In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
Filed: January 25, 2023

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LIANG ZHAO, *Parent and natural guardian of G.L., a minor,*	*	Unpublished
Petitioner,	*	No. 19-735V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal Decision; Severity Requirement; Intussusception.
Respondent.	*	
* * * * * * * * * * * * *		

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for petitioner.
Felicia Langel, U.S. Dept. of Justice, Washington, D.C., for respondent.

DECISION DISMISSING PETITION[1]

On May 17, 2019, Liang Zhao, as parent and natural guardian of G.L., a minor ("petitioner"), filed a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that G.L. suffered from intussusception after receiving the third rotavirus vaccine on November 18, 2016. Petition (ECF No. 1).

For the reasons set forth before, after a review of the record as a whole, including the medical records, affidavits, and expert reports, I find by preponderant evidence that the petitioner has failed to demonstrate that G.L. suffered the residual effects or complications of the alleged vaccine-related injury for more than six months after the administration of the rotavirus vaccine,

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[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the opinion is posted on the Court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

as required by the Vaccine Act. *See* 42 U.S.C. § 300aa-11(c)(1)(D)(i). Therefore, respondent's motion to dismiss this petition is hereby **GRANTED** and the petition is **DISMISSED.**

I. Procedural History

Petitioner filed the petition for compensation on May 17, 2019. Petitioner also filed medical records and an affidavit to accompany the petition. *See* Petitioner's Exhibits ("Pet. Exs." 1-6.

On November 26, 2019, respondent filed the Rule 4(c) report, recommending against compensation. Respondent's ("Resp.") Report ("Rept.") (ECF No. 11). Respondent stated that G.L.'s intussusception, which he developed twelve days following the third dose of the rotavirus vaccination, does not meet the criteria of the Vaccine Injury Table " because the '[o]nset….[o]ccured with or after the third dose of a vaccine containing rotavirus.' " Resp. Rept. at 4 (citing 42 C.F.R. § 100.3(c)(4)(ii)(A)). Therefore, respondent stated, "petitioner is not entitled to a presumption of vaccine causation and must proceed on a theory of causation-in-fact." *Id.* Respondent also stated, "….the record does not reflect that petitioner has the requirements of 42 U.S.C. § 300aa-11(c)(1)(D). In relevant part, that provision requires petitioner to demonstrate that G.L. "suffered the residual effects of complications of his illness, disability, injury or condition for more than 6 months after the administration of the vaccine." *Id.* at 6. Respondent stated that "the record does not reflect that G.L. experienced any ongoing medical issues related to his intussusception." *Id.*

This case was initially assigned to a different special master, who ordered petitioner to address the six-month severity requirement and to also file an expert report. *See* Scheduling Order (ECF No. 17); Scheduling Order (ECF No. 21). Petitioner filed an expert report on September 16, 2020, from Dr. Thomas Sferra, along with supporting medical literature. Pet. Ex. 11 (ECF No. 25). Respondent filed an expert report from Dr. Chris Liacouras on January 15, 2021. Resp. Ex. A. On March 24, 2021, petitioner filed a supplemental expert report from Dr. Sferra. Pet. Ex. 12.

The case was reassigned to my docket on December 8, 2021. Notice of Assignment (ECF No. 44). The undersigned held a status conference on March 9, 2022. During the status conference, I explained that the record did not demonstrate that G.L. suffered the residual effects of his intussusception for six-months or more, nor did he have any surgical intervention to repair the surgical intervention, thus I recommended that petitioner voluntarily dismiss her claim. Scheduling Order (ECF No. 46).

The undersigned held another status conference on October 27, 2022, where petitioner was present, along with her counsel. *See* Scheduling Order (ECF No. 52). During this status conference, the undersigned explained the underlying issues with her claim, specifically the lack of records to support a showing that G.L.'s injury met the severity requirement of the Vaccine Act. *See* Scheduling order (ECF No. 53). The undersigned gave the petitioner the opportunity to voluntarily dismiss her claim or have the respondent file a motion to dismiss.

On November 30, 2022, petitioner filed a status report stating that she would not voluntarily dismiss her claim. As such, respondent filed a motion to dismiss on December 28,

2022. Resp. Motion ("Mot.") (ECF No. 55). Petitioner filed a response to respondent's motion on January 17, 2023. Pet. Response (ECF No. 56).

This matter is now ripe for adjudication.

II. Legal Standard

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

For either a Table or off-Table injury, petitioners are required to demonstrate that they meet the Vaccine Act's six-month severity requirement. A vaccinee must demonstrate that he or she has: (i) 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 (ii) died from 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. §300aa-11(c)(1)(D)(i)-(iii).

The "surgical intervention" language was added to the Vaccine Act in the year 2000 to allow for recovery for intussusception, which is an intestinal prolapse that is often severe enough to require surgery but which typically does not include significant residual effects after surgery. *See e.g. Spooner v. Sec'y of Health & Human Servs.,* No. 13-159V, 2014 WL 504728 (Fed. Cl. Spec. Mstr. Jan. 16, 2014); *Stavridis v. Sec'y of Health & Human Servs.,* No. 07-261V, 2009 WL 3837479 (Fed. Cl. Spec. Mstr. Oct. 29, 2009).

In *Cloer,* the Federal Circuit explained that the six-month severity requirement "is a condition precedent to filing a petition for compensation." *Cloer v. Sec'y of Health & Human Servs.,* 654 F.3d 1322, 1335 (2011), *cert. denied,* 132 S.Ct. 1908 (2012). A petitioner must demonstrate that they have satisfied the severity requirement by preponderant evidence. *See Song v. Sec'y of Health & Human Servs.,* 31 Fed. Cl. 61, 65-66 (1994), *aff'd* 41 F. 3d 1520 (Fed. Cir. 1994). Finding that a petitioner has met the severity requirement cannot be based on petitioner's word alone, though special masters need not base their findings on medical records alone. §13(a)(1); *see Colon v. Sec'y of Health & Human Servs.,* 156 Fed. Cl. 534, 541 (2021).

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 [he or 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, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. 42 U.S.C. § 300aa-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." 42 U.S.C. § 300aa-13(b)(1). The undersigned must weigh the submitted evidence and the testimony of the parties' offered experts and rule in petitioners' favor when the evidence weighs in their favor. *See Moberly*, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence"); *Althen*, 418 F.3d at 1280 ("close calls" are resolved in petitioner's favor).

Medical records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." *Cucuras v. Sec'y of Health & Human Servs.,* 993 F. 2d 1525, 1528 (Fed. Cir. 1993); *Lowrie v. Sec'y of Health & Human Servs.,* No. 03-158V, 2006 WL 3734216, at*8 (Fed. Cl. Spec. Mstr. Nov. 29, 2006). Medical records created contemporaneously with events they describe are presumed to be accurate and complete. *Doe/70 v. Sec'y of Health & Human Servs.,* 95 Fed. Cl. 598, 608 (2010).

However, there is no presumption that medical records are complete as to all of a patient's conditions, as the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions.". *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1382-83 (Fed. Cir. 2021). After all, "[m]edical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs*., No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). And, importantly, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991) (quoting the decision below), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992). The *Murphy* Court also observed that "[i]f a record was prepared by a disinterested person who later acknowledged that the entry was incorrect in some respect, the later correction must be taken into account." *Id.*

III. Evidence Submitted

a. G.L.'s Medical Records

G.L. was born on May 17, 2016. Pet. Ex. 3 at 21. On May 31, 2016, G.L. had a newborn check-up with Dr. Linda DeLessio. Pet. Ex. 3 at 20. Dr. DeLessio noted that G.L. was being fed every two hours and was voiding and had stools. *Id.* However, G.L.'s father reported concern that G.L.'s abdomen was "inflated." *Id.* It was noted that G.L.'s respiratory rate was low. *Id.* at 21. However, G.L.'s physical exam was normal and he was "progressing as expected." *Id.* at 22. G.L.'s heart murmur was "not heard today," so an echocardiogram was delayed. *Id.* Dr. DeLessio wrote that G.L. was gaining weight well and his exam was normal. *Id.*

G.L. had his two-month well check on July 19, 2016. Pet. Ex. 3 at 23. G.L. was brought in by his father. *Id.* He reported that G.L. was breast feeding often, voiding and stooling well and sleeping well. *Id.* G.L.'s development screen was 'within normal limits." *Id.* at 24. At this appointment, G.L. received his first rotavirus vaccination. *Id.* at 24.

G.L. had an appointment on August 11, 2016, with Dr. Brian Moshier. Pet. Ex. 3 at 26. Petitioner reported that G.L. "had been sweating a lot of he received vaccines, about three weeks ago," and she also expressed concern that G.L. "has a digestion issue because [he] has been having a lot of gas and is spitting up with feedings." Pet. Ex. 3 at 26. Petitioner reported that G.L. had been spitting up during the two hours after a feeding, but that the spit up was non-bloody, nonbilious, and non-projectile. *Id.* Additionally, G.L. had approximately 10 wet diapers a day and stooling once a day. *Id.* G.L. was assessed with gastroesophageal reflux disease and was sent for an echocardiogram for a heart murmur. *Id.* at 28.

G.L. returned to Dr. DeLessio on August 25, 2016, after the finding of a secundum ASD (atrial septal defect) on the echocardiogram. Pet. Ex. 3 at 29. Petitioner reported that G.L. did not have rapid breathing with feeding, but that he was sweating more around the head and back of neck when he wakes up. Pet. Ex. 3 at 29. Petitioner reported that G.L. was feeding well, he was not fussy and had no fever. *Id.* Dr. DeLessio diagnosed G.L. with secundum ASD and explained to petitioner that "most small ASDs close by 1-2 years of life without residual complications." *Id.* at 30. Further, Dr. DeLessio noted that G.L. was dressed in two layers of clothing when the outside temperature was 80 degrees and recommended that dressing G.L. in one light layer during the summer may help reduce sweating. *Id.* Additionally, Dr. DeLessio explained that G.L. was "growing very well" and that his spit ups were infrequent, and he was gaining weight. *Id.* Petitioner inquired as to whether it was safe for G.L. to receive his four-month vaccines given G.L.'s heart condition. *Id.* Dr. DeLessio "encouraged" petitioner to bring the information in with her to the next appointment. *Id.*

G.L. had his four-month well child exam on September 15, 2016. Pet. Ex. 3 at 32. Petitioner had concerns for thrush and atopic dermatitis. *Id.* It was noted that G.L.'s sweating had decreased, but G.L. was uninterested in bottle feeding and had a recent bout of thrush. *Id.* After a physical exam, G.L. was assessed as "progressing as expected." *Id.* at 34. At this appointment, G.L. received multiple vaccinations, including his second rotavirus vaccination. *Id.* at 34.

On October 7, 2016, petitioner and G.L. had an appointment with Dr. Keith Kappel for "white spots in his mouth." Pet. Ex. 1 at 46. Petitioner reported that G.L. had been taking Nystatin for three weeks, but still had spots in his mouth. *Id.* It was noted that G.L. was given this medication, but then feeding afterwards and mother was nursing but was not treating herself. *Id.*

On November 18, 2016, G.L. presented to Dr. Kappel for his six-month well child exam. Pet. Ex. 1 at 41. It was noted that one of G.L.'s ongoing disorders was "heart murmur." *Id.* Under "Nutrition History" it was recorded that G.L. was eating baby food, uses a bottle, and is also breast fed. *Id.* Further, G.L. was also consuming Similac Advanced. *Id.* At this appointment, he weighed 20 lbs. *Id.* at 41. Under assessment, G.L. had no abnormal findings

and Dr. Kappel recommended that G.L. move to "stage II foods," and to feed him solids three times a day. *Id.* at 42. G.L. was also administered the third rotavirus vaccine, along with the DTap-Hib-IPV, third does of the hepatitis B vaccine, and the pneumococcal PCV-13. *Id.* at 43.

On November 30, 2016, G.L.'s mother called Dr. Kappel's office and reported that G.L. was "not eating and crying all the time." Pet. Ex. 1 at 35. G.L. was seen later that day by Dr. Kappel and at this time, G.L. had vomited three times and he was fussy. *Id.* at 30.

As G.L.'s vomiting continued, he also began to have bloody stools. Pet. Ex. 2 at 96. Petitioner brought G.L. to the Children's Hospital of New Orleans emergency department and reported, "persisted vomiting" and that several hours later G.L. had "strawberry jelly" like stool. *Id.* An abdominal ultrasound revealed a small bowel intussusception and G.L. was admitted to "attempt reduction" with a contrast enema. *Id.* at 97.

On December 1, 2016, G.L. was admitted to the hospital and a water-soluble contrast enema was used to reduce the intussusception. Pet. Ex. 2 at 104. Approximately twelve hours later, G.L. had a recurrent intussusception, which again was reduced with a water-soluble enema. *Id.* at 173. G.L. was discharged on December 3, 2016. On December 6, 2016, G.L. returned to the hospital emergency department with abdominal complaints. Pet. Ex. 2 at 40. At first an ultrasound showed what appeared to be a short segment small bowel intussusception, but once the exam was complete, the intussusception was no longer visualized. *Id.* at 44. The impression was "transient small segment small bowel intussusception."

On December 28, 2016, G.L. had a follow-up appointment with Dr. David Yu, a pediatric surgeon, who reviewed G.L.'s past medical history and noted that since December 6th, "G.L. has done well. At home he seems to be tolerating a regular diet with good bowel function." Pet. Ex. 2 at 8.

On February 8, 2017, G.L. had an appointment with Dr. Vickie Pyevich for his heart condition. Pet. Ex. 6 at 22. Petitioner expressed concern over his septal defects.[3] *Id.* She also explained that G.L. enjoyed breast feeding and formula and he was feeding well. *Id.* Dr. Pyevich wrote that G.L.'s exam was "suggestive of a small VSD," but that G.L. was growing well and had no symptoms of concern. *Id.* Dr. Pyevich recommended that G.L. have a chest x-ray and if that is normal, then follow-up can be in one year. *Id.* Nurse McDonald called petitioner on February 14, 2017 reporting that G.L.'s chest x-ray was normal. *Id.* at 26.

On March 21, 2017, G.L. had a well-child appointment with Dr. Linda DeLessio. Pet. Ex. 3 at 35. At this appointment, petitioner reported that G.L. was having nursing/formula six times a day, eating baby foods, but also that G.L. was experiencing some constipation. *Id.* Petitioner reported that G.L. was having hard stools and having difficulty with bowel movements. *Id.* Dr. DeLessio recommended that petitioner add prune juice to G.L.'s diet. *Id.* at 37. On May 9, 2017, G.L. had another appointment with Dr. DeLessio. *Id.* at 43. Petitioner reported that G.L. was again experiencing constipation and expressed concern that the intussusception caused G.L.'s constipation. *Id.* Dr. DeLessio explained that the intussusception

[3] Dr. Pyevich felt that G.L. may also have a small ventricular septal defect (VSD) based on her examination.

would not cause the constipation and recommended a small amount of Miralax for G.L. *Id.* at 44.

On July 3, 2017, G.L. had an appointment with Dr. Keith Kappel for diarrhea. Pet. Ex. 1 at 12. During this appointment, G.L.'s mother stated that G.L. had diarrhea with an onset of three weeks ago. *Id.* Additionally, she reported that G.L. had been constipated for a "few weeks" and only had a bowl movement 2 to 3 days. *Id.* Dr. Kappel's assessment was "slow transit constipation" and recommended that G.L. stop using formula, switch to low-fat milk, and increase his water intake. *Id.* at 18. The next medical record is from July 28, 2017, where petitioner called Dr. Kappel's office regarding "cough, congestion, and running nose." Pet. Ex. 4 at 11.

On November 20, 2017, G.L. had a follow-up appointment with Dr. Pyevich for his heart condition. Pet. Ex. 6 at 32. It was noted that while he does wake up in the middle of the night, he is growing and developing well. *Id.* It was noted that G.L. was still breastfeeding at age 18-months, but it was mostly for comfort. *Id.* The physical exam was relatively difficult, but his blood pressure was recorded as normal. *Id.* at 34. Petitioner expressed concern that G.L. had hypertension and Dr. Pyevich attempted to explain that there was no evidence of hypertension. *Id.*

On February 19, 2018, G.L. had an appointment with Dr. Catherine Degeeter, pediatric gastroenterologist. Pet. Ex. 6 at 48. Petitioner self-referred G.L. to the pediatric gastroenterologist, reporting "alternating constipation and loose stools." *Id.* Dr. Degeeter noted that at six months of age, G.L. experienced an intussusception which was resolved by an enema and then a recurrence, which was also relieved by a barium enema. *Id.* Petitioner reported that G.L.'s "bowel habits changed after the episode of intussusception," including "loose stools for 3 months at the beginning of last year (2017) and these resolved, now stools have been on the more firm side." *Id.* Petitioner also reported that G.L. had bowel movements every 2-3 days and will give Miralax to soften stools. *Id.* Additionally, petitioner reported having concerns that G.L. was not gaining weight since six months old, however, the growth chart was reviewed and Dr. Degeeter wrote "his weight is tracking nicely at the 85th percentile." *Id.* After a physical exam, Dr. Degeeter wrote, "Discussed with mother that we can better control his constipation with proper mixing and use of Miralax. I do not think his constipation is due to his history of intussusception and as he has not had any further episodes, I do not think at this time it is necessary to evaluate his GI track any further. Discussed in detail that his growth has been appropriate." *Id.* at 50.

On March 27, 2018, G.L. was seen by Dr. Benjamin Reinking for his heart condition. Pet. Ex. 6 at 55. Petitioner, along with G.L.'s father and grandmother attended this appointment. *Id.* The family reported "occasional episodes of perioral cyanosis," and that they were "unsure if it is triggered by cold or bathing." *Id.* G.L. had an EKG and echocardiogram at this appointment. After the examination, Dr. Reinking diagnosed G.L. with "innocent heart murmur," and wrote, "G.L. has a history of a possible ASD and VSD noted on an echo at three months of age. He [does] not [have] concerning symptoms that would suggest cardiac problems. His exam reveals an innocent sounding heart murmur. Echo and EKG done during his visit today were normal. I reassured [G.L.'s] family that he has a normal heart." *Id.* at 57.

On May 18, 2018, G.L. had appointment with Dr. Deepna Kukreja. Pet. Ex. 5 at 16. Petitioner reported that G.L. had vomiting and diarrhea for three days, with decreased wet diapers. *Id.* Petitioner reported G.L. as "fussy" and "fatigued," along with a decreased appetite. *Id.* Under physical exam it noted that G.L., "did not appear exhausted," and that he was in "no acute distress." *Id.* His bowel sounds were hyperactive. *Id.* Dr. Kukreja recommended that G.L. be given Pedialyte or Gatorade in small amounts and to let his stomach rest for about an hour after vomiting. *Id.*

On August 28, 2018, G.L. had a two-year well child appointment with Dr. Sarah Hartman. Pet. Ex. 5 at 13. At this appointment, it was reported that G.L. had normal bowel movements daily and had a normal appetite. *Id.* It was also noted that G.L. had a normal number of wet diapers and "normal toilet training." *Id.*

b. Expert Reports

i. Petitioner's Expert: Dr. Thomas J. Sferra

Petitioner submitted two expert reports from Dr. Thomas J. Sferra. Pet. Ex. 11; Pet. Ex. 12. While his two reports discuss vaccine causation, most relevant to this decision is his opinion about G.L.'s residual symptoms after G.L. experienced the intussusceptions in December 2016.

Dr. Sferra wrote that "G.L. was a six-month male, infant who developed recurrent intussusception requiring a contrast enema on two occasions for relief of the condition." Pet. Ex. 11 at 3. He explained that on November 30, 2016, G.L. developed persistent emesis, he developed bloody stools and he was taken to a pediatric emergency room "at which time an abdominal ultrasound demonstrated a large ileocecal intussusception extending to the hepatic flexure. The intussusception was reduced radiologically (enema with water-soluble contrast agent) on December 1, 2016." *Id.* He noted that G.L. developed a recurrence of the intussusception which also required a radiologic reduction (enema with water-soluble contrast agent). *Id.* Dr. Sferra also observed that on December 6, 2020, G.L. again had bowel movements containing blood and was taken back to the emergency room where ultrasound showed a self-resolving small bowel-small bowel intussusception. *Id.* Dr. Sferra wrote, "Since these events, G.L. has had ongoing concerns with constipation requiring the use of a stool softener." *Id.*

Dr. Sferra stated that G.L.'s long term medical issues that were related to his intussusception was his diagnosis of "functional constipation." *Id.* at 6. He wrote that, "Functional disorders of the bowel frequently are triggered by an acute infection or other adverse process affecting the bowel. This has been frequently described [as] irritable bowel syndrome in adults and children. However, it is applicable to children in which irritable bowel syndrome with constipation as an associated symptom can occur." *Id.* He concluded, "Thus, G.L.'s ongoing concerns with constipation can reasonably be related to the acute inflammation following the vaccine that led to the two episodes of intussusception." *Id.*; Pet. Ex. 12 at 3-4.

ii. Respondent's Expert: Dr. Chris Liacouras

Respondent's expert, Dr. Liacouras does not disagree that G.L. experienced two intussusceptions in December 2016 twelve days after he received the third dose of the rotavirus vaccine. Resp. Ex. A at 3.

Dr. Liacouras opined that G.L.'s functional constipation was unrelated to the intussusception. *Id.* at 3. He wrote that "functional constipation is one of the most common disorders that occurs in infants and toddlers and makes up approximately 15-20% of all outpatients seen by pediatric gastroenterologist." *Id.* He explained that "The cause of functional constipation is typically related to dietary intake, toilet training, and a delay in recognition. It is not caused by intussusception." *Id.* Dr. Liacouras stated, "G.L.'s medical history is completely consistent with the development of functional constipation." *Id.* at 4. Dr. Liacouras observed that two of G.L.'s treating physicians also "explicitly stated that the patient's intussusception was *not* the cause of constipation." *Id.* (original emphasis).

Dr. Liacouras wrote that, "it is certainly possible that intussusception can cause constipation when it is acutely present and actively causing symptoms. However, once intussusception is treated and resolved, especially if surgery was not required, no further episodes occur, and no evidence exists that there was chronic irreversible intestinal damage, intussusception does not cause chronic constipation." *Id.* at 5. Further, he argued that G.L.'s dietary history, bowel movement history, and response to constipation treatments are all entirely consistent with functional constipation. *Id.* at 7. He explained, "G.L.'s pediatrician confirmed that G.L. had functional constipation which was not related to his intussusception and after developing constipation, G.L. demonstrated multiple outpatient visits when he was having normal bowel movements that responded to changes in diet without medical treatment." *Id.*

Dr. Liacouras concluded his report stating, "With regard to [G.L.'s] constipation, after the immediate period of intussusception, G.L. had no further episodes of intussusception and no evidence of chronic anatomic or neuromuscular abnormalities. Instead, G.L.'s constipation was intermittent, was often related and responsive to dietary changes, always responded to medical therapy, and was consistent with the vast majority of young children who have functional constipation." *Id.*

IV. Analysis

The medical records demonstrate that G.L. received the third rotavirus vaccination on November 18, 2016. Pet. Ex. 1 at 43. Under the Vaccine Injury Table, intussusception can be a Table Injury after the first and second dose of the rotavirus vaccine, but not the third. *See* 42 C.F.R. §§ 100.3(a)(XI)(A), 100.3(c)(4)(A). Therefore, petitioner is not entitled to a presumption of vaccine causation. Regardless of whether petitioner is alleging a Table or cause-in-fact claim, petitioners must demonstrate that his alleged injury meets the severity requirement. However, the medical records and expert opinion do not demonstrate that G.L.'s alleged vaccine-related injury continued past December 6, 2015.

Petitioner states that G.L.'s functional constipation was the residual effect of the intussusception that G.L. suffered as a result of receiving the third rotavirus vaccination, and that

it continued for more than six months. Pet. Response at 6. Petitioner argues that G.L.'s functional constipation was "likely triggered by an adverse process affecting the bowel: in this case it was the intussusception caused by the rotavirus vaccine." *Id.*

Respondent argues that the "petitioner cannot satisfy the six-month severity requirement, or the alternative severity requirement of inpatient hospitalization and surgical intervention." Resp. Mot. at 6. Respondent states, "G.L.'s intussusceptions resolved within a few days, and there were no sequelae." *Id.* Respondent asserts that G.L.'s treating physicians did not attribute his subsequent constipation to his intussusception. *Id.* Further, respondent states that G.L.'s intussusceptions did not require surgical intervention and they resolved with a water soluble contrast enema. *Id.* Respondent concludes that "petitioner's claim does not meet the statutory severity requirement." *Id.*

The undersigned agrees with respondent. The medical records demonstrate that approximately twelve days after G.L. received the third dose of the rotavirus vaccine, he suffered an intussusception. The intussusception likely began on November 30, 2016, and it was resolved by a contrast enema on December 1, 2016. *See* Pet. Ex. 2 at 104. While G.L. did have a recurrence of the intussusception twelve hours later, that too was also resolved by a contrast enema. Barium contrast enemas are non-surgical interventions that are used reduce intussusceptions.[4] It also appears that on December 6, 2016, G.L. had another recurrence of an intussusception, but it was resolving on its own and no medical intervention was required. *See* Pet. Ex. 2 at 8.

At G.L.'s follow-up appointment with Dr. David Yu, pediatric surgeon on December 28, 2016, it was stated that since the G.L.'s ultrasounds on December 6th, he was "tolerating a regular diet with good bowel function." Pet. Ex. 2 at 8. Between December 28, 2016, and March 21, 2017, the focus of G.L.'s medical appointments was on his heart condition.

On March 21, 2017, nearly 3 months after the last report of G.L.'s abdominal pain, petitioner reported that G.L. was experiencing constipation. Pet. Ex. 3 at 35. At this appointment, Dr. DeLessio weighed G.L. at 23 lbs. His development screen was "within normal limits." *Id.* at 36. Dr. DeLessio recommended that petitioner introduce prune juice into G.L.'s diet for constipation and urged petitioner to make an appointment with Dr. Pyevich for his cardiac condition. *Id.* On May 9, 2017, petitioner brought G.L. to see Dr. DeLessio again with concerns about constipation. Pet. Ex. 3 at 43. At this appointment, petitioner expressly stated that she was concerned that the intussusception caused G.L.'s constipation. *Id.* Dr. DeLessio explained to petitioner "that intussusception would not cause constipation but it would be important to control constipation to prevent further complications." *Id.* at 3.

When G.L. was seen by Dr. Kappel on July 3, 2017, G.L. was experiencing diarrhea. Pet. Ex. 1 at 12. Petitioner also reported that G.L. was constipated for a few weeks. *Id.* Dr. Kappel diagnosed G.L. with "slow transit constipation" and recommended that petitioner stop using formula for G.L. and switch to low-fat milk, while increasing his water intake. *Id.* at 18.

[4] An enema is a liquid injected or to be injected into the rectum for the reduction of an intussusception. *Dorland's Illustrated Medical Dictionary*, 33rd Ed. at 615 (2020).

Thereafter, it was not until February 2018, when G.L. was seen by a pediatric gastroenterologist, Dr. Catherine Degeeter. Pet. Ex. 6 at 48. At this appointment, petitioner reported that G.L. experienced loose stools in the following months after the intussusception, but then his stools have been "more on the firm side." *Id.* After reviewing his medical history and reviewing G.L.'s growth progress, Dr. Degeeter counseled petitioner on how to better control G.L.'s constipation with "proper mixing and use of Miralax." *Id.* at 50. Additionally, Dr. Degeeter stated, "I do not think his constipation is due to his history of intussusception and as he has not had any further episodes, I do not think at this time it is necessary to evaluate his GI track any further. Discussed in detail that his growth has been appropriate." *Id.*

Aside from the opinion of Dr. Sferra, two of G.L.'s treating physicians do not associate his intussusception from December 2016 to his constipation. *See* Pet. Ex. 3 at 44; Pet. Ex. 6 at 50. In the appointment twenty-two days following his last abdominal ultrasound, G.L. was noted to be having normal bowel movements and eating well. *See* Pet. Ex. 2 at 8. The two statements from the treating physicians, independent from one another reviewed G.L.'s medical history and examined him, are persuasive evidence that G.L.'s constipation was not a residual effect of the intussusception he experienced in December 2016. Further, there is no evidence in the medical records to suggest that his constipation was a result of his intussusception. Additionally, the first report of G.L.'s constipation came over three months after the intussusception, making it less likely that his constipation was attributable to the intussusception, rather than something else, such as dietary changes. Furthermore, Dr. Liacouras persuasively explained that functional constipation is a very common disorder in infants and is treated with good results in the same manner in which G.L. was treated. He also explained, consistent with the treating physicians, that when the constipation occurs remotely from the resolution of the intussusception as was the case here, the constipation was not caused by the intussusception.

As such, I am not persuaded by petitioner's argument that G.L.'s constipation was the residual effect of the intussusception that occurred twelve days after this third rotavirus vaccination.

V. Conclusion

After evaluation of the evidence submitted in this case, including the medical records and expert reports, I find that petitioner has not established by preponderant evidence that she has met the Vaccine Act's statutory six-month severity requirement. Accordingly, respondent's motion is hereby **GRANTED** and petitioner's claim for compensation is **DISMISSED.**

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.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master