# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**
**No. 20-1292V**
UNPUBLISHED

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| JACLYN GODOY, as Parent and Natural Guardian of infant, L.G.,<br><br>Petitioner,<br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | Chief Special Master Corcoran<br><br>Filed: December 2, 2022<br><br>Special Processing Unit (SPU); Ruling on the Record; Decision Without a Hearing; Severity or Six Month Residual Effect Requirement; Rotavirus Vaccine; Intussusception |

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## FACT RULING DISMISSING TABLE CLAIM[1]

On September 30, 2020, Jaclyn Godoy, as parent and natural guardian of infant L.G., filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). On October 2, 2020, Petitioner filed an amended petition. Petitioner alleges that her minor child L.G. suffered Table injuries or, in the alternative, off Table injuries, including intussusception, Sandifer Syndrome, gastroesophageal reflux disease, esophagitis, and constipation, as a result of a rotavirus vaccine received on November 13, 2018. Amended Petition, filed Oct. 2, 2020, at 1. The case was assigned to the Special Processing Unit ("SPU") of the Office of

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[1] Because this unpublished Decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

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

Special Masters. For the reasons discussed herein, I determine that Petitioner is not entitled to compensation on the Table claim, and thus it is dismissed. But Petitioner may be able to substantiate a causation-in-fact claim based on the same facts – and to that end I will transfer the matter out of SPU for further factual development, including expert input.

## I. Relevant Procedural History

On July 27, 2021, Respondent filed his Rule 4(c) Report asserting that the case should be dismissed for failure to meet the severity requirement. (ECF No. 30). On August 11, 2021, a status conference was held to discuss how to proceed, after which a deadline was set for Respondent to file a motion to dismiss. Scheduling Order, filed Aug. 11, 2021 (ECF No. 31).

On September 10, 2021, Respondent moved to dismiss the petition for failure to meet the six month severity requirement (ECF No. 32). Petitioner filed a response in opposition on October 12, 2021 (ECF No. 33), and Respondent replied on October 26, 2021 (ECF No. 35). This matter is now ripe for resolution.

## II. Relevant Medical History

L.G. was born on September 8, 2018. Ex. 1 at 1. On November 13, 2018, L.G. received Rotateq, a rotavirus vaccine, during his nine-week well child visit. Ex. 3 at 50.

Seven days after the rotavirus vaccination, on November 20, 2018, L.G.'s pediatrician was paged with a report that L.G. was lethargic, not eating well, and vomited. Ex. 4 at 11. The pediatrician recommended that L.G. be evaluated by PM Pediatrics or be taken to the emergency room due to his young age. *Id.*

L.G.'s mother took him to the Westchester Medical Center Emergency Department the evening of November 20, 2018. Ex. 6 at 19, 22. She reported that he was lethargic and not eating well. *Id.* While in the waiting room, L.G. had an episode of "forceful projectile vomit" and became uncomfortable and arching. *Id.* at 22. An abdominal ultrasound was performed, and showed ileocolic intussusception. *Id.* at 23, 26. On November 21st, a barium enema with air successfully reduced the intussusception. *Id.* at 23-27, 46. The enema appears to have been administered by the radiologist during an ultrasound. *Id.* at 46 (record of successful reduction of ileocolic intussusception signed by radiologist). The consent form signed by L.G.'s father for the enema was a broad consent form labeled "Informed Consent for Surgical, Invasive Diagnostic Procedures and/or Treatment." *Id.* at 50-51. The form was also signed by the radiologist who performed the procedure, and states that anesthesia may be required, although there is no indication that anesthesia was administered. *Id.* at 16, 17, 50.

Following the successful reduction of the intussusception, L.G. was admitted for observation. Ex. 6 at 24-25, 35. A repeat abdominal ultrasound performed on November 21, 2018 showed no recurrence, and L.G. was discharged the morning of November 22. *Id*. at 16-17. His parents were cautioned that intussusception can recur within a few days and they have a "low threshold to return to ER." *Id*. at 18. Because it occurred within a week of his rotavirus vaccine, Dr. Kristina Melchert indicated that a report was made to VAERS, the Vaccine Adverse Event Reporting System. *Id*. at 35.

On November 21, 2018, Dr. Hernandez at Westchester Medical Center called L.G.'s pediatrician reporting that L.G. presented to the emergency department with intussusception. Ex. 4 at 12. He reported that the intussusception had been reduced, and L.G. was feeding. *Id*. On the same day, L.G.'s pediatrician provided Dr. Melchert with information about the vaccines that had been given to L.G. at the nine week appointment. *Id*. at 13.

On the evening of November 22, 2018, L.G.'s parents called Dr. Christina Blanco of WestMed Pediatrics. Ex. 4 at 14. They reported that L.G. had been discharged from the hospital in the morning, and now in the evening was experiencing similar symptoms, including bouts of abdominal pain, and they were taking him to the ED. *Id*.

L.G. presented to the Westchester Medical Center ED the evening of November 22, 2018. Ex. 6 at 104. L.G.'s mother reported that he was fussy and not eating, which were similar to his symptoms when he was experiencing intussusception. *Id*. L.G. was observed to be in mild distress, with an occasional grimace or frown, squirming, and restless legs. *Id*. at 105. His caretakers reported that at 6 pm, L.G. had "a sudden episode of severe pain and crying that lasted a few moments and spontaneously resolved." *Id*. at 107. His grandfather also reported that while he was holding L.G., he "seemed very uncomfortable and let out a high pitch scream x 1 and then episode resolved." *Id*. An abdominal ultrasound was done to rule out intussusception, and was found to be negative. *Id*. at 110-11. L.G. was discharged with instructions to follow up with his pediatrician within one or two days. *Id*. at 111. The discharge paperwork indicated it was providing instructions for "Acute Intermittent Porphyria, Intussusception (Peds)," although the instructions appear to discuss only intussusception. *Id*. at 113-14.

On November 23, 2018, L.G. was seen by his pediatrician, Dr. Peter Acker, for an intussusception follow up. Ex. 3 at 45. Dr. Acker noted that L.G. had an intussusception that was reduced via air enema, and had been seen at the ER again the night before and had a normal ultrasound. *Id*. at 46-47. Dr. Acker indicated that L.G. currently looked well. *Id*. He discussed feeding, and instructed L.G.'s parents to call for sustained crying, lethargy, or refusal to feed. *Id*. at 47.

On December 11, 2018, L.G. was seen by Dr. Acker for a 13 week well child visit. Ex. 3 at 42. The record indicates that L.G. was a "[w]ell 3 month old with normal growth and development." *Id.* at 44. The record adds, "[d]iscussed feeding," but does not indicate anything further about feeding. *Id.*

On December 19, 2018, L.G.'s mother called Dr. Acker to discuss L.G.'s eating habits. Ex. 4 at 15. Dr. Acker returned the call and documented that he "talked to mother about feeding." *Id.* No further details were noted.

On January 4, 2019, L.G. was seen by Dr. Acker for a 16 week well child visit. Ex. 3 at 38. In the history, the record states, "Feeding problems: N[o]" and "Stools: Nl [normal]." *Id.* L.G.'s parents were instructed to introduce solids and pureed foods gradually. *Id.* at 39-40. Dr. Acker noted that L.G. was a "[w]ell 4 month old with normal growth and development." *Id.* at 40. He added that L.G. should not be given Rotateq, as he had intussusception after it previously. *Id.*

On January 29, 2019, L.G. was seen by his pediatrician because he was fussy and experiencing a right earache that began three days earlier. Ex. 3 at 35. He was diagnosed with an acute upper respiratory infection. *Id.* at 37. His parents were instructed to increase fluids and use saline and a cool mist humidifier, and acetaminophen or ibuprofen as needed. *Id.* The record does not document any other concerns.

On March 1, 2019, L.G. was seen for a six month well child check. Ex. 3 at 31. His parents reported that he was eating solids and had normal stools. *Id.* Dr. Acker noted that he was a "[w]ell 6 month old with normal growth and development." *Id.* at 33. He recorded that he "[d]iscussed feeding and continued introduction of new foods." *Id.*

On March 27, 2019, L.G.'s mother called Dr. Acker reporting that L.G. was "acting weird like [h]is upper body is tense (Muscles). It started this morning at 7am episodes are happening every 30 seconds." Ex. 4 at 17. Dr. Wendy Proskin, a colleague of Dr. Acker, returned the call right away. *Id.* She noted that "pt stiffened several times this am during am bottle. arched a little" and "suggested this may be d/t reflux and d/w parents possible sandifer syndrome – but also to make appt to see pcp this am and to bring the video." *Id.* L.G.'s mother attempted to make an appointment the next day, but the earliest opening was on April 1. *Id.* at 18.

On April 1, 2019, L.G.'s father called the pediatrician's office to clarify what L.G. was being seen for that day. Ex. 4 at 19. He was told that L.G. was "coming in for concerns about intussusception and [e]ffects on pt stomach or digestion." *Id.*

On April 1, 2019, L.G. was seen by Dr. Acker. Ex. 3 at 28. The record indicates that the reason for the visit was "GI concerns." *Id.* Dr. Acker noted that L.G. was:

> Here with symptoms after feeding either bottle or pureed food – back arching, jerking of arms and throwing headback – seems to correlate with increased amounts of food – so now taking less than before. Started rather abruptly a week ago. Video of events viewed. Pmhx [previous medical history] – had [intussusception] at age 2months after rotateq. has been thriving since then. Imp Sandifer's syndrome – ranitidine started [sic] – counseled on thickened feeds, holding upright after meals. Will refer to Peds GI . . . . Weight gain is fine so far.

Ex. 3 at 30. L.G.'s parents were instructed to provide smaller feeds frequently, and to keep L.G. upright for 10-15 minutes after feeding. *Id.* They were to elevate the head of his crib, and give him Maalox four times daily before feeding. *Id.* If these changes did not help within two or three days, they were to start Prevacid. *Id.*

On April 4, 2019, L.G. was seen by pediatric gastroenterologist Dr. Danya Rosen. Ex. 8 at 11. The record indicated that he was referred by Dr. Acker for evaluation of reflux and possible Sandifer's Syndrome. *Id.* at 12. L.G.'s father reported that the week before they were giving L.G. a bottle and he "immediately tensed up including his face, arms stiffened." *Id.* This happened six times. *Id.* They had now stopped introducing purees. *Id.* L.G. had also pushed the bottle away. *Id.* L.G.'s parents reported that on Friday they tried giving him carrots, but he tensed up again. *Id.* L.G. was also waking more frequently during naps. *Id.* His parents reported that the tensing used to "just be after feeds, now can be up to 3 hours after feeds." *Id.* They reported that they had been giving him solids twice daily for two months "with no issues." *Id.* This week they had started him on Zantac and his feeding had improved since then. *Id.* He was taking more formula and not stiffening as much. *Id.* The stiffening tended to happen more with solids than bottles. *Id.*

At the April 4, 2019 appointment, Dr. Rosen diagnosed L.G. with gastroesophageal reflux disease ("GERD"), esophagitis presence not specified. Ex. 8 at 14. She advised that reflux would be atypical to occur at six months of age, but that pushing the bottle away may be a sign of reflux and it was reassuring that his parents had seen improvement since starting Zantac. *Id.* She recommended increasing the Zantac dose and continuing to offer solids twice daily. *Id.* If this did not help in one to two weeks, she would consider a trial of another medicine and/or thickening feeds. *Id.*

On April 16, 2019, L.G. was seen by his pediatrician for a measles vaccine. Ex. 3 at 25. The record does not indicate that any feeding or gastrointestinal concerns were reported.

On June 11, 2019, L.G. was seen by Dr. Acker for a nine month well child check. Ex. 3 at 21. No feeding problems were reported, and his stools were normal. *Id*. He was found to be a "[w]ell 9 month old with normal growth and development." *Id*. at 24. Dr. Acker discussed feeding and communication. *Id*.

On July 5, 2019, L.G. was seen by Dr. Acker for a right ear ache. Ex. 3 at 18. Dr. Acker determined that it was teething syndrome, and recommended Tylenol and/or motrin for teething pain. *Id*. at 19-20.

On September 13, 2019, L.G. was seen for a 12 month well child check. Ex. 3 at 13. No feeding problems were reported, and his stools were normal. *Id*.

On October 9, 2019, L.G. was seen for a head injury and vomiting that had started that day. Ex. 3 at 8. His parents reported that he had fallen and hit his head on a wooden floor, then cried and vomited once, and had been fine thereafter. *Id*. at 10. Dr. Acker diagnosed him with an accidental fall, and instructed his parents to call for any vomiting or lethargy. *Id*.

On November 5, 2019, L.G.'s mother messaged Dr. Acker through a patient portal. Ex. 4 at 36. She reported:

> For a few weeks now (I think since transitioning to whole milk from his dairy free formula), [L.G.] has been very uncomfortably constipated. . . . We've been giving him pureed apples and prunes but its not really working. Do you have any other recommendations? It's affecting his day to day life.

Ex. 4 at 36. Dr. Acker responded that Petitioner could try a probiotic or corn syrup. *Id*.

On April 24, 2020, L.G. had a telemedicine appointment with Dr. Rosen. Ex. 9 at 28. L.G.'s mother stated that he had been showing signs of discomfort after eating. *Id*. at 29. The discomfort was worse after milk, and cheese also bothered him. *Id*. Dr. Rosen noted that he had been on Zantac for about a month but stopped because it was not making much improvement. *Id*. He tried yogurt around nine months, and seemed uncomfortable and fussy. *Id*. He had some constipation after the introduction of whole milk, and his bowel movements varied from loose to hard. *Id*. Dr. Rosen explained that the differential diagnoses included reflux vs milk protein intolerance vs milk allergy. *Id*. at 30. Dr. Rosen diagnosed him with gastroesophageal reflux disease, esophagitis presence not specified, and milk protein intolerance. *Id*. at 28. She recommended a two week elimination of all dairy products. *Id*. at 30.

On August 4, 2020, L.G.'s mother messaged Dr. Acker, reporting, "[f]or about at least *a week* now [L.G.] has been extremely constipated (*nothing like his usual self*)." Ex. 4 at 60 (emphasis added). Dr. Acker suggested pedilax. *Id.*

On January 24, 2021, L.G. presented to the Maria Fareri Childrens Hospital ED. Ex. 12 at 52. L.G.'s grandmother reported that he was lethargic and crying in pain, and had a history of intussusception with a similar presentation. *Id.* She reported that L.G.'s abdominal pain began the day before and since then he had been acting tired, lying down, and had no interest in playing. *Id.* at 53. The previous evening at 5:30pm he began crying, and at 7pm he began pulling on his diaper. *Id.* He was slightly pale, and for a week had been avoiding bearing weight on his right leg. *Id.* He complained of pain with movement. *Id.* His last bowel movement was the day before and was normal. *Id.* He demonstrated mild improvement with Tylenol. *Id.* at 54. He showed marked improvement after catheterization. *Id.*

At 12:21pm on January 24th, L.G. exhibited guarding and abdominal tenderness in all quadrants. Ex. 12 at 149, 152. An abdominal ultrasound performed shortly thereafter showed no evidence of intussusception. *Id.* at 17, 56, 139-40. A bladder/renal ultrasound performed several hours later showed normal size kidneys, no bladder wall thickening, and no hydronephrosis. *Id.* at 138-39. A lumbar spine x-ray showed "[l]imited visualization of sacrum secondary to large amount stool rectosigmoid. Correlate with history of constipation." *Id.* at 137.

Dr. Evan Spencer, a urology resident, examined L.G. on the evening of January 24, 2021. Ex. 12 at 65. The record states:

> [L.G.] is a 2 yo boy who presents after experiencing severe abdominal pain and agitation in the morning. He presented to the ED for evaluation of possible intussusception (prior episode @10 weeks treated with air contrast enema). On abdominal US [ultrasound] no evidence of intussusception, but bladder highly distended. Straight cathed [catheter] for 400 mL by ED attending. Still unable to urinate for next 3-4 hours and urology consulted.
>
> Parents deny PMH/PSH [past medical history/past surgical history] aside from intussusception, no allergies or chronic medications. Noted to be engaged with physical therapy for possible neck contractures and leg weakness.
>
> RBUS [renal bladder ultrasound] obtained and shows 187 mL in bladder w/o hydro. Pt [patient] still unable to void.

Ex. 12 at 66.

Dr. Spencer noted that L.G.'s abdominal exam was limited due to muscle tensing. Ex. 12 at 66. L.G. was assessed as having "seemingly longstanding urinary retention as judged by highly enlarged bladder for age." *Id.*

On the evening of January 24, 2021, L.G. was examined by pediatric resident Dr. Daniel Brady. Ex. 12 at 63. Dr. Brady noted that L.G.'s grandmother noticed that "he woke up crying this morning, which isn't abnormal for him, but that he seemed tired throughout the day. He had little appetite and was pulling at his diaper. Grandma thought the diaper might be too tight, so she loosened the diaper and noticed that he was reluctant to have anyone go near his abdomen or diaper area. Dad notes that in the past several weeks, [L.G.] has been going longer between wet diapers, but that this was only remarkable in hindsight." *Id.* A review of systems noted reduced oral intake, urinary retention, and abdominal pain. *Id.* at 64. He was assessed with acute urinary retention. *Id.* Urology recommended imaging of the urinary system, a lumbar sacral x-ray, and foley catheterization overnight. *Id.* Dr. Brady noted, "[p]ossible etiologies include neurologic (e.g. tethered cord), toxic ingestion (e.g. anticholinergic), or structural (e.g. posterior urethral valve)." *Id.*

In the early morning of January 25, 2021, while still hospitalized, L.G. was found to still be experiencing urinary retention. Ex. 12 at 152. That afternoon, he was seen for a follow up by urologist Dr. Richard Schlussel. *Id.* at 65. Dr. Schlussel noted that L.G. had a "[s]ignificant amount of constipation" and had received an enema, resulting in a bowel movement. *Id.* Dr. Schlussel assessed L.G. with urinary retention, and determined that the enema should be repeated "as the constipation may be the cause of the retention." *Id.*

L.G. was discharged from the hospital on January 26, 2021. Ex. 12 at 17-31. He was to follow up with his pediatrician within 2-4 days, and follow up with Dr. Schlussel in two weeks. *Id.* at 18. The hospital record includes a table labeled problem list, with "Intussusception (Confirmed)" listed with a status of "Active." Ex. 12 at 36. The columns for effective dates, health status, and informant are empty. *Id.*

On February 8, 2021, L.G. was seen by Dr. Schlussel. Ex. 13 at 7. Dr. Schlussel noted that L.G. "has been on Miralax and has had good bowel movements and wet diapers and has been comfortable." *Id.* A sonogram revealed normal kidneys and bladder. *Id.* Dr. Schlussel remarked that L.G. was doing well and seemed to be voiding normally. *Id.*

On April 12, 2021, L.G. was seen by Dr. Schlussel for a follow up. Ex. 14 at 8. The record indicated that L.G. was experiencing constipation again. *Id.* A bladder ultrasound was done. *Id.* Dr. Schlussel recommended an enema on that day and the following day, and a consult with a gastroenterologist. *Id.*

On April 22, 2021, L.G. was seen by pediatric gastroenterologist Dr. Rosen. Ex. 16 at 11. The record noted:

> [L.G.] is a 31 m.o. male here today for evaluation of constipation. Referred by Dr. Acker/urologist Dr. Schlussel. Previously seen by me for infantile reflux. In January mother was giving birth and he was home with grandparents. Developed urinary retention and so brought to Maria Fareri Children's Hospital had 490cc in his bladder. Admitted because he could not urinate on his own. Did an X-ray that showed he was constipated, gave 2 enemas with good response and then he was able to start urinating on his own again. Sent home on Miralax 1/2 capful daily.
>
> Lately has been having constipation issues again. Mostly having 2 soft stools daily although this past week has been harder and less volume. Had been trying to potty train but now backed off.

Ex. 16 at 11.

A review of systems noted constipation, urinary retention, and "stiffening episodes." Ex. 16 at 12. Dr. Rosen's impression stated:

> 2 y.o. 7 m.o male previously seen by me for reflux here today for evaluation of constipation. Constipation is likely functional in etiology, low suspicion for organic process at this point although differential includes celiac disease, hypothyroidism, hirschsprung's, motility disorder.

Ex. 16 at 13. Dr. Rosen recommended that L.G. continue Miralax 1/2 to one capful daily, a high fiber diet, limit milk, encourage water, and hold off on potty training. *Id.*

On June 16, 2021, L.G. was seen by Dr. Rosen for a follow up. Ex. 16 at 13. The record noted that he was "[s]een today in joint bowel/bladder clinic. Had urology evaluation today due to episodes of urinary retention, U/S [ultrasound] in office today showed hard stool." *Id.* Dr. Rosen noted that she had last seen L.G. two months earlier. *Id.* L.G. had cut back on milk intake and was continuing to take 1/2 capful of Miralax daily, and had daily bowel movements ranging in consistency from hard to more loose. *Id.* at 13-14. He was having good weight gain. *Id.* at 14. The review of systems was identical to

that of the April visit, noting constipation, urinary retention, and stiffening episodes. *Id*. Dr. Rosen's impression contained the identical note from the previous visit, other than updating his age and noting that it was a follow up:

> 2 y.o. 9 m.o. male previously seen by me for reflux here today for follow up of constipation. Constipation is likely functional in etiology, low suspicion for organic process at this point although differential includes celiac disease, hypothyroidism, hirschsprung's, motility disorder.

Ex. 16 at 15. Dr. Rosen recommended that L.G. continue 1/2 capful of Miralax, add 1/2 Ex-Lax square daily at lunchtime, and continue a high fiber diet. *Id*. L.G. was to follow up in two to three months. *Id*.

## III. Affidavit Evidence

Petitioner filed an affidavit in support of the case as Exhibit 5. She averred that on November 20, 2018, she noticed that L.G. began to act lethargic and more tired than usual. Ex. 5 at ¶ 5. He was not eating as much as normal, and barely drinking formula. *Id*.

On November 21, 2018, L.G. started throwing up, was eating even less, and seemed tired and sleepy. Ex. 5 at ¶ 6. Petitioner took him to Westchester Medical Center. *Id*. While in the waiting room, L.G. grimaced and forcefully vomited, after which he was uncomfortable and was arching. *Id*. An ultrasound showed intussusception, which resolved with a barium enema. *Id*. L.G. was discharged the morning of November 22, 2018. *Id*.

On the evening of November 22, 2018, L.G.'s parents brought him back to Westchester Medical Center because he was having severe stomach pain, crying, and appeared very uncomfortable. Ex. 5 at ¶ 7. An abdominal ultrasound was normal, and L.G. was discharged. *Id*.

Petitioner avers that on December 19, 2018 she called the pediatrician's office "to talk to Dr. Acker regarding my concerns about L.G.'s eating habits." Ex. 5 at ¶ 11. However, she provides no further information about any such discussion.

Petitioner asserts:

> From January 2019 to February 2019, L.G. continued to experience stomach pains, was irritable, and would have days where he wouldn't eat his normal amount. I did not take him to the doctor regarding his residual

> intussusception symptoms or mention it during visits to Dr. Acker because I was able to manage it. L.G., however, did continue to have symptoms throughout this time period.

Ex. 5 at ¶ 12.

Petitioner states that she called the pediatrician's office on March 27, 2019 because L.G. was "acting weird" and tensing and stiffening his upper body after drinking his bottle. Ex. 5 at ¶ 16. She brought him to see Dr. Acker on April 1, 2019 about these episodes. *Id*. at ¶ 18. Petitioner avers that Dr. Acker diagnosed L.G. with Sandifer Syndrome and referred him to a pediatric gastroenterologist. *Id*.

Petitioner reports that on April 4, 2019, Dr. Rosen diagnosed L.G. with gastroesophageal reflux disease and esophagitis. Ex. 5 at ¶ 20. She increased L.G.'s zantac dosage and advised his parents to give him solid food twice daily. *Id*.

Petitioner avers that on November 5, 2019, she contacted Dr. Acker through the patient portal, reporting:

> *[F]or the past few weeks, since transitioning to whole milk* from his dairy free formula, my son has been very uncomfortably constipated. That he either has multiple small hard poops throughout the day and sometimes even 2-3 tiny rabbit poop hard balls.

Ex. 5 at ¶ 26 (emphasis added). Dr. Acker recommended probiotics or a teaspoon of karo corn syrup in four ounces of water once daily. *Id*.

Petitioner states that L.G. had a telehealth appointment with Dr. Rosen on April 24, 2020, during which she informed Dr. Rosen that L.G. had been showing signs of discomfort after eating, which was worse after milk. Ex. 5 at ¶ 27. Dr. Rosen advised that it could be reflux or a milk allergy or intolerance, and recommended stopping all dairy products for two weeks. *Id*.

Petitioner reports that on August 4, 2020, she sent Dr. Acker a message through the patient portal, stating:

> *[F]or about at least a week now* my son had been extremely constipated, which was unlike his usual self. My husband and I tried giving him tons of prunes, prune pouches, etc., with no relief. I also told Dr. Acker that my son has become a very picky eater and has not been consuming many vegetables, however, he was still eating a good amount of fruit. Additionally,

> I informed Dr. Acker that he had been unusually irritable the past week, which I though could possibly be teething. However, there were no other of his usual teething signs that he had in the past.

Ex. 5 at ¶ 28 (emphasis added).

Finally, Petitioner concluded that "L.G. has suffered residual effects from his intussusception and Sandifer Syndrome for more than six months after the November 13, 2018 vaccination." Ex. 5 at ¶ 30.

## IV. Applicable Legal Standards

Pursuant to the Vaccine Act, Petitioner must show that L.G. received a vaccine covered by the Program, 42 U.S.C. §300aa–14(a); sustained an injury on the Vaccine Injury Table, an injury that was caused-in-fact by the vaccine, or had an injury significantly aggravated by the vaccine, *and* either "(i) suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or . . . (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention[.]" 42 U.S.C. §300aa–11(c)(1)(D).

It is Petitioner's burden to prove her case, including the six month requirement, by a preponderance of the evidence. 42 U.S.C. §300aa-13(a)(1)(A). A finding that the severity requirement has been met cannot be made based upon unsupported claims of Petitioner alone. 42 U.S.C. §300aa–13(a)(1). Failure to satisfy this requirement may result in dismissal. *See Ojeda Colon v. Sec'y of Health & Human Servs.*, No. 18-1065V, 2021 WL 2809582 (Fed. Cl. Spec. Mstr. June 3, 2021), *mot. for rev. den.*, 156 Fed. C. 534 (Oct. 18, 2021) (while even mild symptoms may satisfy the severity requirement, ongoing treatment for conditions unrelated to the alleged vaccine injury do not); *Delzer v. Sec'y of Health & Human Servs.*, No. 17-0462V, 2019 WL 994582 (Fed. Cl. Spec. Mstr. Jan. 18, 2019) (dismissing case for failure to meet severity requirement).

"Medical records, in general, warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, the fact that a medical record is silent on a condition does not give rise to a presumption that the condition did not exist. *Kirby v. Sec'y of Health & Human Servs*., 997 F.3d 1378, 1382-83 (Fed. Cir. 2021). Rather, a special master may accept testimony that does not conflict with medical records in evaluating whether the six month requirement is satisfied. *Id*.

## V. The Parties' Arguments

### A. Respondent's Motion to Dismiss

Respondent asserts that the medical records do not support a finding that L.G. suffered sequela of his intussusception for at least six months. Motion to Dismiss ("Mot.") at *7. This is because the medical records "indisputably show that L.G.'s condition was diagnosed and successfully reduced *without surgery* on November 20, 2018, seven days after his November 13, 2018 rotavirus vaccination." *Id.* (emphasis added). Respondent acknowledges that L.G. was seen at the hospital for a suspected possible recurrence on November 22, 2018, but adds that an ultrasound showed no evidence of recurrent intussusception. Mot. at *8.

Respondent also questions whether any of L.G.'s subsequent symptoms could be the basis for a claim, arguing that there is "no reliable evidence that a rotavirus vaccine can cause, or does cause, Sandifer syndrome, esophagitis, or GERD." Mot. at *8. At most, L.G. "began to demonstrate a new behavior and appeared to tense when he was first introduced to solid foods in late March 2019." *Id.* But this was four and a half months after his acute intussusception resolved. *Id.* Respondent adds that L.G.'s father reported to Dr. Rosen that these symptoms began one week before L.G.'s April 4, 2019 visit. *Id.* Dr. Rosen diagnosed L.G. with GERD, and that L.G.'s symptoms improved with Zantac, a medication used to treat GERD. *Id.* Ultimately, "no provider associated these symptoms with L.G.'s prior intussusception or the November 13, 2018 rotavirus vaccination." *Id.* at *8-9.

Later, the record establishes that L.G. "developed a new symptom of constipation in November 2019 and April 2020," but it occurred "a year or more after the rotavirus vaccine" and that "those symptoms were associated with the transition from non-dairy baby formula to whole milk." Mot. at *9. At bottom, the records belie Petitioner's claim that L.G. had ongoing feeding issues after his intussusception in November 2018. *Id.* Instead, they demonstrate that L.G. was not just healthy, but thrived, following his intussusception, with no feeding issues and normal growth and development. *Id.* Respondent adds that L.G. consistently measured significantly above average in height and weight. *Id.*

### B. Petitioner's Opposition

Petitioner argues that the medical records and affidavit testimony establish that L.G. suffered from intussusception and resulting sequela for over six months following the November 13, 2018 rotavirus vaccination. Opp. at *15. Petitioner cites "recurrent reflux symptoms" from April 2019 to April 24, 2020; constipation that continued after following Dr. Rosen's instructions after the April 24, 2020 appointment; L.G.'s January 2021

hospitalization, including the notation of L.G.'s history of intussusception; and L.G.'s constipation that resulted in longstanding urinary retention. *Id.* at *15-16.

Petitioner takes issue with Respondent opting not to cite an August 4, 2020 patient portal message to Dr. Acker, L.G.'s January 2021 hospital admission, and subsequent treatment by Dr. Schlussel in February and April 2021 and Dr. Rosen in June 2021. Opp. at *16. Petitioner asserts that these records "are sufficient for the Chief Special Master to conclude that Petitioner could meet the Vaccine Act's requirements and prevail." *Id.*

Petitioner argues that I should examine whether Respondent has demonstrated the absence of a genuine issue of material fact, drawing every inference concerning disputed facts in Petitioner's favor, citing *Warfle v. Sec'y of Health & Human Servs*., No. 05-1399V, 2007 WL 760508 (Fed. Cl. Spec. Mstr. Feb. 22, 2007). Opp. at *16. The *Warfle* petitioner was able to provide school records and fact witness affidavits corroborating the symptoms complained of, and there were no contradictory medical records. Opp. at *16-17. Petitioner argues that based on this evidence, the special master denied a motion to dismiss, and that I should do the same in this case. *Id.*

This case involves "critical medical records that document [L.G.'s] need for recurrent and ongoing treatment for gastroenterological care as a result of his Intussusception." Opp. at *16. In response to Respondent's argument that L.G.'s records following the November 2018 intussusception demonstrate normal growth and development, Petitioner maintains that the significance of L.G.'s "ability to maintain his weight and eat requires an expert's opinion." *Id.* Petitioner also asserts that L.G. "continues to suffer from resulting sequela since his intussusception." Opp. at *17. Petitioner also argues that L.G. "still suffers from constipation and has suffered from constipation for over 6-months." *Id.*

Petitioner asserts that Respondent's motion is "premature" because an expert report is required in this case to opine as to L.G.'s purported sequelae. Opp. at *17. L.G.'s treating physicians were never asked to opine that his constipation, Sandifer Syndrome, and/or GERD were related to intussusception, and that Petitioner "should not be precluded from the opportunity to offer Expert testimony as to that notion." *Id.* at *18.

### C. Respondent's Reply

In response to Petitioner's opposition, Respondent argues that Petitioner's apparent theory has changed.[3] In the petition, Petitioner asserted a claim for an

[3] It is not clear that Petitioner has changed her theory. The petition asserts that L.G. suffered residual effects or complications of his injuries for more than six months. Amended Pet. at ¶ 36. The fact that the petition

intussusception Table injury or, in the alternative, that his intussusception, Sandifer Syndrome, GERD, and constipation were caused in fact by the November 13, 2018 rotavirus vaccine. Reply at *1. However, in opposing the motion to dismiss, Petitioner alleged that as a result of the rotavirus vaccine, L.G. sustained intussusception and resulting sequela, including Sandifer Syndrome, GERD, esophagitis, and constipation. *Id.* at *1-2. Nonetheless, Respondent asserts that both the claim in the Petition as well as the theory set forth in the opposition fail to state a claim. *Id.* at *2. Respondent argues that there is "no evidence that an isolated event of intussusception, which resolved without surgery, can cause sequelae months or years later." *Id.*

In response to Petitioner's argument that the August 4, 2020 portal message to Dr. Acker, January 2021 hospitalization, and February-April 2021 Dr. Schlussel records bolster Petitioner's case, Respondent contends that these records not only fail to satisfy the severity requirement, but that they further undermine Petitioner's claim. Opp. at *2. Respondent points out that portal message indicates that L.G. was constipated, but contains no suggestion that this was associated with L.G.'s November 2018 intussusception. *Id.* As for the January 2021 hospitalization, Respondent notes that L.G. was evaluated for possible intussusception, but that an abdominal ultrasound showed no evidence of one. *Id.* at *3. The February and April 2021 records of Dr. Schlussel, Respondent points out, indicate that Dr. Schlussel considered L.G.'s constipation to be likely functional in etiology, and found low suspicion for an organic process. *Id.* Respondent asserts that Dr. Schlussel "did not conclude that L.G.'s constipation was, in any way related to his prior intussusception." *Id.* Respondent asserts that Dr. Rosen also thought L.G.'s constipation was likely functional, and did not mention L.G.'s prior intussusception. *Id.* at *4.

Respondent argues that, contrary to Petitioner's suggestion, there are no records documenting ongoing or recurring intussusception. Opp. at *4. While the January 2021 hospitalization records include intussusception as "active" in a problem list and noted a history of intussusception with a similar presentation, an ultrasound performed showed "no evidence of intussusception." *Id.* at *4-5 (citing Ex. 13 at 11).

Respondent argues that none of L.G.'s treating physicians ever opined that Sandifer Syndrome, GERD, esophagitis, or constipation, or any symptoms occurring after November 2018, have any connection to L.G.'s intussusception. Reply at *5. Although L.G. sought care for gastrointestinal concerns in 2019 and 2020, Respondent asserts that "there is simply no basis to state that those symptoms are related to his isolated event of intussusception." *Id.*

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asserted Sandifer Syndrome, GERD, esophagitis, and constipation as vaccine-related injuries is not inconsistent with Petitioner now asserting these conditions as sequelae of intussusception.

Respondent asserts that an April 1, 2019 record indicates that L.G.'s father called the pediatrician's office to ask why L.G. was being seen and was told that L.G. was coming in for concerns about intussusception and effects on his stomach or digestion. Opp. at *5. However, other than this inquiry, Respondent argues that the medical records show that L.G.'s treating physicians "were keenly aware of his resolved intussusception in November 2018 and provided opinions on the etiologies of his various later complaints." *Id.* For example, Respondent notes that in April 2020, Dr. Rosen discussed a possible milk protein intolerance as a cause of L.G.'s constipation. *Id.* Further, in January 2021, testing was done to rule out intussusception. *Id.* at *6. In 2021, both Dr. Schlussel and Dr. Rosen opined that L.G.'s constipation was likely functional in etiology. *Id.* Respondent asserts that none of L.G.'s treating physicians suggested a connection to L.G.'s November 2018 intussusception or the rotavirus vaccine. *Id.*

## VI. Analysis

The amended petition asserts a claim for a Table intussusception, plus a causation-in-fact claim that L.G.'s receipt of the rotavirus vaccine in November 2018 caused intussusception *plus* Sandifer syndrome, GERD, esophagitis, and constipation. Amended Pet. at ¶¶ 34, 35. I will address the viability of these claims separately.

### A. Table intussusception claim

The sole dispute relating to Petitioner's Table intussusception claim is whether the statutory severity requirement is met. Respondent does not contest that the literal injury experienced by L.G. otherwise meets the Table requirements – and as a Table claim, Petitioner need only establish (as she has) that the relevant vaccine was administered in the defined timeframe before manifestation of the injury.

Intussusception as defined in the Qualifications and Aids to Interpretations ("QAI") is a time-limited injury involving "invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus." 42. C.F.R. § 100.3(b)(4)(i). It is an acute, life-threatening illness, and treatment can include an air enema or surgical intervention. *Carda v. Sec'y of Health & Human Servs*., No. 14-191V, 2017 WL 6887368, at *19 (Fed. Cl. Spec. Mstr. Nov. 16, 2017).

Thus, inherent to a Table intussusception claim is the fact that the injury is by definition self-limiting and readily-treated. Indeed – it exists as a Table claim *in part*

because of a desire to make the injury actionable *despite* its acute nature (which defeats the Act's six-month severity requirement). Children's Health Act of 2000, Pub. L. No. 106-310, Sec. 1701 (2000). This amendment to the Act allowed vaccinees to meet the severity requirement by demonstrating that they had undergone surgical intervention and inpatient hospitalization. *Id.* at Sec. 1701 (amending section 11(c)(1)(D) of the Vaccine Act). In proposing this amendment, the Senate bill's sponsors acknowledged that most cases of intussusception would not be compensable under current law, and proposed the amendment to expand the cases that would be compensable to those involving both surgical intervention and inpatient hospitalization. 145 Cong. Rec. 15213-03 (Nov. 19, 1999) (statement of Sen. Jeffords). In other words, intussusception is generally compensable as a Table claim only if surgical intervention is required.[4]

Here, although L.G. was hospitalized, he did not undergo surgical intervention. A barium enema is a treatment for intussusception, and as such would seem to qualify as an "intervention." However, it is not performed by a surgeon under anesthesia. Rather, the enema was performed by a radiologist, and there is no indication that anesthesia was administered. *Green v. Sec'y of Health & Human Servs.*, No. 19-1295V, 2020 WL 1845325 (Fed. Cl. Spec. Mstr. Mar. 18, 2020) (intussusception claim dismissed at Petitioner's request, noting that "the Court has repeatedly held that intussusception treated with a barium enema does not qualify as surgical intervention" and that Petitioner's claim did not satisfy the six month requirement); *Parsley v. Sec'y of Health & Human Servs.*, No. 08-781V, 2011 WL 2463539, at *n.19 (Fed. Cl. Spec. Mstr. May 27, 2011) (noting that "[t]he parties have agreed that the barium enema was not a 'surgical procedure'" under the Vaccine Act).

Intussusception that can be treated less invasively, and resolved, cannot meet the severity "surgical intervention" exception. And here, the record demonstrates that L.G.'s intussusception resolved on November 21, 2018, after the administration of the barium enema. Ex. 6 at 45. L.G. was admitted for observation, and discharged two days later. *Id.* at 16-35. While he was twice later evaluated for recurrence, on November 22, 2018 (Ex. 6 at 104-114) and in January 2021 (Ex. 12 at 17-31), on both occasions, no intussusception was found. Thus, the Table claim for intussusception cannot in this case be established.

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[4] By contrast, self-resolving intussusception instances, even when vaccine-associated, were deemed non-compensable by the Act. *Boman v. Sec'y of Health & Human Servs.*, No. 15-0256V, 2016 WL 2979760, at *7 (Fed. Cl. Spec. Mstr. Mar. 22, 2016) (stating that the statutory amendment was "of no help in the present" in intussusception case that resolved spontaneously).

### B. Causation-in-Fact Claim

While it is a close case, I find that Petitioner should be afforded the opportunity to prove a non-Table claim: that the rotavirus vaccine could cause a presenting intussusception that *subsequently* resulted in the litany of gastrointestinal maladies she alleged L.G. experienced over time. Admittedly, not all of these symptoms appear to have robust record support. A close review of the record shows that L.G.'s other GI symptoms occurred months or years after his intussusception, and there is no indication that his treating physicians considered them to be related to his intussusception. Indeed, it is not evident that a single vaccine-caused intussusception could *itself* result in these later symptoms, even if the intussusception itself is deemed vaccine-caused. But Petitioner has persuasively established that she should be given the opportunity to locate and offer expert support for this kind of claim. This will, however, have to occur outside of SPU.

## Conclusion

- **The motion to dismiss is granted in part and denied in part. Petitioner's Table claim is dismissed.**
- **The case is transferred out of the SPU for further proceedings relating to Petitioner's off Table claims.**
- **Petitioner may file, by no later than Tuesday, January 31, 2023, an expert report.**

**IT IS SO ORDERED.**

**s/Brian H. Corcoran**
Brian H. Corcoran
Chief Special Master