, the government argued that Petitioner "has not shown by preponderant evidence that A.C.'s symptoms began in the fall of 2012." The government first argued that it "strains reason" to conclude that A.C.'s symptoms began in the fall of 2012 because the Special Master "would be required to find that either petitioner consistently misreported the onset of A.C.'s symptoms or that all of the medical providers affiliated with various institutions inaccurately recorded the same incorrect onset of January 2013." The government then argued that because Theresa Joseph, Irvin Joseph, Jennifer Rowe, and Jeremy Gordon, the four relatives of Petitioner and A.C. who submitted affidavits in this case, "have no independent recollection as to when they observed [A.C.'s] symptoms, their affidavits can be of little if any persuasive value as to onset, particularly given . . . petitioner's many and consistent contemporaneously recorded statements to medical providers that A.C.'s symptoms began in January 2013." The government also argued that the Special Master should not hold a fact hearing regarding the onset of A.C.'s symptoms, as requested by Petitioner in her brief regarding onset, because "[t]here is nothing in the record to suggest that at any time petitioner failed to report or inaccurately reported the onset of her son's symptoms."

Before Special Master Hamilton-Fieldman ruled on Petitioner's request for a fact hearing on onset or established an onset date, Petitioner's case was reassigned to Special Master Mindy Michaels Roth on January 14, 2016. Special Master Roth subsequently ordered that Petitioner's request for an onset hearing would be granted to discuss the probative value of the affidavits and date book. Before the onset hearing in front of Special Master Roth, Petitioner submitted her second, supplemental affidavit on June 21, 2016. This affidavit was identical to her previous affidavit submitted on November 16, 2015, with the exception of the final paragraph, which states that "[t]he reason that we did not seek medical evaluation for several months was due to a disagreement between me and my husband as to whether evaluation was necessary."

On July 11, 2016, the Special Master held a video conference fact hearing to determine the timing of onset. For the Petitioner, only Ms. Caron, the Petitioner, testified. On direct examination, Petitioner stated that she did not notice anything out of the ordinary immediately following the administration of A.C.'s alleged injurious vaccinations on August 2, 2012. "In the coming weeks or months" of the administration of the alleged injurious vaccines, Petitioner testified that A.C. "was having an abnormal gait . . . limping a little, complaining about a boo-boo on his foot. Nothing that was really too alarming." When asked by her counsel when A.C. first "started complaining about any foot-related pain, and being tired" Petitioner stated in August. When asked by her counsel whether she had "some significant concerns about [A.C.'s] foot complaints in the months following the vaccinations," Petitioner responded "[n]ot initially."

As previously discussed, Petitioner testified at the July 11, 2016 fact hearing that she kept a date book in 2012 and recorded "[j]ust about everything I don't want to forget" in her date book. She also testified, however, that she did not contemporaneously document A.C.'s complaints but instead went back in 2014 and made notes in the date book of when A.C. complained about foot pain at the suggestion of Dr. Holly Brown. Petitioner also discussed at the hearing the five occasions between August and December 2012 that A.C. presented with, what she alleged, were vaccine related symptoms. Petitioner then testified that she and her husband did not immediately seek medical attention for A.C.'s foot pain because her husband was "very insistent" that A.C.'s symptoms were "growing pains" and that they "weren't going to take him to the doctor," so Petitioner "had to listen" to her husband.

Petitioner eventually took A.C. to the doctor's office on December 4, 2012 for an ear ache. The medical records do not indicate that Petitioner mentioned A.C.'s foot pain at that visit. Petitioner, however, testified at the July 11, 2016 hearing before Special Master Roth that she did mention A.C.'s foot pain and that the "doctor agreed that they thought it was just growing pains and if it was something . . . just to bring him back" When Petitioner discussed A.C.'s next medical visit in January 2013, she initially testified at the July 11, 2016 hearing that she could not remember whether she had mentioned to the doctor that A.C. had been having foot pain throughout the fall. She later testified at that same hearing that she was "pretty sure" that she had discussed it "but it wasn't documented."

At the hearing, after the direct-examination of Petitioner concluded, the government did not cross examine Petitioner. Special Master Roth, however, posed several questions to Petitioner, including asking Petitioner about A.C.'s medical visits beginning in January 2013:

- Q. Let me just understand correctly that you said you believe that A.C.'s symptoms started in August, correct? Is that what you said?
- A. Yeah, I know they started in August.
- Q. Okay. What symptoms were those in August?
- A. It was just mild foot pain and fatigue.
- Q. And this fatigue, was that unusual for him?
- A. Yes.
- Q. And how long did it go on?
- A. It continued to progress on and off, and the fatigue would correspond with the foot pain. And then like in January was when things started to get severe.
- Q. Okay. So, your counsel took you through various doctors' visits. I want to take you back to January. I believe that you took A.C. to Mid Coast Hospital on January 9th, 2013, with 20 hours of high fever, and they did a joint exam and neuro exam on him which was normal. Did you mention to the doctors that he had been having this foot pain and this fatigue?
- A. Yes.
- Q. And they didn't document it?
- A. I guess not.
- Q. Okay. And in February, on the 8th, you took him to the pediatrician with a cold and a fever, five days of cough and fever of 103. Do you recall that?
- A. Yes.
- Q. Did you mention to the doctors that he had this foot pain that was continuing intermittently over the last several months?
- A. Yes.
- Q. You did?
- A. I mentioned that he was complaining about his foot and that my husband thought it was just growing pains.

Q. And what did the doctor say?

- A. They told me -- you know, it probably is, it doesn't seem like something we should be concerned about. They palpated his foot. And, you know, just told me to return if things get worse.
- Q. Okay. And on March 1st, you took him to the pediatrician with stomach pain for over an hour, crying, but it had resolved by the time you got there. Do you recall that?

A. Yeah.

Q. Did you mention to the doctor that he was still having this intermittent foot pain at that point?

A. I asked her if it could be connected, if they were all one thing, and she said probably not, he was probably just having some gas pain and, you know, wasn't concerned at all, just poo-poo'd the whole foot thing.

On December 14, 2016, Special Master Roth issued a Ruling On Onset, finding "that A.C.'s symptoms of CRMO began in January of 2013." See Caron v. Sec'y of Health & Human Servs., 2016 WL 7664309, at *15. The Special Master found that "the contemporaneous medical records and histories provided by petitioner to her child's medical providers at the time of the events more accurately reflect the onset of A.C.'s CRMO" than Petitioner's testimony, affidavits and date book. Id. at *2. Specifically, Special Master Roth found that the medical records "consistently reflect that A.C.'s symptoms started in January 2013-not before." Id. at *13. The Special Master highlighted that Petitioner showed no hesitation in seeking medical intervention for A.C. when he was ill, hurt or even had large bug bites. See id. at *15. She also noted that the medical records documented that A.C. began having foot pain in January of 2013 and Petitioner took him to the pediatrician with that complaint. See id. The Special Master reiterated that it "strains reason" to conclude that Petitioner would have failed to accurately report to physicians the onset of A.C.'s symptoms. Id. She also noted that it was equally unlikely that all of the various doctors who had seen A.C., who are presumably trained in taking medical histories, would have failed to document or would inaccurately have documented the mother's complaints of the onset of his condition. See id. Special Master Roth also stated that:

Petitioner is ordered to provide a copy of this fact ruling to each of her expert witnesses. Petitioner's expert(s) must rely on the facts as I have found them in this Ruling. In crafting their expert report, no expert may rely on Ms. Caron's testimony, affidavit, or the affidavits submitted by the various individuals who relied solely on Ms. Caron's date book for their recollections of events. . . . By no later than Tuesday, March 14, 2017, petitioner must file either an expert report that is based on the facts as I have found them herein, or a status report indicating how she intends to proceed. If petitioner is unable to secure reports from her expert(s) based on the timing of onset

as I have found it, she must file either a motion to dismiss, a joint stipulation for dismissal, or a motion for a ruling on the record, all of which will result in the dismissal of her claim.

ld.

Thereafter, Petitioner filed a status report with Special Master Roth requesting a deadline for filing a request for a ruling on the record so as to seek "judicial review" of the "Court's conclusion that [A.C.'s] symptoms started much later than what his mother testified to " Petitioner filed her Request For Ruling On The Record on May 15, 2017. Petitioner stated that Special Master Roth should "reconsider the earlier decision regarding onset of A.C.'s symptoms and hold a hearing." Petitioner argued "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." Further, Petitioner challenged Special Master Roth's previous order in her December 14, 2016 Ruling On Onset that any expert witnesses engaged by Petitioner must rely on the Special Master's finding that the onset of A.C.'s symptoms of CRMO began in January 2013. Id. Petitioner argued to Special Master Roth "that had she been allowed to seek an expert opinion regarding the cause of the osteomyelitis occurring just weeks after the vaccination . . . she would have been fully able to meet her burden under Althen [Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005)]." Petitioner claimed that she "can establish at hearing that [A.C.'s] vaccinations caused his osteomyelitis under the Althen standard." She attached two exhibits to her Request For Ruling On The Record as support: an on-line article providing a general overview of vaccinations, and a five-page article reporting two cases of osteomyelitis as a complication of the Varicella virus.

On September 7, 2017, Special Master Roth issued her Decision Denying Entitlement, finding that Petitioner had failed to carry her burden of proving causation and the Special Master dismissed the Petition. See Caron v. Sec'y of Health & Human Servs., 2017 WL 4349189, at *10. Special Master Roth explained that Petitioner had "failed to provide any expert or medical evidence to support her claim that the vaccinations A.C. received in August 2012 caused his injuries." Id. The Special Master also noted that "none of A.C.'s treating physicians related the CRMO to any of the vaccinations he received." Id. Special Master Roth concluded that Petitioner "cannot sustain her burden of proof on any of the Althen prongs." Id.

In that same decision, Special Master Roth also denied Petitioner's request for reconsideration of her December 14, 2016 Ruling On Onset regarding the Special Master's determination of a January 2013 onset date and Petitioner's demand for a hearing. The Special Master explained that it was procedurally improper because, pursuant to the Vaccine Rules, a party may only seek reconsideration of a special master's "decision on whether the petitioner is entitled to 'an award of compensation' and 'if so, the amount thereof." Id. at *8 (quoting Vaccine Rule 10(a) (2017)). According to Special Master Roth, the Special Master's December 14, 2016 Ruling On Onset "was not a decision but rather, it was a *ruling* following a fact hearing which resolved" evidentiary discrepancies and was "thus not a 'decision' that was subject to a motion for

reconsideration under the Vaccine Rules." <u>Id.</u> (emphasis in original). Special Master Roth also stated that Petitioner's request for reconsideration was "without basis" because Petitioner "has not identified anything that would change the outcome of the Ruling On Onset." <u>Id.</u> Thus, according to Special Master Roth, "petitioner's discontent with the Ruling On Onset would not satisfy the standard [for a motion for reconsideration] under Vaccine Rule 10(e)(3)." <u>Id.</u> at *9. Petitioner then filed her Motion For Review Of Special Master's Decision And Memorandum In Support Of The Same in this court on September 26, 2017.

DISCUSSION

Before this court, Petitioner frames the Motion For Review as challenging the Special Master's December 14, 2016 Ruling On Onset, in which Special Master Roth found a January 2013 onset of symptoms, and also Special Master Roth's September 7, 2017 Decision Denying Entitlement. In her Motion For Review, 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 are sufficient to overcome the rebuttable presumption that the information contained in the medical records is accurate." Although Petitioner essentially admits in her Motion For Review before this court that she has not presented evidence of causation to meet her burden of proof for compensation under the Vaccine Program, Petitioner argues that the Special Master's December 14, 2016 Ruling On Onset establishing a January 2013 onset prevented her from presenting such evidence. Petitioner argues that she "has been denied the opportunity to even present evidence to meet her burden by the Special Master's decision regarding onset of symptoms." Petitioner asserts that "[b]ecause of the Special Master's ruling [of a January 2013 onset]. Petitioner was unable to secure an expert opinion regarding the relationship between the administration of the vaccinations and an onset of symptoms that long after the vaccinations." Petitioner argues that "[h]ad the Special Master allowed Petitioner to show an expert credible evidence that A.C. was experiencing symptoms soon after the vaccination, she could have likely established at a hearing that the vaccinations caused his osteomyelitis under the Althen standard." Thus, according to Petitioner, "the Special Master's decision effectively precluded Petitioner from establishing causation, because Petitioner was unable to tell an expert that A.C. was experiencing symptoms soon after the vaccination." Petitioner "submits that she . . . should be allowed to pursue obtaining an expert opinion consistent with this evidence and have an evidentiary hearing to establish whether she is entitled to compensation."

The government responds that "Petitioner has not shown that the special master's determination was arbitrary, capricious, an abuse of discretion, or not in accordance with law," and thus, "the special master's Decision must be affirmed." According to the government, in her decision, the Special Master "carefully articulated and properly applied the controlling law . . . [and] thoroughly reviewed and evaluated the evidence as a whole." In particular, the government argues that "the medical records . . . reveal petitioner to be a very observant parent, who did not hesitate to take her son to see the doctor for more minor health issues." The government also notes that "the medical records from both before and after vaccination show petitioner to be a very reliable historian" and that

"petitioner consistently told each of her son's doctors that his symptoms began in January 2013." The government explains that "for the special master to have concluded that A.C.'s symptoms began earlier [than January 2013], she would be required to find that either petitioner consistently misreported the onset of AC's symptoms or that all of the medical providers affiliated with various institutions inaccurately recorded the same incorrect onset of January 2013." As it stated earlier in the proceedings, according to the government, such a conclusion "strains reason."

When reviewing a Special Master's decision, the assigned Judge of the United States Court of Federal Claims shall:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
- (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The legislative history of the Vaccine Act states: "The conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Rep. No. 101-386, at 517 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3120.

In order to recover under the Vaccine Act, Petitioners must prove that the vaccine caused the purported injury. See W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1355-56 (Fed. Cir. 2013) ("The Vaccine Act created the National Vaccine Injury Compensation Program, which allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had significantly aggravated' a vaccine-related 'illness, disability, injury, or condition." (quoting 42 U.S.C. § 300aa–11(c)(1)(C))); Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1350 (Fed. Cir. 2011) ("A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine."); see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. 353, 358 (2012), aff'd, 503 F. App'x 952 (Fed. Cir. 2013); Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54 (2011).

Regarding the standard of review, articulated in Markovich v. Secretary of Health and Human Services, the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1355-56 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363,

1366 (Fed. Cir.) (The United States Court of Appeals for the Federal Circuit stated that "we 'perform[] the same task as the Court of Federal Claims and determine[] anew whether the special master's findings were arbitrary or capricious." (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000))) (brackets in original), reh'g and reh'g en banc denied (Fed. Cir. 2013); W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355; Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012); Avera v. Sec'y of Health & Human Servs., 515 F.3d 1343, 1347 (Fed. Cir.) ("Under the Vaccine Act, we review a decision of the special master under the same standard as the Court of Federal Claims and determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." (quoting 42 U.S.C. § 300aa-12(e)(2)(B))), reh'g and reh'g en banc denied (Fed. Cir. 2008); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1350 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2008); Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 47 (2013); Taylor v. Sec'y of Health & Human Servs., 108 Fed. Cl. 807, 817 (2013). The arbitrary and capricious standard is "well understood to be the most deferential possible." Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 (Fed. Cir. 1992).

Therefore, this court may set aside a Special Master's decision only if the court determines that the "findings of fact or conclusion of law of the special master . . . [are] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" 42 U.S.C. § 300aa-12(e)(2)(B); see also Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1350 ("We uphold the special master's findings of fact unless they are arbitrary or capricious.") (internal citations omitted); Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Markovich v. Sec'y of Health & Human Servs., 477 F.3d at 1356-57; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360. The United States Court of Appeals for the Federal Circuit has indicated that:

These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard . . . ; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.

Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d at 871 n.10; see also Carson ex rel. Carson v. Sec'y of Health & Human Servs., 727 F.3d 1365, 1369 (Fed. Cir. 2013); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355; Griglock v. Sec'y of Health & Human Servs., 687 F.3d 1371, 1374 (Fed. Cir. 2012); Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010)) (explaining that the reviewing court "do[es] not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder"); Dodd v.

<u>Sec'y of Health & Human Servs.</u>, 114 Fed. Cl. at 56. "With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The Claims Court owes these findings and conclusions by the special master great deference – no change may be made absent first a determination that the special master was 'arbitrary and capricious." <u>Munn v. Sec'y of Health & Human Servs.</u>, 970 F.2d at 870; <u>see also</u> 42 U.S.C. § 300aa-12(e)(2)(B).

Generally, "if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (quoting Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)); see also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1253-54; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360; Avila ex rel. Avila v. Sec'y of Health & Human Servs., 90 Fed. Cl. 590, 594 (2009); Dixon v. Sec'y of Health & Human Servs., 61 Fed. Cl. 1, 8 (2004) ("The court's inquiry in this regard must therefore focus on whether the special master examined the 'relevant data' and articulated a 'satisfactory explanation for its action including a "rational connection between the facts found and the choice made." (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)))).

As noted by the United States Court of Appeals for the Federal Circuit:

Congress assigned to a group of specialists, the special masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the special masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

<u>Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.</u>, 9 F.3d 958, 961 (Fed. Cir. 1993)) (modification in original); <u>Hibbard v. Sec'y of Health & Human Servs.</u>, 698 F.3d at 1363; <u>Locane v. Sec'y of Health & Human Servs.</u>, 685 F.3d 1375, 1380 (Fed. Cir. 2012). The Court of Appeals for the Federal Circuit has further explained that the reviewing courts "do not sit to reweigh the evidence. [If] the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious." <u>See Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.</u>, 717 F.3d at 1367 (quoting <u>Lampe v. Sec'y of Health & Human Servs.</u>, 219 F.3d at 1363) (modification in original); <u>see also Hibbard v. Sec'y of Health & Human Servs.</u>, 698 F.3d at 1363 (citing <u>Cedillo v. Sec'y of Health & Human Servs.</u>, 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

The Special Master has discretion to determine the relative weight of evidence presented, including contemporaneous medical records and oral testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (finding that the Special Master had thoroughly considered evidence in record, had discretion not to hold an additional evidentiary hearing); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1368 (finding it was not arbitrary or capricious for the Special Master to weigh diagnoses of different treating physicians against one another, including when their opinions conflict). "Clearly it is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder." Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56 (quoting Munn v. Sec'y of Dept. of Health & Human Servs., 970 F.2d at 870 n.10); see also Rich v. Sec'y of Health & Human Servs., 129 Fed. Cl. 642, 655 (2016); Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. 457, 467 (2012) ("A special master's findings regarding the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are 'supported by substantial evidence." (quoting Doe v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir.), cert. denied, 562 U.S. 1029 (2010))).

Additionally, a Special Master is "not required to discuss every piece of evidence or testimony in [his or] her decision." Snyder ex rel. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 728 (2009); see also Paluck ex rel. Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. at 467 ("[W]hile the special master need not address every snippet of evidence adduced in the case, see id. [Doe v. Sec'y of Health & Human Servs., 601 F.3d at 1355], he cannot dismiss so much contrary evidence that it appears that he 'simply failed to consider genuinely the evidentiary record before him.'" (quoting Campbell v. Sec'y of Health & Human Servs., 97 Fed. Cl. 650, 668 (2011))).

With regard to the Special Master's weighing of evidence when testimony conflicts with contemporaneous medical records, the Special Master generally should afford contemporaneous medical records greater weight than conflicting testimony offered after the fact. Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed Cir. 1992) (citing United States v. United States Gypsum Co., 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")). This is because medical records created contemporaneously with the events they describe are presumed to be accurate and complete. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). The United States Court of Appeals for the Federal Circuit has explained:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

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Nevertheless, there are situations when oral testimony may be more persuasive than written records. For example, this may be so where medical records are inaccurate or incomplete. See Campbell ex rel. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 779 (2006) ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent. Records which are incomplete may be entitled to less weight than records which are complete." (quoting Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. at 733)). Inconsistencies in medical records may result from (1) a petitioner's failure to recount to the medical professional everything that happened during the relevant time period, (2) the medical professional's failure to document everything that petitioner told him or her, (3) a petitioner's faulty recollection of events when presenting testimony, or (4) a petitioner purposely recounting symptoms that did not exist. See La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 203-04 (2013) aff'd 746 F.3d 1334 (Fed. Cir. 2014). There are "perfectly valid reasons why [medical records] may not be complete." Id. at 203 n.33. For example, "it would not surprise the court if [Petitioner] did not recall, or recount to the pediatrician, each and every symptom that she observed" given that Petitioner "had just endured a sleepless, and undoubtedly terrifying, night caring for a child experiencing an anaphylactic reaction . . . serious enough to cause the pediatrician to call for an ambulance " ld.

"Oral testimony that is inconsistent with medical records must be consistent, clear, cogent and compelling to outweigh the medical records prepared for the purpose of diagnosis and treatment." Camery v. Sec'y of Dep't of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998). Thus, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Human Servs., 569 F .3d 1367, 1379 (Fed. Cir. 2009). "Such a determination of credibility is uniquely within the purview of the special master." Burns v. Sec'y of Dep't of Health & Human Servs., 3 F.3d at 417 (special master did not err in accepting contemporaneous medical records over the testimony of fact witnesses).

Regarding the causation analysis, as indicated by the United States Court of Appeals for the Federal Circuit in <u>Althen v. Secretary of Health and Human Services</u>:

The [Vaccine] Act provides for the establishment of causation in one of two ways: through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ("Table injury"), see 42 U.S.C. § 300aa-14(a); or where the complained-of injury is not listed in the Vaccine Injury Table ("off-Table injury"), by proving causation in fact, see 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I).

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356; Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346; Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 551 U.S. 1102 (2007);

<u>Dodd v. Sec'y of Health & Human Servs.</u>, 114 Fed. Cl. at 50; <u>Paluck v. Sec'y of Health & Human Servs.</u>, 104 Fed. Cl. at 467-68; <u>Fesanco v. Sec'y of Health & Human Servs.</u>, 99 Fed. Cl. 28, 31 (2011). The United States Supreme Court has explained that:

Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation. No showing of causation is necessary; the Secretary bears the burden of disproving causation. A claimant may also recover for unlisted side effects, and for listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation.

Bruesewitz v. Wyeth LLC, 562 U.S. 223, 228-229 (2011) (footnotes omitted); Kennedy v. Sec'y of Health & Human Servs., 99 Fed. Cl. 535, 539 (2011), aff'd, 485 F. App'x. 435 (Fed. Cir. 2012).

As both parties recognize, the injuries Petitioner alleges A.C. suffered as a result of the DTaP, HIB, MMR and Varicella vaccinations are not included on the Vaccine Injury Table. See 42 U.S.C. § 300aa-14. Petitioner, therefore, must proceed under an off-Table theory of recovery. Under the off-Table theory of recovery, a petitioner is entitled to compensation if he or she can demonstrate, by a preponderance of the evidence, see 42 U.S.C. § 300aa-13(a)(1)(A), that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table, but which was caused by a vaccine that is listed on the Vaccine Injury Table. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); see also LaLonde v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014); W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 ("Nonetheless, the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." (quoting Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322)); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Human Servs.. 940 F.2d at 1525. While scientific certainty is not required, the Special Master "is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly ex rel. Moberly ex rel. v. Sec'y of Health & Human Servs., 592 F.3d at 1324; see also Hazlehurst v. Sec'y of Health & Human Servs., 88 Fed. Cl. 473, 439 (2009), aff'd, 604 F.3d 1343 (Fed. Cir. 2010) (quoting Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009)).

Additionally, Petitioner must prove causation-in-fact. See Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992). The United States Court of Appeals for the Federal Circuit has held that causation-in-fact in the Vaccine Act context is the same as the "legal cause" in the general torts context. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "a substantial factor in bringing about the harm." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting the Restatement (Second) of Torts § 431(a)); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 ("To prove causation, a

petitioner 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." (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352–53)). A "substantial factor' standard requires a greater showing than 'but for' causation." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). "However, the petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor." Id. (citing Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007)). A Judge of the United States Court of Federal Claims has explained the relationship between "but-for" causation and "substantial factor" causation in our court's decision in Deribeaux ex rel. Deribeaux v. Secretary of Health and Human Services:

The <u>de Bazan</u> [<u>de Bazan v. Sec'y of Health & Human Servs.</u>, 539 F.3d at 1351] court defined but-for causation as requiring that "the harm be attributable to the vaccine to some nonnegligible degree," and noted that, although substantial is somewhere beyond the low threshold of but-for causation, it does not mean that a certain factor must be found to have definitively caused the injury. <u>Id.</u> [<u>de Bazan v. Sec'y of Health & Human Servs.</u>, 539 F.3d at 1351] Accordingly, a factor deemed to be *substantial* is one that falls somewhere between causing the injury to a non-negligible degree and being the "sole or predominant cause." <u>Id.</u>

This definition of substantial—somewhere between non-negligible and predominant—is applicable to respondent's burden to prove a sole substantial factor unrelated to the vaccine. Accordingly, a respondent's burden is to prove that a certain factor is the only *substantial* factor—one somewhere between non-negligible and predominant—that caused the injury.

<u>Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.</u>, 105 Fed. Cl. 583, 595 (2012), <u>aff'd</u>, 717 F.3d 1363 (Fed. Cir.), <u>reh'g and reh'g en banc denied</u> (Fed. Cir. 2013) (emphasis in original).

As indicated above, a petitioner must prove his or her case by a preponderance of the evidence. See 42 U.S.C. § 300aa-13(a)(1)(A). According to the United States Court of Appeals for the Federal Circuit, the preponderance of evidence standard is "one of proof by a simple preponderance, of 'more probable than not causation." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80 (citing concurrence in Hellebrand v. Sec'y of Dep't of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 ("In this off-table case, the petitioner must show that it is 'more probable than not' that the vaccine caused the injury." (quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80)). A petitioner who meets this burden is then entitled to recovery under the Vaccine Act, unless the respondent proves by preponderant evidence that the injury was caused by factors unrelated to the vaccine. See Stone v. Sec'y of Health & Human Servs., 676 F.3d 1373, 1379-80 (Fed. Cir. 2012); see also Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl.

672, 680 (2016) (citing 42 U.S.C. § 300aa-13(a)(1)(B); Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995)); Walther v. Sec'y of Health & Human Servs., 485 F.3d at 1151. "But, regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case." Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. at 680 (citing Stone v. Sec'y of Health & Human Servs., 676 F.3d at 1379; de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1353).

For Petitioner to establish a prima facie case in a vaccine case, decisions of the Federal Circuit permit the use of circumstantial evidence, which the court described as "envisioned by the preponderance standard" and by the vaccine system created by Congress, in which "close calls regarding causation are resolved in favor of injured claimants" without the need for medical certainty. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280; see also Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322, 1332 n.4 (Fed. Cir. 2011), <u>cert. denied</u>, 566 U.S. 956 (2012); Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1379 ("In Althen, however, we expressly rejected the Stevens test, concluding that requiring 'objective confirmation' in the medical literature prevents 'the use of circumstantial evidence . . . and negates the system created by Congress' through the Vaccine Act.") (modification in original); La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. at 198 ("Causation-in-fact can be established with circumstantial evidence, i.e., medical records or medical opinion."). The Althen court further noted that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id. (citing Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356. When proving eligibility for compensation for an off-Table injury under the Vaccine Act, however, Petitioner may not rely on her testimony alone. According to the Vaccine Act. "[t]he 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." 42 U.S.C. § 300aa-13(a)(1).

The Federal Circuit in <u>Althen</u> defined a three-prong test which a petitioner must meet to establish causation in an off-Table injury case:

To meet the preponderance standard, [petitioner] must "show a medical theory causally connecting the vaccination and the injury." <u>Grant v. Sec'y of Health & Humans Servs.</u>, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]" <u>Grant</u>, 956 F.2d at 1148. [Petitioner] may recover if she shows "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." <u>Shyface</u>, 165 F.3d at 1352-53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic

elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant, 956 F.2d at 1149. Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] 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.

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (brackets in original); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367; Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1249; Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322; Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355; Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006); C.K. v. Sec'y of Health & Human Servs., 113 Fed. Cl. 757, 766 (2013).

With regard to the first Althen prong, "a medical theory causally connecting the vaccination and the injury," Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278, the Federal Circuit in Althen analyzed the preponderance of evidence requirement as allowing medical opinion as proof, even without scientific studies in medical literature that provide "objective confirmation" of medical plausibility. Id. at 1278, 1279-80; see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. at 358. In rejecting a requirement that a claimant under the Vaccine Act prove confirmation of medical plausibility from the medical community and medical literature, the Althen court turned to the analysis undertaken in Knudsen ex rel. Knudsen v. Secretary of Health and Human Services, 35 F.3d at 549. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80. In Knudsen ex rel. Knudsen v. Secretary of Health and Human Services, the United States Court of Appeals for the Federal Circuit wrote, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 549. The Federal Circuit in Knudsen stated further:

[t]he Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. The special masters are not "diagnosing" vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury or that the [petitioner's] injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a

factor unrelated to the vaccine caused the child's injury. <u>See</u> 42 U.S.C. § 300aa-13(a)(1), (b)(1).

Id. (brackets added).

The Federal Circuit also has indicated that:

Although a finding of causation "must be supported by a sound and reliable medical or scientific explanation," causation "can be found in vaccine cases . . . without detailed medical and scientific exposition on the biological mechanisms." Knudsen v. Sec'y of the Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of the evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be.

Simanski v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1384 (Fed. Cir. 2012) (omission in original).

The second prong of the <u>Althen</u> test requires the petitioner to demonstrate "a logical sequence of cause and effect, showing that the vaccination was the reason for the injury" by a preponderance of the evidence. <u>Althen v. Sec'y of Health & Human Servs.</u>, 418 F.3d at 1278; <u>see also Pafford v. Sec'y of Health & Human Servs.</u>, 451 F.3d at 1355. In order to prevail, the petitioner 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." <u>Althen v. Sec'y of Health & Human Servs.</u>, 418 F.3d at 1278 (quoting <u>Shyface v. Sec'y of Health & Human Services</u>, 440 F.3d at 1352). In <u>Capizzano v. Secretary of Health and Human Services</u>, 440 F.3d at 1326, the Federal Circuit stated, "[a] logical sequence of cause and effect' means what it sounds like – the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." <u>Capizzano v. Sec'y of Health & Human Servs.</u>, 440 F.3d at 1326 (quoting 42 U.S.C. §§ 300aa-11(c)(1) – 13(a)(1) (2006)); <u>see also Cozart v. Sec'y of Health & Human Servs.</u>, 126 Fed. Cl. 488, 498 (2016) (quoting <u>Althen v. Sec'y of Health & Human Servs.</u>, 418 F.3d at 1278).

The third prong of the <u>Althen</u> test requires the petitioner to demonstrate, by a preponderance of evidence, "a proximate temporal relationship between vaccination and injury." <u>Althen v. Sec'y of Health & Human Servs.</u>, 418 F.3d at 1278. The United States Court of Appeals for the Federal Circuit emphasized the importance of a temporal relationship in <u>Pafford v. Secretary of Health and Human Services</u>, when it noted that, "without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm." <u>Pafford v. Sec'y of Health & Human Servs.</u>, 451 F.3d at 1358. Requiring evidence of strong temporal linkage is consistent with the third requirement articulated in <u>Althen</u> because "[e]vidence demonstrating petitioner's injury occurred within a medically acceptable time frame

bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis." <u>Id.</u> (citing <u>Capizzano v. Sec'y of Health & Human Servs.</u>, 440 F.3d at 1326). The <u>Pafford</u> court further explained,

[i]f, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor. Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury.

<u>Pafford v. Sec'y of Health & Human Servs.</u>, 451 F.3d at 1358. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." <u>de Bazan v. Sec'y of Health & Human Servs.</u>, 539 F.3d at 1352. Determining what constitutes a medically appropriate timeframe, thus, is linked to the petitioner's theory of how the vaccine can cause petitioner's injury. <u>See id.</u>; <u>see also K.T. v. Sec'y of Health & Human Servs.</u>, 132 Fed. Cl. 175, 186 (2017); <u>Shapiro v. Sec'y of Health & Human Servs.</u>, 101 Fed. Cl. 542, 542 (2011).

According to the court in <u>Capizzano v. Secretary of Health and Human Services</u>, evidence used to satisfy one of the <u>Althen</u> prongs may overlap with and be used to satisfy another prong. <u>Capizzano v. Sec'y of Health & Human Servs.</u>, 440 F.3d at 1326 ("We see no reason why evidence used to satisfy one of the <u>Althen III</u> [Althen v. Sec'y of Health & <u>Human Servs.</u>, 418 F.3d at 1274] prongs cannot overlap to satisfy another prong."). If a petitioner satisfies the <u>Althen</u> burden and meets all three prongs of the test, the petitioner prevails, "unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." <u>Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs.</u>, 35 F.3d at 547 (brackets in original; quotation omitted).

In her Motion For Review, Petitioner challenges the Special Master's December 14, 2016 Ruling On Onset, in which the Special Master found that A.C.'s onset of symptoms occurred in January 2013, as evidenced by the medical records, submitted by Petitioner. Petitioner argues "that the testimony of A.C.'s parents[10] and the affidavits submitted by independent witnesses regarding the onset of A.C.'s symptoms are

¹⁰ Although Petitioner refers here to "A.C.'s parents," the record demonstrates that A.C.'s father did not testify at the July 11, 2016 fact hearing, nor did he submit an affidavit. A.C.'s mother, Petitioner Heather Caron, was the only parent of A.C. to provide testimony in this case.

sufficient to overcome the rebuttable presumption that the information contained in the medical records is accurate." Petitioner then argues that the December 14, 2016 Ruling On Onset also "denied [her] the opportunity to even present evidence to meet her burden" of proving causation under the Act. In particular, Petitioner alleges that because of the Special Master's December 14, 2016 finding of a January 2013 onset, Petitioner "was unable to secure an expert opinion regarding [sic] relationship between the administration of the vaccinations and an onset of symptoms that long after the vaccinations." Petitioner also argues that the Special Master's September 7, 2017 Decision Denying Entitlement, which resulted in her petition for compensation being dismissed, should be "set aside" and that she "should be allowed to pursue obtaining an expert opinion consistent with this evidence and have an evidentiary hearing to establish whether she is entitled to compensation."

The government responds that the Special Master "thoroughly reviewed and evaluated the evidence as a whole and properly concluded that the onset of AC's CRMO occurred in January 2013, and that petitioner failed to offer a persuasive medical theory causally connecting the vaccinations and AC's alleged injury." In particular, the government argues that "[i]n order for the special master to have concluded that AC's symptoms began earlier, she would be required to find that either petitioner consistently misreported the onset of AC's symptoms or that all of the medical providers affiliated with various institutions inaccurately recorded the same incorrect onset of January 2013." As noted above, the government argues that "[t]his conclusion strains reason."

"With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master." Munn v. Sec'y of Health & Human Servs., 970 F.2d at 870. The reviewing Court of Federal Claims judge owes the findings of the Special Master great deference, and the court should not overrule the Special Master absent a determination that the Special Master acted arbitrarily, capriciously, or against the law. See id. This court "must therefore focus on whether the Special Master examined the relevant data and articulated a satisfactory explanation for [his or her] action including a rational connection between the facts found and the choice made." Dixon v. Sec'y of Dep't of Health & Human Servs., 61 Fed. Cl. at 8 (internal quotations omitted). For example, in Cucuras v. Secretary of Department of Health and Human Services, to which Special Master Roth cited and discussed in her December 14, 2016 Ruling On Onset, the Cucuras Special Master, "after considering the record as a whole," determined that two contemporaneous medical records, which indicated a later onset, were more persuasive than the Cucuras Petitioners' testimony that their child's seizures began within one day of her vaccinations. Cucuras v. Sec'y of Health & Human Servs., 26 Cl. Ct. 537, 542 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993). The reviewing judge held that the Special Master's finding of a later than alleged onset documented by contemporaneous medical records was not arbitrary or capricious and that the Special Master's conclusion that the Cucuras Petitioners' testimony did not overcome the medical record evidence was reasonable. The Cucuras court explained:

In light of this concern for Nicole's treatment and petitioners' specific suspicion that the DTP was implicated in causing Nicole's problems, it

strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred.

<u>Id.</u> at 543.

In the case currently before the court, the record demonstrates that Special Master Roth "examined" Petitioner's sworn testimony, as well as the affidavits of the four family members, and Petitioner's reconstructed date book, submitted by the Petitioner. Once assigned to the case after Special Master Hamilton-Fieldman, Special Master Roth ordered and held an evidentiary hearing regarding onset and heard Petitioner's testimony that A.C.'s onset of symptoms began during the fall of 2012. Following Petitioner's presentation at the July 11, 2016 fact hearing, Special Master Roth also further questioned Petitioner about A.C.'s condition and medical visits after receiving the allegedly causal vaccinations. The government did not cross-examine Petitioner and Petitioner was the only person to testify at the evidentiary hearing.

In her Ruling On Onset, Special Master Roth noted that Petitioner's evidence of a fall 2012 onset conflicted with the contemporaneous medical records which established a January 2013 onset. See Caron v. Sec'y of Health & Human Servs., 2016 WL 7664309, at *1. In her Ruling On Onset, Special Master Roth individually reviewed Petitioner's affidavits and the four affidavits from relatives. See id. at *9-11. She also carefully reviewed Petitioner's testimony at the July 11, 2016 onset fact hearing. See id. at *11-13. The Special Master noted that Petitioner did not submit an affidavit from her husband or from Dixy Love-O'Neill, the individual who, according to Petitioner, A.C. allegedly visited on October 15, 2012 and to whom A.C. allegedly complained to about his foot pain. See id. at *11. The Special Master also stated: "Of the affidavits submitted, none was based on an independent recollection of the events. Everyone relied upon the date book that had been provided to them by Ms. Caron." Id. at *11. The Special Master specifically explained in her Ruling:

Each of these individuals based their recall of the events on a "date book" provided to them by Ms. Caron. At the Hearing, Ms. Caron confirmed that she went back to her date book almost two years later and added the details upon which the affiants relied in drafting their Affidavits. Tr. 10.2. to 10.9. None of these individuals testified at Hearing.

<u>ld.</u> at *10.

The Special Master also indicated in her Ruling On Onset why she found that Petitioner's evidence did not overcome the presumption in favor of the contemporaneous medical records. Special Master Roth explained:

Ms. Caron showed no hesitation in seeking medical intervention for A.C. when he was ill, hurt or even had large bug bites. Ms. Caron is a vigilant mother who routinely took A.C. to the pediatrician for any and all health related issues. To that end, the medical records document that A.C. began having pain in his foot in January and that Ms. Caron took him to the pediatrician with that complaint. . . . [I]t strains reason to conclude that petitioner would fail to accurately report the onset of A.C.'s symptoms to his physicians. It is equally unlikely that all of the various doctors that saw A.C., who are presumably trained in taking medical histories, would fail to document or would inaccurately document the mother's complaints of onset of his condition.

See id. at *15.

The record before this court supports the Special Master's Ruling On Onset and demonstrates that the Special Master rationally explained and concluded that Petitioner's testimony and multiple affidavits, affidavits of relatives and friends, and her date book do not overcome the presumption in favor of the information contained in the contemporaneous medical records. See Carson ex rel. Carson v. Sec'y of Health & Human Servs., 727 F.3d at 1369; see also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1253-54; Munn v. Sec'y of Health & Human Servs., 970 F.2d at 870. The record establishes that Petitioner as a vigilant mother, took A.C. to the pediatrician's office over forty times during A.C.'s first three years of life. She also took A.C. to the emergency room. For instance, when A.C. was two years old, Petitioner took A.C. to the emergency room after falling forward and cutting his forehead with his toy train. Shortly after that visit, Petitioner took A.C. to the emergency room again for a cough and sinus congestion, because Petitioner was unable to get A.C. in to see his primary care physician. Petitioner's pattern was, repeatedly, to seek medical attention for her son's health issues. The record before the Special Master and this court demonstrates that Petitioner did not seek medical treatment for A.C.'s alleged vaccine related symptoms until January 2013. almost five months after the administration of the vaccines on August 2, 2012. The contemporaneous record supports a finding that A.C.'s alleged vaccine related onset of symptoms began in January 2013, and that his mother sought medical attention for those symptoms at that time.

The medical records consistently reflect a January 2013 onset of the symptoms allegedly caused by the August 2, 2012 vaccinations. Notably, none of the medical records of the various medical providers who A.C. saw prior to January 2013 documented information that support a fall 2012 onset. For example, on April 2, 2013, A.C.'s rheumatologist noted that "[h]e was well until January [2013] when he started complaining of pain in the right foot and ankle." During A.C.'s April 2013 hospital stay, the pediatric oncologist noted that "[i]n January of 2013 [complaining of] intermittent pain in foot. Pain self resolved. Pain reoccurred And seen by orthopedics." During that same hospital stay, the resident pediatric specialist also stated that "[m]om reports that in January, he had right foot with limping . . . Symptoms resolved within 1 week." The pediatric infectious disease consult in April 2013 also noted that "[t]he history was obtained from mother. . . .

[A.C.] was in his typical state of health until mid January when he began to have pain of his right foot and ankle." There is no evidence in the records before the court that Petitioner told, or that A.C.'s medical providers found, that A.C.'s symptoms began earlier than January 2013, in fact, to the contrary.

The only indication of a fall 2012 onset comes from Petitioner's own testimony and affidavits, her reconstructed date book, and the four affidavits provided by relatives of A.C., which all are dependent on Petitioner's version of the alleged dates regarding A.C.'s alleged symptoms before January 2013. As Special Master Roth noted in her Ruling On Onset, none of the four affiants can independently remember the dates when A.C. visited them and presented with symptoms. They all attested that they could only remember the specific dates of A.C.'s visits because "Heather Caron apparently maintained a date book with dates" and that she "recently shared that date book with me." As discussed above, A.C.'s mother admitted she did not note A.C.'s alleged complaints of vaccine related injuries in the 2012 date book contemporaneously with the alleged events. Petitioner wrote in her notes regarding A.C.'s alleged complaints in the 2012 date book approximately two years later in 2014. According to the Vaccine Act, regarding a finding of when onset occurred, "[t]he 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." 42 U.S.C. § 300aa-13(a)(1). The Special Master's explanation and conclusion that Petitioner's evidence did not outweigh the presumption in favor of the accuracy of medical records was not arbitrary, capricious, an abuse of discretion or contrary to law. Likewise, the Special Master's finding that A.C.'s onset of symptoms occurred in January 2013, as documented by the medical records, was not arbitrary, capricious, an abuse of discretion or contrary to law. See Burns v. Sec'y of Dep't of Health & Human Servs., 3 F.3d at 417; see also Cucuras v. Sec'y of Health & Human Servs., 993 F.2d at 1528; see also Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. at 734.

This court is tasked upon review of a Special Master's decision, to determine whether Special Master Roth "examined the relevant data and articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made," Dixon v. Sec'y of Dep't of Health & Human Servs., 61 Fed. Cl. at 8 (internal citations omitted), not to reweigh the evidence. See Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56. As discussed above, the record demonstrates that Special Master Roth held an onset hearing and thereafter carefully examined the medical records as well as the evidence submitted by Petitioner. She rationally concluded that Petitioner's testimony and her affidavits submitted in this case did not overcome the presumption in favor of the contemporaneous medical records in the record before the court. Therefore the Special Master's ruling of a January 2013 onset was not arbitrary, capricious, an abuse of discretion or contrary to law.

Petitioner also alleges that she has been "denied the opportunity to even present evidence to meet her burden by the Special Master's decision regarding onset of symptoms" and continues to request the opportunity to "obtain[] an expert opinion consistent with this evidence and have an evidentiary hearing to establish whether she is entitled to compensation." In her Ruling On Onset, Special Master Roth ordered that any

Petitioner's expert would be required to "rely on the facts as I have found them in this Ruling [On Onset]." <u>Caron v. Sec'y of Health & Human Servs.</u>, 2016 WL 7664309, at *15. Special Master Roth also stated in her Ruling On Onset that "[i]n crafting their expert report, no expert may rely on Ms. Caron's testimony, affidavit, or the affidavits submitted by the various individuals who relied solely on Ms. Caron's date book for their recollections of events." <u>Id.</u>

It is well-established under Vaccine Rule 3(b) (2017) that the Special Master has the duty to conduct the proceedings and "endeavor[]" to make them "expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creat[e] a record sufficient to allow review of the special master's decision." Vaccine Rule 3 (b)(2). Moreover, pursuant to Vaccine Rule 3(b), "[a] special master . . . has wide discretion in conducting proceedings in a case." Burns v. Sec'y of Health & Human Servs., 3 F.3d at 417 (citing Vaccine Rule 3(b)). The Special Master also has broad discretion under Vaccine Rule 8 to "determine the format for taking evidence and hearing argument based on the specific circumstances of each case and after consultation with the parties." Vaccine Rule 8(a) (2017). In doing so, the Special Master "must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties." Vaccine Rule 8(b)(1); see also Campbell ex rel. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. at 778 (The concept of "fundamental fairness" incorporated into Vaccine Rule 3(b) "surely entails notice and an effective opportunity to be heard at a meaningful time and in a meaningful manner."). "Plainly, Vaccine Rules 3(b) and 8(c) together contemplate fundamental due process rights that the Special Masters ought to observe in all proceedings." Boley v. Sec'y of Health & Human Servs., 82 Fed. Cl. 407, 413 (2008). "Although it has been held that this fundamental fairness concept does not incorporate the rigors of the Federal Rules of Evidence . . . it plainly requires a search for the truth, " Campbell ex rel. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. at 778 (internal citations omitted). "Moreover, consistent with due process, this fairness surely entails notice and an effective opportunity to be heard at a meaningful time and in a meaningful manner." ld.

For example, the Federal Circuit has found that it was proper for a Special Master not to hear oral, expert medical testimony when the expert's opinion was "based . . . on facts not substantiated by the record." See Burns v. Sec'y of Health & Human Servs., 3 F.3d at 416-17. Moreover, the Federal Circuit has approved of a Special Master's decision to forego any expert testimony and decide a case solely on the written record. See D'Tiole v. Sec'y of Health & Human Servs., 132 Fed Cl. 421, 434 (2017) (finding that the Special Master did not violate Vaccine Rule 3(b) when he decided not to hold an evidentiary hearing on an otherwise fully developed record); Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. at 730 (finding that, if the Special Master finds that the written record is fully developed, the Special Master may decide the case without an evidentiary hearing, notwithstanding the desires of one or both of the parties). In contrast, the court in Campbell ex rel. Campbell v. Secretary of Health and Human Services, 69 Fed. Cl. 775, 780 (2006), found that the Special Master violated Vaccine Rules 3 and 8 when she declined to hold an evidentiary hearing "in light of the other actions she took," which included the following: the Special Master "made short shrift" of petitioner's affidavit "even

though the various medical records . . . disagree on basic facts, such as when [Petitioner's child] had her fever(s) in relation to her seizures," <u>id.</u> at 780; the Special Master, despite the "fuzziness" of the medical records, "wielded these records as if they were crystal clear," <u>id.</u>; the Special Master introduced internet articles on afebrile seizures "sua sponte into the record shortly before rendering her decision" that "do not—at least on their face—remotely meet this reliability requirement" under <u>Daubert v. Merrell Dow Pharm., Inc.</u>, 509 U.S. 579, 597 (1993). <u>Id.</u>

Contrary to Petitioner's allegation, Special Master Roth acted within her discretion under Vaccine Rules 3(b) and 8 when she determined that based on the record before the court, and after holding a hearing on the date of onset, that Petitioner's expert must rely on the Special Master's the ruling that onset was January 2013 and that an earlier date was not supported by the record. See Burns v. Sec'y of Health & Human Servs., 3 F.3d at 417 (the Special Master properly rejected the testimony of petitioner's expert after concluding that "the expert based his opinion on facts not substantiated by the record."). Special Master Roth stated:

Petitioner has not put forward evidence sufficient to refute the contemporaneous medical records, which firmly support the onset of CRMO in January 2013. I have carefully and meticulously reviewed the record. Consistent with the foregoing, I find that A.C.'s symptoms of CRMO began in January of 2013, five months after his vaccinations of August 2, 2012.

Caron v. Sec'y of Health & Human Servs., 2016 WL 7664309, at *15.

In this case, Petitioner had multiple opportunities to present her case and support her allegations regarding the timing of A.C.'s onset of symptoms. <u>See</u> Vaccine Rule 3(b)(2). First, Special Master Hamilton-Fieldman, who initially presided over this case, requested from Petitioner additional evidence to establish Petitioner's version of a fall 2012 onset. Petitioner responded by providing to Special Master Hamilton-Fieldman her supplemental affidavit, four affidavits from A.C.'s relatives, and her reconstructed date book. Petitioner argued that A.C. presented with symptoms on five separate occasions throughout the fall of 2012 while visiting and/or staying with relatives and friends. Petitioner also alleged that the reason she and her husband delayed in seeking medical attention for A.C. until January 2013 was because "the symptoms did not appear to be significant" at the time. The four affiants on whom Petitioner tried to rely similarly alleged that A.C. presented with some symptoms during the fall of 2012, based on reviewing Petitioner's date book.

Next, Special Master Hamilton-Fieldman ordered Petitioner to submit a "brief regarding the alleged timing of onset" that shall "address the undersigned's concerns regarding the reliability of the evidence in support of the earlier alleged onset." In response, however, Petitioner did not offer further evidence or explain why her evidence supporting a fall 2012 onset was reliable. Petitioner simply stated that she "has offered multiple affidavits in support of the onset of A.C.'s symptoms" and "that those affidavits

are overwhelmingly more persuasive than the medical records regarding the onset of A.C.'s symptoms."

Finally, Special Master Roth, to whom the case was reassigned, ordered and held an "onset hearing" so that Petitioner could again have an opportunity to offer evidence and "testify as to the onset of A.C.'s alleged injury." At the hearing, Petitioner did not present any witnesses besides herself. Petitioner testified about the various times, according to Petitioner, A.C. presented with symptoms throughout the fall of 2012. Petitioner also stated that she and her husband did not immediately seek medical attention for A.C.'s foot pain because her husband was "very insistent" that A.C.'s symptoms were "growing pains" and that they "weren't going to take him to the doctor." So, according to Petitioner, she "had to listen" to her husband. Petitioner admitted at the hearing that the handwritten notes in her 2012 date book documenting A.C.'s complaints of foot pain were not contemporaneously made. Petitioner stated that she went back in 2014 to add to the date book regarding when A.C. complained about foot pain. She stated that she could remember, despite it being almost two years later, the specific dates on which he had complained because she "could remember those events and what was going on that day." Petitioner also did not submit additional evidence in advance of the onset hearing with the exception of her own second supplemental affidavit. This affidavit was identical to her previously filed supplemental affidavit except for the final paragraph, which stated that "[t]he reason that we did not seek medical evaluation for several months was due to a disagreement between me and my husband as to whether evaluation was necessary."

In her Ruling On Onset, issued after the hearing, Special Master Roth carefully examined Petitioner's evidence and appropriately explained that such evidence did not overcome the presumption in favor of the information in the medical records, which demonstrate a January 2013 onset. See Caron v. Sec'y of Health & Human Servs., 2016 WL 7664309, at *9-13; see also Cucuras v. Sec'y of Health & Human Servs., 993 F.2d at 1528. The Special Master noted that Petitioner was a "vigilant" mother who consistently obtained timely medical care for her son. See Caron v. Sec'y of Health & Human Servs., 2016 WL 7664309, at *15. The Special Master wrote in her ruling that it "strains reason" to conclude that Petitioner would inaccurately report A.C.'s onset of symptoms to his physicians at the time of the earlier visits or for his physicians to inaccurately document Petitioner's complaints of A.C.'s conditions. See id. The Special Master also noted that the individuals who submitted affidavits in this case were Petitioner's relatives and friends and did not independently recollect the dates when A.C. visited them throughout the fall of 2012, but, instead, relied on Petitioner's reconstructed date book to refresh their memories on the dates. Id. at *11. The Special Master also reiterated that Petitioner had added to her date book the relevant handwritten notes regarding A.C.'s alleged complaints of foot pain during the fall of 2012 two years later in 2014. See id. at *10. Special Master Roth, therefore, found that Petitioner's evidence did not overcome the presumption in favor of the accuracy of the contemporaneous medical records and that A.C.'s onset of symptoms was January 2013. Such findings by the Special Master reflect the record and were not arbitrary, capricious, an abuse of discretion or contrary to law. See Carson ex rel. Carson v. Sec'y of Health & Human Servs., 727 F.3d at 1369; see

also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1253-54; Munn v. Sec'y of Health & Human Servs., 970 F.2d at 870.

Petitioner alleges that she "has been denied the opportunity to even present evidence to meet her burden by the Special Master's decision regarding onset of symptoms." From the time she filed her petition for review in this court, Petitioner was free to engage experts who were willing to offer opinions that the alleged injurious vaccinations caused A.C.'s onset of symptoms. Even after Special Master Roth issued her Ruling On Onset, Petitioner was still free to try to engage experts based on the medical records, but as Special Master Roth ordered in her Ruling On Onset, any expert would be required to "rely on the facts as I have found them in this Ruling," and that "[i]n crafting their expert report, no expert may rely on Ms. Caron's testimony, affidavit, or the affidavits submitted by the various individuals who relied solely on Ms. Caron's date book for their recollections of events." Caron v. Sec'y of Health & Human Servs., 2016 WL 7664309, at *15. As discussed above, Special Master Roth's Ruling On Onset was not arbitrary, capricious, an abuse of discretion or contrary to law. Further, also discussed above, Special Master Roth acted within her discretion under Vaccine Rules 3(b) and 8 when she ordered that any Petitioner's expert would be required to "rely on the facts as I have found them in this Ruling." Id. Petitioner stated, however, in her Request For Ruling On The Record and, similarly in her Motion For Review, that she was "unable to secure an expert opinion regarding an onset of symptoms that long after the vaccinations," not that she was prevented to from doing so.

Moreover, since the initiation of proceedings in this court, Petitioner has not provided any expert opinion showing that any of the vaccinations A.C. received *can* cause CRMO, that the vaccinations *did* cause CRMO in this case, or to establish an earlier onset date based on the record before the Special Master and the court. See Althen v. Sec'y of Health & Human Servs., 418 F. 3d at 1278 (Petitioner has the burden to prove the vaccination at issue caused the 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.").

Petitioner ultimately did attach two articles to her Request For Ruling On The Record and then again in her Motion For Review in this court in an attempt to show that she "could have likely established at a hearing that the vaccinations caused [A.C.'s] osteomyelitis under the *Althen* standard." These articles, however, do not assist Petitioner to prove causation. The first article simply explains how vaccines work. The second five-page article reports two cases of osteomyelitis as a complication of the Varicella virus, not the Varicella vaccine. Neither of these articles conclude that the Varicella vaccination can cause CRMO, although Petitioner argues that "[t]he Varicella vaccination injects the Varicella bacteria into the body," and "[l]iterature indicates Varicella can also cause osteomyelitis." Therefore, based on the record before both Special Master Hamilton-Fieldman and Special Master Roth, Petitioner was not denied her opportunity to present evidence to meet her burden of proof to establish an earlier symptom onset date prior to January 2013 or to establish a right to compensation under the Vaccine Act. As indicated

above, Special Master Roth found in her September 7, 2017 Decision Denying Entitlement that:

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, 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.

Caron v. Sec'y of Health & Human Servs., 2017 WL 4349189, at *10 (footnote omitted).

Based on a review of the record, the court finds that Special Master Roth's decision to dismiss the petition was not arbitrary, capricious, an abuse of discretion or contrary to law. As noted earlier, even Petitioner in her Motion For Review to this court stated that she has not presented evidence to meet her burden to prove causation. With regard to the Althen prongs, discussed above, under the first prong of Althen, Petitioner presents no expert testimony to establish a "medical theory causally connecting" the alleged injurious vaccinations to A.C.'s CRMO. The two articles she submitted, as described above, do not even allege that the Varicella vaccination can cause CRMO, and, therefore, do not establish a medical theory causally connecting the vaccination and the injury. See Simanski v. Sec'y of Health & Human Servs., 671 F.3d at 1384 ("[A] finding of causation must be supported by a sound and reliable medical or scientific explanation,") (internal citations omitted).

With regard to the second <u>Althen</u> prong requiring a logical sequence of cause and effect, a petitioner 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." <u>Althen v. Sec'y of Health & Human Servs.</u>, 418 F.3d at 1278. Again, Petitioner has not submitted evidence demonstrating that the alleged injurious vaccinations were a substantial factor in causing A.C.'s CRMO. Petitioner does state in her Motion For Review that A.C.'s rheumatologist reported in April 2013 that A.C. had suffered no obvious injury or illness that would have explained his injury. "[A] simplistic elimination of other potential causes of the injury," however, does not suffice, "without more, to meet the burden of showing actual causation." <u>Id.</u> Petitioner, therefore, has not proven a logical sequence of cause and effect between the alleged injurious vaccinations and A.C.'s CRMO.

As for the last <u>Althen</u> prong, which requires a proximate temporal link, Petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." <u>de Bazan v. Sec'y of Health & Human Servs.</u>, 539 F.3d at 1352. Petitioner has not submitted any expert opinion or medical literature stating

that the five months between the administration of the alleged causal vaccinations and A.C.'s January 2013 onset constitute proximate timing. Notably, Petitioner admits that she was unable to find an expert willing to opine on such relationship of causation "that long after the vaccinations." Based upon the record before this court, the court finds that Petitioner has not proven proximate timing between A.C.'s alleged injurious vaccinations received on August 2, 2012 and A.C.'s January 2013 onset of symptoms. Because Petitioner has presented no evidence establishing causation under Althen, and because "[t]he special master or court may not make such a finding based on the claims of a petitioner alone," the Special Master's Decision Denying Entitlement was not arbitrary, capricious, an abuse of discretion or contrary to law. See 42 U.S.C. § 300aa-13(a)(1). This court, therefore, denies Petitioner's requests to overturn Special Master Roth's December 14, 2016 Ruling On Onset and her September 7, 2017 Decision Denying Entitlement. The court also denies Petitioner's request to remand the case to the Special Master to allow Petitioner to further pursue obtaining an expert opinion and have another evidentiary hearing to establish entitlement to compensation.

CONCLUSION

Upon review of the record before this court, including the testimony taken at the July 11, 2016 fact hearing before Special Master Roth, the medical records, affidavits, and reconstructed date book, the court **AFFIRMS** Special Master Roth's finding of a January 2013 onset and her decision denying compensation to Petitioner on behalf of A.C.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge