



Petitioner has failed to show that B.E. suffered from a partial intussusception and, further, that his injury was caused by the vaccination he received. The petition is accordingly dismissed.

## **I. Procedural History**

The case was initially assigned to Special Master Gowen on December 4, 2015 (ECF No. 5). Petitioner filed medical records, and then her statement of completion (ECF No. 12). This case was reassigned to now-retired Special Master Hastings on February 22, 2016 (ECF No. 10).

Respondent filed his Rule 4(c) Report on June 3, 2016, stating that Petitioner's case "is not appropriate for compensation," and that the Petition "should be dismissed for failure to demonstrate entitlement to compensation." Resp't's Report at 1-2, ECF No. 16. Respondent argued that Petitioner had not provided enough evidence or a plausible medical theory linking the vaccine to B.E.'s injuries. *See generally* Resp't's Report.

Petitioner submitted her expert report from Dr. John Santoro on November 18, 2016. Ex. 5, ECF No. 23. Respondent filed his expert report from Dr. Chris Liacouras on February 20, 2017. Ex. A, ECF No. 27.

This case was reassigned to my docket on December 5, 2017. ECF No. 32. Subsequently, I held a status conference on March 13, 2018. *See* Minute Entry for 3/13/2018. In that conference, Respondent noted that there was a discrepancy between the injury alleged in the Petition and the injury proposed by Petitioner's expert. ECF No. 34. Petitioner's counsel represented that B.E.'s alleged injury was a partial intussusception. *Id.* I directed Petitioner to file an amended Petition by April 12, 2018, reflecting the change in alleged injury. *Id.*

Petitioner filed her Amended Petition on April 12, 2018. ECF No. 37. On July 25, 2018, and October 15, 2018, Petitioner filed additional medical records. ECF No. 38; ECF No. 39. On October 24, 2018, Petitioner filed medical literature in support of her expert report and her amended position alleging that B.E. suffered from a partial intussusception following his October 20, 2014 rotavirus vaccination. ECF No. 40; *see also* ECF No. 37.

The parties filed their pre-hearing submissions on October 26, 2018. ECF No. 41; ECF No. 42; ECF No. 43. I held an entitlement hearing in this matter on November 28, 2018. *See* Minute Entry for 11/28/2018. The parties both elected not to file post-hearing briefs. This matter is now ripe for adjudication.

## **II. Factual Background**

### **A. B.E.'s Health Prior to the Allegedly Causal Vaccination**

B.E. was born on August 8, 2014. Ex. 1 at 7. On September 15, 2014, Petitioner brought B.E. to the Primary Care Clinic at Pagosa Springs Medical Center (hereinafter "Pagosa Clinic") with complaints of congestion and a cough. *Id.* Petitioner told Dr. Bricca that B.E. was more "colicky." *Id.* Petitioner stated that he cried and drank formula constantly from 5:00 pm until 9:00

pm. *Id.* Dr. Bricca recommended that Petitioner feed B.E. less in the afternoon and evening, and that she try diluting his formula. *Id.* at 8.

B.E. had a well exam on October 13, 2014. Ex. 2 at 35. The notes from this visit indicate that B.E. was weaned from breastmilk to Gentlease formula, and that he had become colicky. *Id.* When B.E.'s formula was switched to Nutramigen, his colic improved. *Id.* The notes with respect to elimination indicate, "[s]tringy, yellow stools, with some darker. Only Nutramigen for ... about 3 weeks. Strange stools are new." *Id.*

On October 20, 2014, B.E. received his rotavirus vaccination at the Pagosa Clinic. Ex. 1 at 17.

### **B. B.E.'s Health after the Allegedly Causal Vaccination**

On October 27, 2014, Petitioner brought B.E. to the Pagosa Clinic with complaints of persistent abdominal pain and blood in his stool for two days. Ex. 1 at 11. Petitioner told the provider that B.E.'s stool was loose and green, containing blood and clots. *Id.* The notes from this visit mention that B.E. received the rotavirus vaccine one week prior, had a temperature of 100.4 after his vaccination, but had been afebrile since. *Id.* The notes further state that B.E. was fed with Nutramigen and had stomach problems since he stopped breastfeeding. *Id.* On this same date, B.E. had an abdominal x-ray (Ex. 1 at 12) and an abdominal ultrasound (Ex. 1 at 13). Both tests yielded normal results.

On October 28, 2014, Petitioner brought B.E. to the Pagosa Springs Medical Center for a follow-up appointment. Ex. 7 at 164. Since his appointment the prior day, Petitioner reported that B.E. had a bowel movement with some blood present. *Id.* The "Gastrointestinal" portion of the "Review of Systems" section of the record notes "Diarrhea, [n]o nausea, [n]o vomiting." *Id.*

B.E. visited Pediatric Partners of the Southwest on October 30, 2014. Ex. 2 at 34. Petitioner reported a continuation of B.E.'s recent gastrointestinal symptoms. He was stooling five to six times per day, and his stool was described as diarrhea. *Id.* Most recently, B.E. was having episodes of screaming at night for 10-15 minutes. *Id.* The notes indicate that B.E. had "[p]robable vaccine-strain rotavirus illness, now improving." *Id.* at 35. Dr. Zemach prescribed Neocate infant powder to replace B.E.'s formula. *Id.*

On November 7, 2014, B.E. presented to the Mercy Hospital Emergency Room because of blood in his stool. Ex. 2 at 25. The history of present illness section of the record indicates that B.E. "was well until stopping nursing at age 2-3 weeks." *Id.* He changed to Gentlease formula "after which he became 'colicky,' with 'screaming all day long.'" *Id.* When B.E. was changed to Nutramigen "he was 'back to normal.' Stools were yellow and brown, slightly stringy." *Id.* The notes indicate that after his rotavirus vaccination, B.E. developed bloody stools within three days. *Id.* The record further states, "4-5 days ago: Began Neocate formula => no change, other than decrease in stool frequency." *Id.* at 26. An abdominal x-ray performed that same day yielded normal results. *Id.* at 33. B.E.'s blood work, also tested on that day, returned an albumin level of 3.5 g/dL. *Id.* at 32. This level is below the normal range of 3.8-5.4 g/dL. *Id.*

On November 12, 2014, B.E.'s stool study was positive for occult blood (Ex. 2 at 47) and negative for rotavirus (Ex. 2 at 48).

On December 10, 2014, B.E. presented to the Pagosa Springs Medical Center for his four-month well exam. Ex. 7 at 134. The exam history indicated that B.E. "had a reaction to rotavirus in which he experienced bloody diarrhea. ... Plan is to avoid further immunization with the rotavirus." *Id.* The well exam was unremarkable for any gastrointestinal problems. *See Id.* at 134-35.

On February 9, 2015, B.E. visited the Pagosa Clinic for his six-month well exam. Ex. 1 at 26. The well exam was unremarkable for any gastrointestinal problems. In fact, "no parental concerns" was listed under the elimination section of the well child history. *Id.* B.E. was noted to be a "[h]ealthy appearing 6 month old male, meeting developmental milestones." *Id.* at 27.

On May 8, 2015, B.E. visited Dr. Zemach. Ex. 2 at 21. The chief complaint from this encounter was that B.E. "has been constipated since rotavirus given at 2 month appointment." *Id.* The record indicates that B.E. was having hard stools that made him bleed. *Id.* The record further states that B.E. went off Neocate to Nutramigen and had been drinking "straight cow's milk for about a month." *Id.* An abdominal x-ray performed on that day was normal except for the presence of "moderate retained stool throughout the colon." *Id.* at 23. Dr. Zemach recommended Miralax for B.E.'s constipation. *Id.* at 22.

On May 26, 2015, Petitioner brought B.E. back to Dr. Zemach for his nine-month well exam. Ex. 2 at 19. B.E. was having hard stools alternating with soft ones. *Id.* Dr. Zemach increased B.E.'s dosage of Miralax from one teaspoon to one tablespoon per day. *Id.* at 20.

On June 7, 2015, B.E. visited the Pagosa Springs Medical Center Emergency Department. Ex. 1 at 34. Petitioner described that B.E. seemed to be in pain; he was pulling his legs up to his chest, thrashing around in bed, and biting his blanket. *Id.* B.E. had a fever of 101.5 °F and "hypoxia down to 85% on room air." *Id.* B.E. was diagnosed with pneumonia. *Id.* B.E. had another abdominal x-ray during this visit, which revealed normal results except that his colon was retaining moderate stool. *Id.* at 37.

On July 15, 2015, B.E. had a barium enema due to his chronic constipation. Ex. 9 at 23. The exam revealed a "moderate amount of retained fecal material throughout the length of the colon" but was otherwise normal. *Id.*

B.E. presented to Pediatric Partners of the Southwest on August 27, 2015 due to blood and slime in his stool the night prior. Ex. 2 at 7. Petitioner reported that B.E. had a fever of 102°F the previous evening. *Id.* B.E.'s abdomen was described as "bulging moderately, firm, not hard". *Id.* at 8. The physician ordered an abdominal x-ray, which yielded normal results. *Id.* at 9. On August 29, 2015, B.E.'s albumin level was reported as low at 3.6 g/dL. *Id.* at 7.

On September 2, 2015, B.E. presented to the Section of Pediatric Gastroenterology, Hepatology, and Nutrition at Children's Hospital Colorado. Ex. 2 at 41. This history section notes that B.E. had had difficulty stooling, which started after he received his rotavirus vaccination. *Id.*

He had been taking Miralax, ExLax, and mineral oil, but Petitioner stopped those medications due to blood in B.E.'s stools. *Id.* Dr. Liu's impression was that B.E. had chronic retentive constipation. *Id.* at 42. He recommended restarting Miralax and ExLax. *Id.* On this same date, B.E. also underwent allergy testing. *Id.* at 5. When exposed to the cow's milk allergen, B.E.'s reaction tested as "normal." *Id.*

B.E. was admitted to the ER at Northwest Texas Hospital on December 14, 2015 due to difficulty breathing and pale skin color. Ex. 4 at 2. The family was driving from California to Oklahoma and they stopped in Amarillo, Texas due to B.E.'s condition. *Id.* B.E. was noted as a picky eater, who drank between four and five 10-ounce bottles of whole milk per day. *Id.* at 3. B.E.'s blood work revealed critically low hemoglobin levels (Hgb), critically low hematocrit (Hct), along with a low red blood count (RBC), a low mean corpuscular volume (MCV), a low mean corpuscular hemoglobin concentration (MCHC), and a high white blood count (WBC). *Id.* He had tachycardia and was in mild respiratory distress. *Id.* at 5. Due to his abnormal blood levels, B.E. received a blood transfusion. *Id.* He was discharged on December 16, 2015 and his parents were advised to exclude dairy from B.E.'s diet. *Id.* at 22.

Although additional, more recent medical records were filed, they were not discussed by the experts, and were not relevant to this analysis.

### **III. Expert Opinions**

#### **A. Dr. John Santoro**

Petitioner filed one expert report from Dr. Santoro who also testified at the hearing. *See* Expert Report, filed as Ex. 5 (ECF No. 23-1), ("Santoro Rep."). Dr. Santoro opined that the RotaTeq vaccination B.E. received caused him to develop a partial intussusception.

Dr. Santoro currently works at Atlantic Gastroenterology Associates, P.A., as a doctor of osteopathic medicine and gastroenterology. *See* Santoro CV (ECF No. 40-2) at 1. He obtained his Bachelor of Arts in biology from LaSalle College in 1973, and his D.O. from Philadelphia College of Osteopathic Medicine in 1978. *Id.* at 1. He completed an internship at John F. Kennedy Memorial Hospital from 1978-79 and performed his residency in internal medicine at the University of Medicine and Dentistry of New Jersey at the School of Osteopathic Medicine from 1979-81. *Id.* Dr. Santoro also completed a fellowship in gastroenterology at the University of Medicine and Dentistry of New Jersey School of Osteopathic Medicine from 1981-83. *Id.* at 2. He is board certified in internal medicine and gastroenterology. *Id.* Additionally, he serves as a clinical associate professor of medicine at Rowan University School of Osteopathic Medicine. *Id.* at 3. Dr. Santoro has published multiple articles in gastroenterology journals. CV at 4-5.

As a gastroenterologist, Dr. Santoro testified that he spends 88-90 percent of his time seeing patients, with the remaining time dedicated to clinical research and teaching. Tr. at 11. While part of his rotation involved pediatric gastroenterology, he more commonly sees patients above the age of 11 and does not treat infants and younger children. *Id.* at 52. He has treated between eight and 10 adult patients with intussusception in the past 15 years. *Id.*

At hearing, Dr. Santoro explained intussusception to be the telescoping of the intestine upon itself, creating a bowel obstruction. Tr. at 19. Intussusception typically occurs in the terminal ileum into the right part of the large intestine and generally occurs in children. *Id.*

Dr. Santoro described a partial intussusception as “one that occurs with ... a partial bowel obstruction ... that resolves spontaneously.” Tr. at 34. He further testified as follows:

Some intussusceptions, you have feet of bowel going inside the other bowel. Sometimes you just get a little segment inside the other bowel, and then it goes through peristalsis, and the bowel pulls apart and it’s gone. That’s what I believe our patient may have had. That’s what I believe the term “partial intussusception” means.

*Id.* at 95. Dr. Santoro did not cite to any medical literature which used the term “partial intussusception.” He testified that the Yen article supports his theory that a partial intussusception can occur because the article notes that intussusceptions can resolve spontaneously. *See* Catherine Yen et al., *Rotavirus vaccination and intussusception – Science, surveillance, and safety: A review of evidence and recommendations for future research priorities in low and middle income countries*, HUMAN VACCINES & IMMUNOTHERAPEUTICS, Jul. 28, 2016, at 2580-89, filed as Ex. 10.9 (ECF No. 40-11) (“Yen”). Tr. at 60. Dr. Santoro further testified that the older medical literature uses the term “chronic intussusception.” Tr. at 33.

B.E. presented to his physician on October 27, 2014, complaining of a two-day history of abdominal pain and bloody stools. Tr. at 27. In Dr. Santoro’s opinion, B.E. suffered a partial intussusception five days after October 20, 2014, the date B.E. received his rotavirus vaccination. *Id.* Dr. Santoro based his opinion on “timing, symptoms, and rotavirus.” *Id.* at 87. In other words, the fact that B.E. received a rotavirus vaccination and that he developed symptoms of abdominal pain and bloody stools five days later led Dr. Santoro to conclude that B.E. suffered a partial intussusception caused by his vaccination.

Dr. Santoro opined that B.E.’s intussusception had resolved by the time B.E. went to the hospital on October 27<sup>th</sup>. Tr. at 27. As a result, B.E.’s imaging on that date did not reveal any intestinal abnormality. *Id.*

Dr. Santoro also testified about B.E.’s GI symptoms in August of 2015 and whether B.E. had experienced another partial intussusception. His testimony on this issue evolved during the course of the proceeding. Dr. Santoro first described the August incident as follows:

I think that ... one of the events a little bit down the line where he presented with abdominal pain, elevated white count, was pretty sick, was probably another partial intussusception, but I can’t prove that. Unfortunately – unfortunately, there – you know, there was no CT scan done. There was no real diagnostic study done on the second event. So it’s just supposition on my part, purely and simply.

Tr. at 33.

The next discussion surrounding B.E.'s August 2015 medical visit occurred several pages later in the proceedings.

MR. MULLER: Also, on August 27<sup>th</sup>, 2015, he presents to Pediatric Partners of the Southwest with blood in his stool, abdominal pain and constipation.

Do you think that any of those other symptoms, the abdominal pain, the – the GI bleeding, could be related to the initial partial intussusception?

DR. SANTORO: Ah, you know, it's not clear. I personally don't think so, but this one event, this is the event that bothered me, and it actually really came to my attention when I read Dr. Liacouras' letter alluding to it.

Between August 27<sup>th</sup> and 29<sup>th</sup> – and this is on page 2 of the Doctor's letter – the patient presented with blood in his stool, abdominal pain, constipation, but his belly was – his exam was this time firm, bulging, hard<sup>3</sup>, (sic) and his lab work revealed a 19,000 white count. That's a little disturbing to me. Perhaps did at that time he have another episode of an intussusception? But again, it wasn't diagnosed, nor was anything else.

But, I mean, like him, see a number of these children with constipation, chronic, and they don't have an elevated white count. So I'm not certain about that event.

Tr. at 37.

Another series of questioning between Mr. Muller and Dr. Santoro on the topic of B.E.'s August 2015 medical appointment and symptoms went as follows:

MR. MULLER: Prior to vaccination, on August 28<sup>th</sup>, he presents – Petitioner presents with gastrointestinal symptoms, and then again on September 15, he presents colicky and with increased crying. Is it your opinion that those visits and presentation had anything to do with the ultimate post-vaccination partial intussusception?

DR. SANTORO: The events in October you mean?

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<sup>3</sup> During the August 27, 2015 visit B.E.'s abdomen is described as “bulging moderately, firm, not hard.” Ex. 2 at 8. The reference in this line of questioning to a hard abdomen is inconsistent with the medical records.

MR. MULLER: Yes.

DR. SANTORO: I don't believe so.

MR. MULLER: Why not?

DR. SANTORO: I can't relate them.

Tr. at 41-42.

Mr. Muller and Dr. Santoro continued to discuss B.E.'s August medical visit.

MR. MULLER: Dr. Santoro, I just want to go back to the August of 2015 visit. So August 27<sup>th</sup>, 2015, Petitioner presents to Pediatric Partners of the Southwest with intermittent blood in his stool, abdominal pain, and constipation.

DR. SANTORO: Yes.

MR. MULLER: His abdominal exam was abnormal, it was firm and hard (sic) and bulging, and you discussed the white blood count. Do you believe that any of that could have been related to the initial partial intussusception as a result of the rotavirus vaccine?

DR. SANTORO: I think it's possible. I think it's also possible that he had another partial intussusception, which he would be more likely to have after the initial event.

Tr. at 47.

By the end of the hearing, Dr. Santoro opined that B.E. most likely had a second partial intussusception in August of 2015 that had also resolved by the time Petitioner sought treatment for her son. Tr. at 101, 103-04. Dr. Santoro testified that either B.E. had a second partial intussusception as a result of his rotavirus vaccination, or he had a second partial intussusception because the initial injury to the mucosal lining of his intestine left B.E. more susceptible to developing this injury again. *Id.* at 47, 102.

## **B. Dr. Chris Liacouras**

Dr. Liacouras offered a single expert report in this case and testified at the hearing. *See* Expert Report, dated February 10, 2017 (filed as Resp't's Ex. A) (ECF No. 27-1) ("Liacouras Rep."). He is currently a professor of pediatrics and pediatric gastroenterology and nutrition at the Perelman School of Medicine at the University of Pennsylvania, Children's Hospital of Philadelphia. Liacouras CV, filed as Resp't's Ex. B (ECF No. 27-13); Tr. at 107. Dr. Liacouras received his undergraduate degree from Johns Hopkins and his medical degree from Harvard Medical School. *Id.* at 106. During medical school, Dr. Liacouras completed a pediatric

gastroenterology fellowship at Children's Hospital of Philadelphia. *Id.* Since then, he has remained at Children's Hospital of Philadelphia, serving in various capacities, including director of the Gastrointestinal Endoscopy Suite, and as a full professor of pediatrics and pediatric gastroenterology. *Id.* at 107. In 2004, Dr. Liacouras was named the codirector of the Pediatric Center for Eosinophilic Disorders. *Id.* at 108. This position enables Dr. Liacouras to work with patients who have different types of food allergies, and in this capacity, he sees between 200-250 food allergy patients per year. *Id.* Dr. Liacouras is board certified in pediatric gastroenterology and maintains an active medical license. *Id.*

Dr. Liacouras testified that he spends 80 to 85 percent of his time seeing patients, with the rest of his time divided between conducting clinical research and teaching. Tr. at 111. Dr. Liacouras regularly treats pediatric patients with GERD, constipation, rectal bleeding, diarrhea, and abdominal pain, as well as children with allergic proctocolitis and food allergy. *Id.* at 112-13. In addition, he has treated more than 100 infants with intussusception. *Id.* at 114.

Dr. Liacouras testified that in his opinion, B.E. had a milk protein allergy and not an intussusception. Tr. at 160-62. Dr. Liacouras began the substance of his testimony by discussing intussusception. He testified that gastroenterologists do not use the term “partial intussusception.” *Id.* at 117-18. “You either make the diagnosis or you don’t. There’s no real – it may cause minimal problems, it may cause severe problems, but it is what it is.” *Id.* at 118. Signs of intussusception include abdominal pain, bleeding, a mass you can feel, and lethargy. *Id.* at 122.

Dr. Liacouras also stressed that in order to make the diagnosis of intussusception, you must see evidence of the intussusception, typically with either a barium enema or an abdominal ultrasound. *Id.* at 120. When an ultrasound is performed and interpreted by a qualified and knowledgeable physician, it is nearly 100 percent definitive. *Id.* at 122. According to Dr. Liacouras, the telescoped bowel on ultrasound actually appears as a target sign. *Id.* Because B.E. never had imaging that showed an intussusception, Dr. Liacouras testified that B.E. did not have an intussusception.

Dr. Liacouras testified persuasively that B.E.’s symptoms were attributable to a milk protein allergy, or allergic proctocolitis.<sup>4</sup> Symptoms of allergic proctocolitis in children include mucousy, stringy stools, and bleeding. Tr. at 130. The typical treatment for allergic proctocolitis is to remove the offending antigen. *Id.* In the case of B.E., Dr. Liacouras pointed to the fact that B.E.’s pediatricians switched his formula several different times, which is the appropriate response to address a potential food allergy. *Id.* at 174. After being breastfed for two to three weeks, B.E. was weaned to Gentlease formula. He was then switched to Nutramigen due to colic. B.E. continued to experience symptoms of stringy stools while on Nutramigen, so he was again switched to Neocate. Ex. 2 at 25-26.

Dr. Liacouras testified as to the differences between these formulas. He testified that

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<sup>4</sup> Allergic proctocolitis or eosinophilic proctocolitis is a “manifestation of a food allergy, consisting of inflammation of the mucosa of the rectum and colon with eosinophilic infiltration, usually in infants during the first two months of life.” It is most often caused by a reaction to cow’s milk or soy milk formulas. Most infants present with rectal bleeding or blood in the feces. Dorland’s Illustrated Medical Dictionary (32<sup>nd</sup> ed. 2012) at 1521 (hereinafter “Dorland’s”).

Gentlease is a milk-based formula. Tr. at 134. Dr. Liacouras described the other two formulas as follows:

Let's say a milk protein or a soy protein is a certain size, ... and that protein causes immunologically a problem with the way your intestine senses it, sees it, and it causes irritation because of the way it – it kind of interacts with that protein.

Nutramigen is a protein that may reduce the size of that by 60 to 70 percent. So now it's more easily digestible, okay? It's not this big, whopping protein that could be causing trouble, but it's not perfect. There's still 20 to 30 percent of that protein that's still there, and it can cause a reaction like the other proteins were doing.

Then you get down to this other formula called Neocate, and that's basically amino acids, if you can remember way back to biology. You're talking about the basic building blocks of protein, so you can't have an allergy to those basic building blocks, and that's why that formula, if you need to, works better.

*Id.* at 139-40.

While B.E. was on Neocate, he did not have any gastrointestinal-related visits to the doctor. According to Dr. Liacouras, this was also suggestive that B.E. had a milk protein allergy. Tr. at 146-47. In fact, B.E. next presented to his doctor with GI complaints on May 8, 2015, approximately six months after his most recent GI-related visit in November. *Id.* at 149. The record from that visit in May indicates that B.E. transitioned from Neocate to Nutramigen and then to cow's milk. Ex. 2 at 21. As Dr. Liacouras described it, "sometime between November and May, the mother changed the formula back to cow's milk, with or without the physician's direction." Tr. at 149. He testified that in his opinion, B.E. began experiencing an allergy to cow's milk, which can be manifested by either diarrhea or constipation. *Id.* at 149-50.

Dr. Liacouras testified that there are different types of allergies to food. An anaphylactic allergy, for example, a peanut allergy, causes the immune system to produce IgE antibodies to an allergen that can cause a susceptible individual to go into shock.<sup>5</sup> The other main type of food allergy is non-IgE T-cell allergy. Tr. at 141. This type of food allergy is caused by an immune reaction not involving IgE antibodies. *Id.* at 140-41. Because an allergy to milk protein is a non-IgE T-cell allergy, there is no diagnostic allergy test that can be performed to detect the food allergy. *Id.* at 140. Dr. Liacouras explained that this is why B.E.'s allergy tests came back as normal. *Id.* at 173-74. Treating physicians generally see that the patient has symptoms, and then eliminate the offending allergen. *Id.* at 140.

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<sup>5</sup> See Jonathan E. Markowitz & Chris A. Liacouras, *Allergic and Eosinophilic Gastrointestinal Disease*, in PEDIATRIC GASTROINTESTINAL AND LIVER DISEASE 429, 429 (Wyllie, Hyams, Kay eds., 2016), filed as Ex. A-11.

Dr. Liacouras further supported his opinion that B.E. had a milk protein allergy by pointing to B.E.'s low albumin levels.<sup>6</sup> On November 7, 2014, B.E. presented to the Mercy Hospital Emergency Room because of blood in his stool. Ex. 2 at 25. B.E.'s blood work returned an albumin level of 3.5 g/dL, which was low. *Id.* at 32. B.E. had changed formula from Nutramigen to Neocate four to five days previously.<sup>7</sup> Further, on August 29, 2015, B.E. saw his physician due to blood and slime in his stool. At this point, B.E. had transitioned to cow's milk. His albumin level was again reported as low at 3.6 g/dL. *Id.* at 7. According to Dr. Liacouras, albumin levels can be low when you have intestinal irritation or colitis. Tr. at 138.

Dr. Liacouras also discussed B.E.'s ER admission on December 14, 2015, and how he believes B.E.'s milk protein allergy was a partial cause of B.E.'s medical problems. Dr. Liacouras testified that B.E. most likely had chronic inflammation and low-grade bleeding as a result of his milk protein allergy. Tr. at 158. In addition to this blood loss, B.E. was drinking 40-50 ounces of whole milk per day and was not eating much of any other food. This milk intake, combined with his milk protein allergy, caused a severe iron deficiency. *Id.* at 157-58, 177. B.E.'s hemoglobin measured at 2.7, while a healthy child of his age should have a hemoglobin of 12-13. *Id.* at 156. This means that B.E. did not have enough red blood cells to transport oxygen throughout his body, which led to respiratory distress. *Id.* at 157.

Ultimately, Dr. Liacouras testified that there is no evidence anywhere in the medical records that B.E. had an intussusception, while there is definitive evidence of a milk protein allergy. Tr. at 160.

#### **IV. Applicable Law**

##### **A. Petitioner's Overall Burden in Vaccine Program Cases**

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that he suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010);

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<sup>6</sup> Albumin is "any protein that is soluble in water and moderately concentrated salt solutions, and is coagulable by heat. ... Decreased serum albumin (hypoalbuminemia) occurs in protein malnutrition, active inflammation, and serious hepatic and renal disease." Dorland's at 44.

<sup>7</sup> According to Dr. Liacouras, allergic proctocolitis can take anywhere from 10 days to six weeks to completely resolve. Tr. at 145.

*see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination he received caused his injury “by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Id.* at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must be only “legally probable, not medically or scientifically certain.” *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec’y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) (“[p]lausibility ... in many cases may be enough to satisfy *Althen* prong one” (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner’s ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position

to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician’s views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing ... that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec’y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff’d*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec’y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at \*17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den’d*, 100 Fed. Cl. 344, 356 (2011), *aff’d without opinion*, 475 Fed. App’x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* 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.” *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec’y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den’d after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

## **B. Law Governing Analysis of Fact Evidence**

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec’y of Health & Human Servs.*,

3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at \*2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), *mot. for review den'd* (Fed. Cl. Feb. 11, 2019); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. 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.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at \*19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and

compelling.” *Sanchez*, 2013 WL 1880825, at \*3 (citing *Blutstein v. Sec’y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’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 reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *LaLonde v. Sec’y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

### C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). See *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec’y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). “The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.” *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec’y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) (“uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted”). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. See, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner’s case. Where both sides offer expert testimony, a special master’s decision may be “based on the credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert’s conclusion “connected to existing data only by the *ipse dixit* of the expert,” especially if “there is simply too

great an analytical gap between the data and the opinion proffered.” *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A “special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert’s credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 (“[a]ssessments as to the reliability of expert testimony often turn on credibility determinations”); *see also Porter v. Sec’y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) (“this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act”).

#### **D. Consideration of Medical Literature**

Finally, although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec’y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) (“We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision.”); *Simanski v. Sec’y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) (“[A] Special Master is ‘not required to discuss every piece of evidence or testimony in her decision.’” (citation omitted)), *aff’d*, 601 F. App’x 982 (Fed. Cir. 2015).

#### **V. Analysis**

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, Petitioner’s claim is classified as “off-Table.” As noted above, to prevail on an “off-Table” claim, Petitioner must prove by preponderant evidence that B.E. suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

##### **A. Overview of Intussusception**

Intussusception is defined as the invagination, or telescoping, of one segment of the gastrointestinal tract into another resulting in intestinal obstruction. Anthony C. Manning & Danny C. Little, *Intussusception in Infants and Children*, in *PEDIATRIC GASTROINTESTINAL AND LIVER DISEASE* 607 (Robert Wyllie et al. 5<sup>th</sup> ed. 2015), filed as Ex. A-1 (ECF No. 27-2) (“Manning”). Intussusception is most common among infants and toddlers in the first two years of life. Manning at 607. Two-thirds of intussusception patients are male. *Id.* The initial signs of intussusception include acute and severe stomach pain and vomiting. Liacouras Rep. at 3. “The classic features, known as the ‘classic triad,’ include severe abdominal pain, vomiting and currant jelly stools.” *Id.*

The cause of intussusception is unknown.<sup>8</sup> Research suggests that an intussusception can be triggered by post-infection hyperplasia in the intestinal tract following rotavirus, and generally

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<sup>8</sup> Christine G. Robinson et al., *Evaluation of Anatomic Changes in Young Children with Natural Rotavirus Infection: Is Intussusception Biologically Plausible?*, 189 J INFECT DIS. at 1382 (2004), filed as Ex. 10.8.

occurs within 21 days after the initial rotavirus vaccination. Yih et al., *Intussusception Risk after Rotavirus Vaccination in U.S. Infants*, 370 *New Eng. J. Med.* 503, 506 (2014), filed as Ex. 10.6 (ECF No. 40-8) (“Yih”).

An intussusception is a life-threatening illness. Yen at 2581. Untreated, intussusception can cause internal bleeding. Tr. at 122. Typically, an intussusception diagnosis can be made using an abdominal x-ray, abdominal ultrasound, or a barium enema. *Id.* at 187-88. Treatment options can include an air enema or a surgical intervention. Yen at 2581.

## **B. Petitioner has not Carried her Burden of Proof**

### 1. I Weighed the Testimony of Dr. Liacouras over that of Dr. Santoro

#### a. *Qualifications*

Dr. Liacouras is board certified in pediatric gastroenterology and he regularly diagnoses and treats children with GERD, constipation, rectal bleeding, diarrhea, and abdominal pain, as well as children with allergic proctocolitis and food allergy. Tr. at 112-13. In addition, he has treated more than 100 infants with intussusception. *Id.* at 114. Dr. Liacouras’ clinical practice and academic career are focused on children with GI issues.

While Dr. Santoro is qualified to testify as an expert, his background is not as strong as that of Dr. Liacouras. For the past 15 years, Dr. Santoro has not treated any children under the age of 11. Tr. at 52. Further, he has treated 8-10 adult patients with intussusception in the past 15 years. *Id.*

#### b. *Familiarity with the Medical Records*

Dr. Santoro did not display the same level of familiarity with the medical records as did Dr. Liacouras. For example, Dr. Santoro testified that one of the reasons he did not believe B.E. suffered from allergic proctocolitis was because B.E. did not experience diarrhea. *See* Tr. at 70. (“Diarrhea, not constipation. That's one of the main reasons . . . I disagree with the Doctor that the patient had [allergic proctocolitis], because in his own article, he states that most kids have significant diarrhea with proctocolitis. He had none.”) In fact, B.E.’s medical records make it clear that B.E. did suffer from diarrhea. On October 28, 2014, B.E.’s medical records note “Diarrhea, [n]o nausea, [n]o vomiting.” Ex. 7 at 164. Further, the records from October 30, 2014 indicate that B.E. was stooling five to six times per day, and his stool was described as diarrhea. Ex. 2 at 34.

As a second example, Dr. Santoro seemed to be unaware that Petitioner had brought B.E. in for GI-related issues prior to his receipt of the rotavirus vaccine.

MS. HEALY: Now, on page 1 of your report, which for the record is Petitioner's Exhibit 5, you state, "At the time of vaccination, Petitioner was a healthy child with no significant history of gastrointestinal disorders."

DR. SANTORO: What page are you on?

MS. HEALY: Page 1.

DR. SANTORO: Yeah, I see that. Yep.

MS. HEALY: But you are aware that during the month leading up to the child's October 20th, 2014, rotavirus vaccination, he on more than one occasion presented to a healthcare provider and concerns were raised about his gastrointestinal system.

DR. SANTORO: Yeah. Actually, I was just made aware of that recently. I didn't -- I didn't appreciate that before.

Tr. at 63.

*c. Dr. Santoro's Testimony was Internally Inconsistent*

On more than one occasion,<sup>9</sup> Dr. Santoro expressed an opinion during this course of his testimony, and then changed that opinion soon thereafter. For example, he testified regarding the issue of B.E.'s constipation and whether that constipation was related to the initial partial intussusception.

DR. SANTORO: I guess the logical next question is -- and I don't want to put words in your mouth -- did his constipation come from the intussusception? Were you thinking of asking that question?

MR. MULLER: I was planning on it, sure.

DR. SANTORO: Okay, all right. I don't think so, actually.

We never discussed this, but, you know, Dr. Talley, when I was in pediatric GI, every other patient was a chronic constipation, usually of the stool withholding variety, and it's a common thing. And my grandchild, who's eight years old and lives with me, has it. You know, it's a very common thing. He never had intussusception. He did have rotavirus vaccine. But I think it's a complex cause probably not related to the vaccine.

Tr. at 36. Soon after expressing this opinion, Dr. Santoro testified that B.E.'s constipation and other GI symptoms were related to the initial event.

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<sup>9</sup> For another example of internal inconsistency, see my discussion of B.E.'s August 2015 medical appointment, discussed *supra*.

MR. MULLER: So page 2 -- Exhibit 4, page 2, the past medical history. He had a rotavirus infection after his two-month rotavirus vaccine [sic]. He developed constipation after that. He was seeing the GI doctor at Denver, received 90 doses of mineral oil, Miralax, barium enema. What I'm asking is, these continued visits post the initial reaction for constipation, for abdominal pain, for rectal bleeding, do you think that that is just happenstance or do you think that that is related to the initial -- do you think his ongoing problems relate to his initial --

DR. SANTORO: My inclination would say that it is related to the initial visit -- I mean, the initial event. Number one, children, after having a serious event like that, can often be sensitized and react with stool withholding, react with constipation.

Tr. at 49-50.

Due to his relative lack of clinical experience with young children when compared with Dr. Liacouras, his level of familiarity with the medical records, and the internal inconsistencies in his testimony, I gave less weight to the opinion of Dr. Santoro than I did to Dr. Liacouras.

2. There is not Preponderant Evidence that B.E. Suffered from a Partial Intussusception

The first step in an “off-Table” claim is to “determine what injury, if any, was supported by the evidence presented in the record.” *Lombardi v. Sec’y of Health & Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). The Vaccine Act “places the burden on the petitioner to make a showing of at least one defined and recognized injury,” and “[i]n the absence of a showing of the very existence of any specific injury[,] . . . the question of causation is not reached.” *Id.*; see *Broekelschen*, 618 F.3d at 1346 (explaining that “identifying the injury is a prerequisite to the [causation] analysis”). In this case, Petitioner has not demonstrated that B.E. suffered from an intussusception, partial or otherwise.

a. *“Partial Intussusception” is not a Recognized Term in the Medical Community*

First, although Dr. Santoro uses the term “partial intussusception,” that term is not mentioned in any of the medical literature, a point that Dr. Santoro acknowledges during his testimony. See Tr. at 71. Dr. Liacouras testified that he has never heard the term, and that a patient either has an intussusception or does not have one. Tr. at 117-18. Dr. Santoro cites to the Yen article for support of his position that a partial intussusception can occur. That article mentions that intussusceptions can spontaneously resolve. See Yen at 2581. However, Dr. Liacouras emphasized in his testimony that any intussusception, to include one that spontaneously resolves, must be seen on imaging in order to make an intussusception diagnosis. Tr. at 124-25. This final and critical point was rebutted by Dr. Santoro.

b. *None of B.E.’s Imaging Indicated that he Had an Intussusception*

Abdominal pain and bloody stools are both symptoms that can be caused by many different conditions, including: constipation, food allergy, inflammatory bowel disease, infection, viral disease, bacterial disease, polyps, and congenital abnormalities of the GI tract. Tr. at 120, 125-26. Abdominal pain and gastrointestinal bleeding are relatively common in infants. Tr. at 113, 125. These symptoms may cause doctors to order imaging to assess for intussusception (as was likely done in this case), but the fact that B.E. had abdominal pain and bloody stools is not, by itself, diagnostic of intussusception.

The only way to definitively diagnose intussusception is through imaging. Tr. at 120. Barium enema and abdominal ultrasound are the most commonly used tests. *Id.* at 187-88. In fact, an abdominal ultrasound is nearly 100 percent accurate if interpreted properly. *Id.* at 122. *See also*, H.M.L. Carty, *Paediatric emergencies: non-traumatic abdominal emergencies*, EMERGENCY RADIOLOGY, Jul. 27, 2002, 2835, 2839, filed as Ex. A-2 (ECF No. 27-3) (stating “[u]ltrasound has a 100% diagnostic accuracy in expert hands.”). Abdominal x-rays are also useful when the condition is severe because they will show evidence of bowel obstruction, altered gas pattern, or other unusual changes to the intestine. *Id.* at 188. B.E. had a total of seven diagnostic imaging tests performed between October 2014 and August 2015. *See* Ex. 1 at 12-13 (an abdominal x-ray and an abdominal ultrasound on October 27, 2014); Ex. 2 at 33 (an abdominal x-ray on November 7, 2014); Ex. 2 at 23 (an abdominal x-ray on May 8, 2015); Ex. 1 at 37 (an abdominal x-ray on June 7, 2015); Ex. 9 at 23 (a barium enema on July 15, 2015); Ex. 2 at 9 (an abdominal x-ray on August 27, 2015). None of these tests showed any evidence of intussusception.

*c. B.E.’s Abdominal Pain Began Before his Rotavirus Vaccination*

Dr. Santoro testified that on two occasions, (October 2014 and August 2015), B.E. suffered from a partial intussusception, and by the time he saw a doctor, each intussusception had resolved. In support of this theory, Dr. Santoro points to B.E.’s symptoms, which included abdominal pain and bloody stools. Because these two symptoms occurred five days after B.E. received his rotavirus vaccination, Dr. Santoro believes that B.E. suffered an intussusception caused by his vaccination.<sup>10</sup>

However, the medical records make clear that B.E. suffered from abdominal pain before he received his rotavirus vaccination. Medical visits on September 15, 2014 and October 13, 2014 both indicate that when he transitioned from breastmilk to Gentlease formula, B.E. became “colicky.” Ex. 1 at 7; Ex. 2 at 35. Even the medical records from the post-vaccination visit on October 27, 2014 indicate that B.E. has had stomach problems since he stopped breastfeeding. *See* Ex. 1 at 11. The records from November 7, 2014 state that B.E. “was well until stopping nursing at age 2-3 weeks.” *Id.* He changed to Gentlease formula “after which he became ‘colicky,’ with ‘screaming all day long.’” *Id.* These records clearly demonstrate that B.E.’s abdominal pain, one

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<sup>10</sup> Dr. Santoro’s theory of causation is unclear with respect to the second episode of partial intussusception in August of 2015. While he bases his opinion regarding the first partial intussusception in October 2014 on “timing, symptoms, and rotavirus” (Tr. at 87), the second partial intussusception in August 2015 would have been 10 months after vaccination. While he opines that it was, “more probable than not” that B.E. experienced an intussusception (Tr. at 103), Dr. Santoro’s reasons for this statement were not fully developed.

of the two symptoms upon which Dr. Santoro relied in arriving at his opinion, actually predated B.E.'s rotavirus vaccination.

d. *B.E. Continued to Experience Symptoms after his Initial "Partial Intussusception" Resolved*

Petitioner's theory that B.E. experienced two separate partial intussusceptions that both resolved before B.E. went into the hospital is not supported by the medical records. Dr. Santoro testified that B.E. experienced his first partial intussusception on October 25, 2014, and that the intussusception spontaneously resolved. However, the medical records demonstrate that B.E. continued to experience abdominal symptoms until at least November 12, 2014 when his stool study tested positive for occult blood. *See* Ex. 2 at 25; Ex. 2 at 48. Dr. Santoro does not explain why B.E.'s symptoms persisted for this long if the intussusception had resolved.

Dr. Santoro testified that a partial intussusception would resolve, "[c]ertainly within a week, but usually in a few days, two to three days, four days." Tr. at 35. A convoluted colloquy on the timeframe for the resolution of B.E.'s intussusception took place later in the proceeding. *See* Tr. at 77-81. This discussion concluded as follows:

THE COURT: What do you think is causing the blood in his stool – on the 7<sup>th</sup> of November?

THE WITNESS: On the 7<sup>th</sup>? One supposition – I don't know, because they don't make a diagnosis here, so I have to guess or I have to make an educated guess. They don't say bleeding from fissure. They don't describe a fissure in this report.

Could he have had a fissure? Maybe. Could he have had an intussusception a few days earlier and it's – or an ulcer related to the initial intussusception and that's bleeding? Yes. I wish they would have made a firm diagnosis.

THE COURT: So you don't really know what's causing the blood one way or another?

THE WITNESS: On this November 7<sup>th</sup> period of time –

THE COURT: Correct.

THE WITNESS: -- yeah, we don't.

Tr. at 80-81.

Dr. Liacouras also addressed this matter: "if you had an intussusception that causes you enough damage that could give you poor resolution and bleeding for weeks, you are going to see something on ultrasound, either thickening of the bowel wall, some – there has got to be some

evidence of ongoing disease giving you that problem.” Tr. at 123. B.E.’s continuation of symptoms into November is not indicative of intussusception given the fact that there was absolutely no evidence of intussusception on any of B.E.’s imaging.

e. *The Mention of Rotavirus in B.E.’s Medical Records Does Not Establish B.E. Suffered an Intussusception*

B.E.’s physicians mention his rotavirus vaccination several times in the medical records. On October 30, 2014, B.E. visited Pediatric Partners of the Southwest for his GI complaints. The records from this visit state, “[p]robable vaccine-strain rotavirus illness, now improving.” Ex. 2 at 35. This note was entered into B.E.’s medical records before his blood tested negative for rotavirus on November 12, 2014. *See* Ex. 2 at 48. There is no evidence in the record that B.E. suffered from vaccine-strain rotavirus.

The medical records from December 10, 2014 state that B.E. “had a reaction to rotavirus in which he experienced bloody diarrhea. ... Plan is to avoid further immunization with the rotavirus.” Ex. 7 at 134. The basis for this entry is unclear.

I have considered the fact that two of B.E.’s treating physicians either considered B.E. had a “probable vaccine-strain rotavirus,” or attributed B.E.’s bloody diarrhea to his vaccination. It is well established that the views of treating physicians are important; however they are also properly subject to evidentiary weighing. *Capizzano*, 440 F.3d at 1326. *See Snyder*, 88 Fed. Cl. at 746. When evaluated in light of the entire record, to include all of B.E.’s negative diagnostic imaging, Dr. Liacouras’ credible testimony, the lack of medical literature mentioning the term “partial intussusception,” and the strong evidence in support of milk protein allergy, I am not persuaded by these two entries.

The Petitioner has established B.E. experienced abdominal pain and bloody stools. These symptoms, without more, do not constitute preponderant evidence that B.E. suffered from an intussusception. Accordingly, Petitioner has failed to meet her burden.

3. Analysis of the *Althen* Prongs

Because Petitioner has not established that B.E. had an intussusception, further analysis is unnecessary. However, for the sake of completeness, I will briefly analyze the *Althen* prongs.

a. *Althen Prong 1: The Rotavirus Vaccine Can Cause Intussusception*

It is well established that the rotavirus vaccine can cause intussusception. *See e.g.*, Yih at 503-06. In fact, intussusception that occurs between one and 21 days after rotavirus vaccination is a Table injury. *See* 42 C.F.R. § 100.3 (2017). Had Petitioner established that B.E. experienced an intussusception, *Althen* prong one would have been met in this case with respect to B.E.’s October 25, 2014 GI incident.

However, Petitioner has not established that the rotavirus vaccine could cause more than one intussusception. Specifically, Petitioner did not offer any evidence to establish that the

rotavirus vaccine could cause an infant to experience recurring partial intussusceptions. Therefore, Petitioner has failed to meet *Althen* Prong 1 with respect to the August 2015 event.

b. *Althen Prong 2: There is not Preponderant Evidence that the Rotavirus Vaccine Did Cause Intussusception in B.E.'s Case*

As discussed above, there is not sufficient evidence in this record to demonstrate that B.E. suffered one or more intussusceptions. B.E.'s symptoms of abdominal pain and bloody stools are relatively non-descript. In fact, B.E. began to experience abdominal pain before his rotavirus vaccination. Further, the absence of any abnormality on any of B.E.'s diagnostic testing demonstrates that he did not have an intussusception, either in October 2014 or in August of 2015.

There is not preponderant evidence that B.E. suffered an intussusception and therefore, that the rotavirus vaccine caused any of B.E.'s injuries.

c. *Althen Prong 3: Five Days Post-Vaccination Is a Medically-Appropriate Onset Interval, but 10 Months Is Not*

The medical literature offered in this case establishes that there is a short temporal association between rotavirus vaccination and intussusception. *See* Yih at 506. This is consistent with the one to 21 day timeframe provided for in the Vaccine Injury Table (*see* 42 C.F.R. § 100.3 (2017)). Dr. Liacouras also testified that the medically-appropriate temporal gap between rotavirus vaccination and intussusception is onset within 21 days. Tr. at 189. In this case, had B.E. experienced an intussusception five days after his rotavirus vaccination, this would have amounted to a medically-appropriate onset interval.

However, the same is not true of B.E.'s purported second partial intussusception in August 2015. This incident occurred more than 10 months after B.E. received the rotavirus vaccination. As noted, *supra*, Dr. Santoro provided inconsistent testimony as to whether he believed this event was an intussusception caused by B.E.'s vaccination. In terms of the timing of the second partial intussusception, Dr. Santoro testified as follows:

Well, assuming that he had some injury to the mucosal lining of the intestine, he could be at risk for further intussusception occurring down the line, at least until the bowel matured, you know, until a couple of years of age, but, you know, there are outliers to the -- to the time frame recommendation, but they're less common.

In one of the reports I reviewed last year, there were cases occurring, you know, 79, 80 days after the rotavirus vaccine, I wish I could be clearer on that, but the records...

Tr. at 102. Petitioner did not file medical literature supporting the proposition that rotavirus vaccine causes intussusception 10 months later. She did not file literature stating an injury to the mucosal lining of the intestine from one intussusception makes patients more likely to suffer a second intussusception nearly one year later. Accordingly, I find there is not preponderant

evidence that an intussusception 10 months post-rotavirus vaccination constitutes a medically-appropriate onset interval.<sup>11</sup>

4. Alternate Causation -- It is More Likely than not that B.E. Suffered from a Milk Protein Allergy

Had Petitioner provided sufficient preponderant evidence that B.E.'s rotavirus vaccination caused him to suffer an intussusception, the burden would then shift to Respondent to establish (also by the same preponderance of the evidence standard) that B.E.'s injuries are due to "factors unrelated" to the vaccine. *C.K. v. Sec'y of Health & Human Servs.*, 113 Fed. Cl. 757, 766 (2013) (citing *Knudsen*, 35 F.3d at 547); *Deribeaux v. Sec'y of Health & Human Servs.*, 105 Fed. Cl. 583, 587 (2012), *aff'd*, 717 F.3d 1363 (Fed. Cir. 2013); *see also Knudsen*, 35 F.3d at 547; 42 U.S.C. § 300aa-13(a)(1)(B). Respondent can meet his burden by relying on evidence derived from the same record that a Petitioner draws upon to carry his initial burden. While I have determined that Petitioner has not met her burden that B.E.'s injury was caused by his vaccination, I will analyze the issue of alternate causation.

Dr. Liacouras' testimony and his citation to the medical records established by a preponderance of the evidence that B.E. suffered from a milk protein allergy.

a. *B.E.'s Symptoms Are Associated with his Change in Formula or the Addition of Milk to his Diet*

The medical records make clear that B.E. first developed abdominal pain after he was weaned from breastmilk. On September 15, 2014, Petitioner brought B.E. to the pediatrician. She mentioned that B.E. was colicky<sup>12</sup>, and that he cried and drank formula constantly from 5:00 pm to 9:00 pm. Ex. 1 at 11. The pediatrician recommended diluting B.E.'s formula. *Id.* at 8. According to Dr. Liacouras, this signified that the doctor "thought the formula may have some relationship to the symptoms." Tr. at 132-33. Additionally, during his well-child exam on October 12, 2014, the records indicate that when B.E. transitioned from breastmilk to Gentlease formula, he became "colicky" (Ex. 2 at 35) and had been "screaming all day long." *Id.* at 25. This is another early indication that B.E. had a milk protein allergy. Tr. at 144.

After recommending dilution of the Gentlease formula, the pediatrician next changed

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<sup>11</sup> Based on this finding, it does not appear Petitioner has established that B.E. met the severity requirement in this case. Under the Vaccine Act's severity requirement, a vaccinee must have: "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or died from the administration of the vaccine, or suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention[.]" § 11(c)(1)(D). B.E. received his rotavirus vaccination on October 20, 2014, suffered a purported partial intussusception on October 25, 2014, and according to Dr. Santoro, experienced residual effects that resolved within one week. Tr. at 35. In order to meet the Act's severity requirement, B.E. would have needed to experience sequelae from his partial intussusception through April 20, 2015.

<sup>12</sup> According to Dr. Liacouras, "colicky" refers to abdominal pain in 99% of infants. Tr. at 171.

B.E.'s formula from Gentlease to Nutramigen. Ex. 2 at 35. Gentlease is a milk-based formula, while Nutramigen "is one of those hydrolyzed formulas that, in theory, is a better nonallergenic formula." Tr. at 133. We can infer that by changing formula from Gentlease to Nutramigen, B.E.'s pediatrician suspected the Gentlease formula to be the cause of B.E.'s symptoms. *See Id.*

Once B.E. transitioned to Nutramigen, his colic improved. Ex. 2 at 35. However, it was noted during his October 13, 2014 well exam that he had developed "stringy, yellow stools, with some darker." *Id.* At the time of this visit, B.E. had been on Nutramigen for about three weeks. *Id.* According to Dr. Liacouras, stringy yellow stools can often mean that the stool contains mucous strands; darker stools can mean that there is some hidden occult blood in the stool. Tr. at 133-34, 172. In his view, the progression of B.E.'s symptoms was consistent with a milk protein allergy: "When you have a milk protein allergy, it often starts out slow and gets worse, and until you do something to correct it ... the symptoms continue and get worse." *Id.* at 134-35.

B.E.'s symptoms did, in fact, get worse. On October 27 and 28, 2014, Petitioner brought B.E. to see a doctor due to abdominal pain and blood in his stool. Ex. 1 at 11. B.E. was noted to have diarrhea. Ex. 7 at 164. His stool was described as loose and green, and it contained blood. Ex. 1 at 11. Diarrhea is a symptom that is consistent with a food allergy. Tr. at 135.

On November 7, 2014, B.E. presented to the ER because he continued to have blood in his stool. Ex. 2 at 25. Significantly, this record indicates that B.E. had begun Neocate formula in the past four to five days. *Id.* at 26. At this point, B.E.'s stooling had decreased, but his stool still contained blood. *Id.* Dr. Liacouras was not surprised by B.E.'s continued symptoms while on Neocate because it can take up to a month for the intestine to fully heal from a milk protein allergy. Tr. at 138-39. Dr. Liacouras testified that Neocate is the amino acid-based formula that is virtually non-allergenic. *Id.* at 137. Neocate is also extremely expensive and can be obtained only through a prescription from a physician. *Id.* at 175. According to Dr. Liacouras, it is so expensive that "[y]ou're not going to do that unless you think milk protein or some kind of food allergy is causing a problem." *Id.*

After beginning Neocate in early November 2014, B.E. did not return to the doctor with any GI complaints until May 2015.<sup>13</sup> This fact is significant in that once B.E. was not exposed to any milk protein allergens, he stopped having GI symptoms.

On May 8, 2015, B.E. presented with constipation, which Petitioner told the physician had been present since B.E. had received the rotavirus vaccination.<sup>14</sup> Ex. 2 at 21. The medical records from this visit state that B.E. went off Neocate onto Nutramigen and had been drinking cow's milk for about one month. *Id.* B.E. continued to experience constipation through June of 2015. *See*

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<sup>13</sup> During this six-month interval, B.E. presented for appointments on December 10, 2014, and on February 9, 2015. Both exams were unremarkable for any type of GI complaint. *See* Ex. 7 at 134-35; Ex. 1 at 26-27; Tr. at 146-47.

<sup>14</sup> The medical records do not support this contention. B.E. experienced diarrhea after transitioning from Gentlease to Nutramigen, *see* Ex. 1 at 11; Ex. 7 at 164; Ex. 2 at 34. The records from May 8, 2015 are the first set of medical records which mention constipation.

Ex. 2 at 19; Ex. 1 at 37. Dr. Liacouras attributed B.E.'s return of GI symptoms to B.E.'s milk protein allergy. Tr. at 149-50. Food allergies can cause both diarrhea and constipation.<sup>15</sup> *Id.* It is notable that B.E.'s GI symptoms only returned when Petitioner reintroduced milk into his diet.

Finally, B.E. presented to the ER on December 14, 2015 with difficulty breathing and pale skin color. Ex. 4 at 2. B.E. had been drinking 40-50 ounces of milk per day. *Id.* at 3; Tr. at 157. Dr. Liacouras testified that because of this excessive milk intake combined with his milk protein allergy, B.E. had become severely anemic. *Id.* at 157-58, 177. Before B.E. was released from the hospital, Petitioner was directed to exclude dairy from B.E.'s diet. Ex. 4 at 22. These facts strongly support the position that B.E. had a milk protein allergy.

b. *B.E.'s Low Albumin Levels Support a Diagnosis of Milk Protein Allergy*

According to Dr. Liacouras, albumin levels can be low when you have intestinal irritation or colitis. Tr. at 138. During the course of his medical care, B.E.'s albumin levels were low on three different occasions. On November 7, 2014, B.E. presented to the Mercy Hospital Emergency Room because of blood in his stool. Ex. 2 at 25. B.E.'s blood work returned an albumin level of 3.5 g/dL, which was low. *Id.* at 32. B.E. had changed formula from Nutramigen to Neocate four to five days previously, but that period of time is not long enough for B.E.'s system to have normalized. B.E. had been drinking Gentlease and Nutramigen formulas since the end of August 2014. This exposure to milk protein likely caused B.E.'s low albumin level. Further, on August 27, 2015, B.E. saw his physician due to blood and slime in his stool. Ex. 2 at 7. At this point, B.E. had transitioned to Nutramigen and then to cow's milk sometime before May of 2015. *Id.* at 21. This means he had been consuming milk protein for at least four months. His albumin level was again reported as low at 3.6 g/dL. *Id.* at 7. Finally, B.E. was admitted to the ER on December 14, 2015 due to difficulty breathing and pale skin color. B.E.'s albumin was 2.5 g/dL. Ex. 4 at 5. Significantly, B.E.'s severe anemia in December 2015 cannot explain his low albumin level. Tr. at 176-77. Accordingly, these low albumin levels, especially when considered in conjunction with the timing of B.E.'s transition to formula and cow's milk, support Respondent's position that B.E. suffered from a milk protein allergy, and that this allergy caused his symptoms.

Accordingly, I find that Respondent has established that B.E.'s injuries are the likely result of his milk protein allergy, a factor unrelated to his rotavirus vaccination.

## VI. Conclusion

Upon careful evaluation of all the evidence submitted in this matter--including the medical records, tests, and reports, as well as the experts' opinions and medical literature--I conclude that Petitioner has not shown by preponderant evidence that B.E. suffered an intussusception, or that any of B.E.'s injuries were caused by his rotavirus vaccination. I further find Respondent has established that B.E. suffered from a milk protein allergy by a preponderance of the evidence. Accordingly, Petitioner's claim for compensation is dismissed.

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<sup>15</sup> Dr. Liacouras testified that approximately 75% of patients with allergic proctocolitis experience diarrhea; 10-15% only have constipation. Tr. at 179.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the clerk shall enter judgment in accord with this decision.<sup>16</sup>

**IT IS SO ORDERED.**

**s/ Katherine E. Oler**

Katherine E. Oler

Special Master

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<sup>16</sup> Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.