

I. Factual History

The essential facts are not in dispute. R.B. was born on November 15, 2012, the product of an uncomplicated pregnancy. Ex. 3 at 7-9. He was evaluated as normal at his newborn checkup on November 19, 2012. Ex. 4 at 1-2.

On January 4, 2013, at approximately seven weeks of age, R.B. was seen by his pediatrician for “vomiting X 2 weeks after every feeding, grunting, drooling, holding breath, fussy.” The record indicates that his mother was “concerned that he may have reflux.” He was diagnosed with “esophageal reflux” and prescribed appropriate medications. Ex. 4 at 4.

On January 25, 2013, R.B. attended his two-month checkup and received a set of vaccinations, including the rotavirus vaccine that petitioner alleges caused R.B. to develop intussusception. During the visit, petitioner reported that R.B. had bowel movements every other day, and the last one had slight blood streaks.⁵ Ex. 4 at 5-6.

On February 4, 2013, R.B. was seen by Dr. David Kappernman for blood in his stool. Petitioner reported that she first noticed blood on February 2, 2013. Dr. Kappernman noted that the amount of blood was “very minute” and that R.B. did not appear “toxic.” The plan was to watch him closely for fever. Ex. 8 at 1.

On February 6, 2013, R.B.’s grandmother contacted Dr. Kappernman’s office on behalf of petitioner to report that R.B. was screaming and doubling over. Based on these and other symptoms, Dr. Kappernman assessed probable colic and provided guidance for appropriate care. Ex. 8 at 2. A subsequently ordered rotavirus test returned with negative results. *Id.* at 4.

On February 12, 2013, R.B. was seen by Dr. Rachelle Vicencio for a history of “bright red stools with JELLY like material,” which reportedly developed two weeks earlier, lasted two consecutive days, resolved, and then returned in a cycle. Ex. 6 at 1. Based on petitioner’s report, Dr. Vicencio was “suspicious of intermittent episodes of intussusception[,]” or a possible milk protein allergy. She ordered lab work and a CT scan. *Id.* at 2; Ex. 3 at 45-55. The scan, performed the same day, revealed a “potential lead point for intussusception,” but showed that no intussusception present at that time. Ex. 3 at 52.

On February 17, 2013, R.B. was taken to an emergency clinic for “[f]luidness and history of probable intussusception.” Ex. 8 at 7. Petitioner recounted R.B.’s recent medical history, noting that he was seen five days earlier and a full set of labs and a CT were performed. *Id.* The results were negative, except for a finding of “an abnormally large lymph node near the ileocecal junction.” *Id.* She reported that R.B.’s last bowel

⁵ In her Rule 4(c) Report (“Resp’t’s Rep.”), respondent stated: “According to personnel at the Department of Health and Human Services, Division of Injury Compensation Programs (“DICP”), this amount of blood is associated with constipation and is common in a newborn. Intussusception, at this point, would be associated with a greater amount of blood and additional problems within a day or two.” Resp’t’s Rep. at 2 n.2.

movement was the prior day and that he had not had any red currant jelly stools in the last 5 days. *Id.* The treating physician assessed intermittent severe fussiness, but ordered an ultrasound at a nearby hospital to rule out intussusception. *Id.* Later that day, petitioner took R.B. to the nearby hospital's emergency room for evaluation and to have the ultrasound. Ex. 3 at 57-74. The clinical intake summary notes a prior history of presumptive intussusception due to Peyer's Patches⁶ and clinical symptoms. *Id.* at 60. The ultrasound was negative for evidence of intussusception. *Id.* at 74. R.B. was discharged early on February 18, 2013. *Id.* at 66.

Later that same day, petitioner took R.B. to another hospital where he was admitted due to reported abdominal pain and possible intussusception. Ex. 5 at 1, 9-10. After obtaining R.B.'s medical history and conducting an examination, Dr. Stefanie Ames, an attending physician, opined that based on "the recurrent and episodic nature of the illness, this is likely intussusception caused by lead point of large lymph node." *Id.* at 22. She hoped "to observe event and potentially capture with radiologic studies during episode." *Id.* at 23. She noted that it was "unusual" that all of the imaging to date had been normal and stated that she would have to entertain the possibility that it was something other than intussusception if the imaging remained negative but the symptoms persisted. *Id.*

On February 19, 2013, a consulting surgeon diagnosed intermittent abdominal pain that was by history "consistent with recurrent intermittent intussusception." Ex. 5 at 36. The surgeon noted that the episodes "seem[ed] to resolve spontaneously" and had not yet been "captured on ultrasound." *Id.* She speculated that "given his age and history of recent immunizations[,] it [was] unlikely to be a pathologic lead point, and ... probably a lymph node." *Id.* She assessed "no role for ACE [air contrast enema] in the absence of a documented, persistent ileocolic intussusception." *Id.*

On February 21, 2013, Dr. Kevin Nelson, another attending physician requested a gastroenterology consultation to obtain a possible alternative diagnosis. Ex. 5 at 48. The gastroenterologist reviewed R.B.'s medical history and performed a physical examination. He then reported:

[T]horough evaluation for potential intussusception has thus far been negative. Though this still may be a potential cause for the patient's symptoms, the gastroenterology service has been requested to provide input on potential alternative diagnoses. I do entertain the potential for milk protein allergy as a cause of the patient's symptoms, especially given a clear picture that perhaps the previously described currant jelly stools may rather be blood-tinged mucousy stools.

Id. at 51.

⁶ In her Rule 4(c) Report, respondent stated: "Peyer's Patches are small masses of lymphatic tissue found in the ileum of the small intestine. As part of the immune system, they monitor intestinal bacteria populations and prevent the growth of pathogenic bacteria in the intestines." Resp't's Rep. at 3 n.3 (citing Tim Taylor, *Peyer's Patches*, INNERBODY, <http://www.innerbody.com/anatomy/immune-lymphatic/peyers-patches>).

R.B. was discharged from the hospital on February 21, 2013, with primary diagnoses of “milk protein allergy” and “intussusception, intermittent and spontaneously resolving,” and a secondary diagnosis of “reaction to rotavirus.” Ex. 5 at 61, 65.

On April 11, 2013, R.B. attended his four-month checkup. Petitioner reported that he had regular bowel movements at least once daily. The examination revealed no abnormalities and his development was normal. Ex. 6 at 5-8.

On April 27, 2013, petitioner took R.B. to an emergency clinic for “abd[ominal] pain, constipation for two weeks, and vomiting this AM.” Ex. 8 at 14.⁷ The physician conducted an examination and noted no abnormalities or signs of distress during the exam and made a diagnosis of constipation. *Id.* at 15. She provided guidance for appropriate care, but advised that petitioner should contact R.B.’s regular pediatrician if problems persisted, due to his “complex past GI history.” *Id.* She further instructed that R.B. should be taken to the hospital emergency room if his symptoms worsened to include diarrhea, fevers, bloody stools, persistent vomiting, or ongoing irritation. *Id.*

Later that day, petitioner took R.B. to a nearby hospital emergency room “because of apparent abdominal pain.” Ex. 7 at 3. Petitioner recounted that R.B. had been hospitalized “at the age of 2 months for intussusception that self-resolved, and after observation for a couple of days ... was sent home. She state[d] that at that time he did have definite ‘currant jelly stools,’ but ha[d] not had that this time, although his discomfort level was very similar[.]” *Id.* She also stated that he had not had any intervening episodes “at all” and had not had any fever, cough or other infectious-type symptoms. *Id.* He was hospitalized overnight as a precaution. Upon admission, Dr. Ruth Anne Tomlinson, an attending physician, saw R.B. and diagnosed him with “projectile vomiting, intermittent fussiness and abdominal pain.” *Id.* at 5. Dr. Tomlinson opined that R.B.’s symptoms “could be related to just a viral illness or his constipation.” *Id.* R.B. was discharged on April 28, 2013, with a differential diagnosis of “resolved intussusception, pyloric stenosis, and constipation.” *Id.* at 6.

On April 30, 2013, R.B. attended a follow-up examination with Dr. Tomlinson. At the appointment R.B. appeared well and no areas of concern were reported. His physical examination was normal and his sole diagnosis was constipation. Ex. 7 at 11.

On May 28, 2013, Dr. Tomlinson saw R.B. for his six-month well-child visit. He reportedly had been having problems with constipation after petitioner discontinued

⁷ In her petition, petitioner cited to this record to support of her assertion that “R.B. required medical attention for gastrointestinal symptoms” in November of 2013. Petition ¶ 8 (citing Ex. 8 at 14). During the initial status conference, the OSM staff attorney assigned to manage this case noted that the record appeared to describe treatment provided on April 27, 2013, rather than in November of 2013. The medical record has a “November 18, 2013” date in the upper right corner, which appears to be the “print date” of the record and not the date of treatment. It was also noted that a fax machine date and time stamp at the bottom of the record reflected the same November date—a strong indication that the medical attention was given on April 27, 2013, while the record was printed and faxed on November, 18 2013. Petitioner’s counsel promised to review the record and provide a response in the status report that would be filed on May 29, 2015 (ECF. No. 14). Petitioner made no mention of the issue in the status report or in any subsequent filing or discussion.

treatment with milk of magnesia; however, once she resumed the treatment, he began “stooling again well.” No other gastrointestinal problems were noted. Ex. 7 at 13.

On August 5, 2013, R.B. was seen by Dr. Robert Kramer at The Children’s Hospital at the University of Colorado for a “consultation for constipation and history of ... intussusception.” Ex. 10 at 1. After obtaining a history and performing a physical examination, Dr. Kramer made the following diagnostic assessment with regard to R.B.’s chronic constipation:

[R.B.]’s only remaining physical complaint/symptom at this point in time is some mild constipation, which has been inconsistently controlled with PRN use of milk of magnesia [“MOM”]. ... I do not suspect there is any significant underlying cause or etiology for the constipation.

Id. at 3.

As to R.B.’s history of intussusception, Dr. Kramer reported:

The mother remains very concerned about his prior issues with intussusception and the possible long-term consequences of this. ... I do not have the complete records of his hospitalization and workup, but based on the history I am getting from the mother and the records from his care in Wyoming, I agree that this sounds most consistent with intussusception related to Rotavirus vaccine administration. In this regard I would advise him to avoid further Rotavirus vaccination, but think the likelihood [of] an underlying leadpoint (such as a polyp or duplication) is low. His risk of recurrent intussusception is therefore very low and the last 6 months of symptom-free time is likewise reassuring. ... I do not see a need for further diagnostic testing with either radiographic or endoscopic studies. I discussed this at great length with [the patient’s mother], who seemed comfortable with this strategy.

Id.

On April 14, 2014, R.B. was seen by Dr. Tomlinson for his 15-month well-child checkup. Ex. 12 at 4-6. He reportedly had been seen by a pediatrician in Colorado for his 9-month and 12-month checkups. *Id.* at 4. At the current visit, petitioner reported that R.B. was stooling well, with soft bowel movements; no gastrointestinal complaints or problems were noted. *Id.*

On November 13, 2014, R.B. was seen by Dr. Tomlinson for his two-year well-child checkup. Again, petitioner reported that R.B. was stooling well and made no mention of any abdominal problems or concerns. Ex. 12 at 17-19.

II. Procedural History

Petitioner filed her petition on March 12, 2015, with the required medical records⁸ and a statement of completion filed by April 13, 2015. The initial status conference was held on April 24, 2015. During the conference, respondent argued that petitioner's claim should be dismissed for failure to meet the six-month requirement under the statute.⁹ Respondent maintained, based on the medical records submitted, that R.B. suffered a self-reduced intussusception, which resolved less than one month after vaccination.¹⁰ In response, petitioner's counsel requested 45 days to review the record, evaluate the issues raised, and consult with petitioner. He proposed filing additional records and a status report within that time frame. Respondent's counsel raised no objections to the request. See Sched. Order, issued Apr. 27, 2015 (ECF No. 12).

On May 29, 2015, petitioner timely filed additional medical records and a second affidavit.¹¹ She also filed a status report wherein she countered respondent's argument that R.B. did not experience residuals of his injury for at least six months. Specifically, petitioner stated that "[w]hile the doctor's notes indicate ... that R.B. ha[d] been 'symptom-free' of intussusception for six months, the note indicates that the doctor did 'not have the complete records of his hospitalization and workup.'" Status Rep., filed May 29, 2015, at 1 (citing Ex. 10 at 3). Petitioner interpreted this to include "R.B.'s hospitalization and treatment for intussusception ... on April 27, 2013," which was "less than four months before the visit documented in Exhibit 10."

Respondent was ordered to file a status report within 30 days proposing a next step. See Sched. Order, issued June 1, 2015 (Non-PDF). In her status report, submitted on July 2, 2015, respondent stated that she had "reviewed petitioner's supplemental materials" and was unchanged in "her position that R.B. did not suffer the residual effects or complications of intussusception for more than six months after his receipt of the Rotavirus vaccine." Respondent proposed filing her Rule 4(c) Report in 45 days. Status Rep., filed July 2, 2015 (ECF No. 15).

⁸ See Exs. 1-11.

⁹ A petitioner 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 ... suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention[.]" 42 U.S.C. §300-aa 11(c)(1)(D)(i),(iii).

¹⁰ In support of her position, respondent cited to a February 21, 2013 discharge record from R.B.'s first hospitalization, which contain a primary diagnosis of "intussusception, intermittent and spontaneously resolving." Ex. 5 at 65. Respondent also cited to an August 5, 2013 record from a subsequent medical appointment, wherein a gastrointestinal specialist noted that R.B. had been "symptom-free" with regard to intussusception for "the last 6 months" and stated that he did not need see the need for "further diagnostic testing with either radiographic or endoscopic studies." Ex. 10 at 3.

¹¹ See Exs. 12 (medical records) and 13 (second affidavit). Petitioner did not assign an exhibit number to her first affidavit.

On August 11, 2015, respondent filed her Rule 4(c) Report (“Resp’t’s Rep.”) formally setting forth her objections to petitioner’s claim. Specifically, respondent argued that petitioner had not “submitted sufficient evidence establishing that R.B. suffered any residual effects of his alleged vaccine-related injury later than April 2013” or that he required surgical intervention. Resp’t’s Rep. at 8.

On August 26, 2015, a telephonic status conference was held to discuss the next steps in light of respondent’s report. At the conference, petitioner proposed obtaining an expert report to opine that R.B. met the six month requirement. Respondent was amenable to this proposal. The staff attorney assigned to manage this case conveyed to petitioner’s counsel that the Chief Special Master¹² was willing to afford petitioner an opportunity to retain an expert; however, absent a sound expert opinion,¹³ any further litigation could be deemed unreasonable. Petitioner’s counsel acknowledged the Chief Special Master’s concern and requested 60 days to seek an expert. A deadline was set for October 30, 2015. See Sched. Order, issued Aug. 26, 2015 (non-PDF).

On October 30, 2015, petitioner was granted an extension of her deadline to file an expert report. See Order, issued Oct. 30, 2015 (non-PDF). On November 30, 2015, petitioner did not file an expert report, but instead filed a motion for ruling on the record. On January 11, 2016, respondent’s counsel filed a response to petitioner’s motion. See Status Rep., filed Jan. 11, 2016. Respondent did not object to petitioner’s motion and asked only that the court consider the facts and arguments outlined in her Rule 4(c) Report in issuing a ruling in this case. *Id.* at 2.

The matter is now ripe for adjudication.

III. Applicable Legal Standards

Pursuant to the Vaccine Act, the petitioner must show that her son received a vaccine covered by the Program, 42 U.S.C. §300aa–14(a)¹⁴; that her son sustained an injury that was caused-in-fact by the vaccine or had an injury significantly aggravated by the vaccine, *and* that her son 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) (emphasis added).¹⁵ Petitioner must

¹² During this time period, the case was assigned to Chief Special Master Vowell, who has since retired. On September 23, 2015, the case was reassigned to her successor, Chief Special Master Dorsey.

¹³ Petitioner’s counsel was strongly encouraged to consult with any potential expert first to see whether the facts were such that a persuasive opinion was even possible.

¹⁴ The most recent version of the Vaccine Injury Table is found at 42 C.F.R. § 100.3.

¹⁵ This case does not involve a “Table Injury,” which is the avenue for receiving compensation under the Act other than proving causation-in-fact. A Table Injury is found if a petitioner is able to prove “(i) that the injury suffered is one listed in the Vaccine Injury Table ...; (ii) that the injury occurred within the time provided within the Table; and (iii) that the injury meets the requirements of second 300aa-14(a).”

prove her case “by a preponderance of the evidence,” 42 U.S.C. §300aa–13(a)(1)(A), and a finding cannot be made based upon unsupported claims of the petitioner alone. 42 U.S.C. §300aa–13(a)(1).

IV. Analysis

There are two decisive issues working against petitioner in this case: first, whether R.B.’s condition lasted more than six months, and second, whether his condition resulted in surgical intervention.¹⁶

A. Six-month Requirement, 42 U.S.C. §300aa–11(c)(1)(D)(i)

Petitioner alleges that her son suffered a vaccine-related injury, intussusception, from a rotavirus vaccine he received on January 25, 2013. Pet. at 1. Petitioner’s claim is challenged by respondent, who states that the submitted medical records fail to show that the alleged injury lasted more than six months as required by the Act; rather, the condition resolved by April 30, 2013.¹⁷ Resp’t’s Rep. at 7.

Petitioner counters by pointing to the August 5, 2013 medical consultation for constipation as proof that R.B. continued to experience residuals of his injury beyond six months. Status Rep., filed May 29, 2015, at 2 (citing Ex. 10 at 3). Petitioner asserts that constipation “can be a symptom of intussusception.”¹⁸ *Id.* Petitioner also reports that R.B. has continued to suffer gastrointestinal problems, although less severe and not requiring a doctor’s visit. Ex. 13.

Evaluation of petitioner’s arguments requires appropriate medical knowledge and expertise, and so the undersigned afforded petitioner an opportunity to obtain the report of a medical expert supporting her contention that R.B.’s gastrointestinal symptoms were sequelae of his alleged vaccine-related injury. Sched. Order, issued Aug. 26, 2015 (Non-PDF). As discussed previously, petitioner was given more than 90 days—

Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317 (Fed. Cir. 2006) (citing *Munn v. Sec’y of Health & Human Servs.*, 970 F.2d 863,865 (Fed. Cir. 1992)).

Although the Vaccine Injury Table has been amended to include a Table Injury for intussusception following the administration of the rotavirus vaccine, the change is applicable only to petitions filed after July 23, 2015, and thus does not apply to petitioner’s claim. 42 C.F.R. § 100.3; see also National Vaccine Injury Compensation Program: Addition of Intussusception as Injury for Rotavirus Vaccines to the Vaccine Injury Table, 80 Fed. Reg. 35,848 (June 23, 2015) (to be codified at 42 C.F.R. pt. 100) (indicating the final rule becomes effective July 23, 2015 and applies only to petitions filed after that date). Petitioner filed this claim more than three months earlier, on March 12, 2015.

¹⁶ Since this case is resolved on petitioner’s failure to meet §300aa–11(c)(1)(D), it is unnecessary to address the causation issue presented in this case.

¹⁷ To fulfill the statutory requirement, R.B. would need to have suffered the residual effects of his alleged vaccine-related injury until at least July 25, 2013. See Resp’t’s Rep. at 7.

¹⁸ Petitioner references the following website in support of her assertion: www.mayoclinic.org/diseases-conditions/intussusception/basics/symptoms/con-20026823 (last visited Mar. 16, 2016). The undersigned reviewed this webpage and notes that constipation is not among the symptoms listed for intussusception.

from August 26, 2015, until November 30, 2015—to obtain and file an expert report, but no expert report was filed.

Petitioner “bears the burden of proving by a preponderance of the evidence that [her son] suffered the residual effects or complications ... for at least 6 months.” *Song v. Sec’y of Health & Human Servs.*, No. 92-279, 1993 WL 534746, at *3 (Fed. Cl. Spec. Mstr. Dec. 15, 1993), *aff’d* 31 Fed Cl. 61 (1994), *aff’d* 4 F.3d 1520 (Table) (Fed. Cir. 1994). In *Song*, the petitioner was able to prove the child suffered a vaccine-related injury, but could not show the vaccine-related injury lasted longer than six months as required by the Act. As a result, the petition in *Song* was dismissed.

In the present case, petitioner claims that R.B. suffered the residual effects of a vaccine-related intussusception for more than six months. However, at his second hospital discharge on April 28, 2013, R.B. received a differential diagnosis of “resolved intussusception, pyloric stenosis, and constipation.” Ex. 7 at 6. At a follow-up visit with Dr. Tomlinson two days later, on April 30, 2013, R.B. appeared well and received the sole diagnosis of constipation. *Id.* at 11. When he returned on May 28, 2013, for his six-month visit, Dr. Tomlinson noted his prior history of constipation, but confirmed that he was now stooling well. *Id.* at 13. Approximately two months later, on August 5, 2013, R.B. was evaluated by Dr. Kramer, a gastroenterologist, who noted that R.B. suffered “mild constipation,” but stated that he did “not suspect ... any significant underlying cause or etiology” for the problem. Ex. 10 at 3. As to the intussusception, Dr. Kramer opined that R.B. had been “symptom free” for “the last 6 months.”¹⁹ *Id.* Subsequently, R.B. attended his 15-month and two-year well-child checkups and was evaluated as normal, without mention of any gastrointestinal problems or concerns. Ex. 12 at 4-6, 17-19.

Based on the foregoing medical evidence, R.B.’s intussusception appears to have resolved by April 30, 2013. Whether his mild chronic constipation and other abdominal symptoms were residuals of intussusception, or instead related to his preexisting gastrointestinal problems, is a medical question that was never addressed by an expert report. Despite ample opportunity, petitioner did not file an expert report on this issue, and petitioner’s assertions alone are insufficient proof. Indeed, the Vaccine Act prohibits the “special master or court [from] ... mak[ing] such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” 42 U.S.C. 300aa-13(a)(1). The undersigned therefore finds that petitioner failed to carry the burden required of her under 42 U.S.C. §300aa-11(c)(1)(D)(i).

¹⁹ Petitioner noted that Dr. Kramer did not have the complete records of R.B.’s hospitalization and workup when he stated that R.B. had been “symptom free” of intussusception for six months. Status Rep., filed on May 29, 2015, at 1. Petitioner speculated that this “apparently include[d] R.B.’s hospitalization and treatment for intussusception in Jackson, Wyoming, on April 27, 2013, (See Exhibit 11, Page 31), less than four months before the visit documented in Exhibit 10.” *Id.* at 1-2. The undersigned notes that even when the April 2013 hospital stay and subsequent treatment is credited as proof of residual symptoms, as the undersigned has done, the claim still falls short of fulfilling the statutory requirement.

B. Surgical Intervention, 42 U.S.C. §300aa–11(c)(1)(D)(iii)

The Vaccine Act was amended in 2000 to make compensation available to petitioners who required “inpatient hospitalization and surgical intervention” but whose injury may have otherwise resolved in less than six months. See *Stavridis v. Sec’y of Health & Human Servs.*, No. 07-261V, 2009 WL 3837479, at *5 (Fed. Cl. Spec. Mstr. Oct. 29, 2009) (discussing the legislative intent of this provision).

Unfortunately, this provision is of no help in the present case, as nothing in the medical records indicates that R.B. underwent any surgical intervention to treat his intussusception. Indeed, Dr. Kramer noted that R.B.’s treatment was negative for surgery. Ex. 10 at 1. Respondent echoed this fact in her Rule 4(c) Report, noting that “although R.B. was admitted to the hospital for his symptoms, his condition did not require surgical intervention.” Resp’t’s Rep. at 8. Petitioner does not argue to the contrary.

Accordingly, the undersigned finds that petitioner failed to carry the burden required of her under 42 U.S.C. §300aa–11(c)(1)(D)(iii).

V. Conclusion

The undersigned has thoroughly reviewed the record and finds that due to the lack of supportive medical records or an expert medical opinion, petitioner has failed to establish a *prima facie* case as required by 42 U.S.C. §300aa–11(c). The undersigned must deny compensation. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master