In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-583V

* *

RODERICK RAMOS AND KELLY RAMOS,
on behalf of their minor son, T.R.,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Chief Special Master Corcoran

Filed: June 3, 2024

Michael Firestone, Marvin Firestone, MD, JD and Associates, San Mateo, CA, for Petitioner.

Bridget Corridon, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On May 11, 2020, Roderick and Kelly Ramos filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Program").[2] Petition (ECF No. 1) at 1. Petitioners allege that their son, T.R., developed intussusception[3] after receiving a Rotavirus vaccine administered to him on October 19, 2017. *Id.*

I determined that the matter could be properly resolved via ruling on the record, and the parties have submitted briefs for resolution of the matter. *See* Petitioners' Motion, dated July 21, 2023 (ECF No. 41) ("Mot."); Respondent's Response, dated September 29, 2023 (ECF No. 43) ("Opp."); Petitioners'

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request 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). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

[3] Intussusception is defined as a "prolapse of one part of the intestine into the lumen of an immediately adjoining part. It is most common in infants, and in adults it is often associated with a neoplasm. Symptoms include partial obstruction, a palpable abdominal mass, and abdominal pain with cramping." Intussusception, *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=25926&searchterm=intussusception (last accessed May 3, 2024).

Reply, dated October 25, 2023 (ECF No. 44) ("Reply"). For the reasons set forth below, and based on the parties' filings and the record, I hereby deny entitlement.

I. Factual Background

T.R. was born on August 17, 2017, with no apparent health issues beyond mild jaundice. Ex 2 at 1. At his two-month checkup on October 19, 2017, his pediatrician noted he was "doing well" and developing normally. Ex. 3 at 2. He received several vaccines at this appointment, including the Rotavirus vaccine at issue. *Id.* at 4.

There are no medical records between the day of vaccination and the hospitalization event in mid-November. Indeed, witness statements filed contemporaneously with the claim's initiation did not mention any symptoms prior to November 17, 2017. *See* Joint Declaration of Kelly and Roderick Ramos, dated May 26, 2020, filed as Exhibit 1 (ECF No. 6-2). Rather, the timeline detailed in this initial declaration begins on November 17, 2017, with no description of T.R.'s condition between vaccination and that date. Ex. 1 at 2 ¶8.

However, Petitioners have since offered several witness statements proposing that T.R. had experienced initial symptoms closer in time to vaccination, but that are now alleged to be connected with his subsequent intussusception. *See,* e.g., Declaration of Emily Ramos, dated May 12, 2021, filed as Exhibit 16 (ECF No. 25-2); Supplemental Joint Declaration of Petitioners, dated May 12, 2021, filed as Exhibit 17 (ECF No. 25-3). For example, T.R.'s grandmother, Emily Ramos, states that between November 5th and 9th, 2017, T.R. began to experience "irritability, colicky pain, crying, burping, and passing gas, enlarged abdomen, loss of appetite after receiving his vaccine from his pediatrician." Ex. 16 at 1 ¶8. She also recounted that, from November 10th to 15th, T.R. experienced "irritability, vomiting, abdominal distention, would negatively profess [sic] to foul-smelling watery diarrhea with clear mucus like discharge." *Id*. at 1 ¶11. Petitioners' supplemental declaration details symptoms of crying, irritability, distended abdomen, and gas starting on November 5th, 2017. Ex. 17 at 1–2. They also stated that he had "severe watery, yellowish diarrhea," and specified that his symptoms over the next weeks "progressively worsened, intermittently." *Id.* at 1 ¶1, 4.

Petitioners later filed a second supplemental declaration adding even more detail about T.R.'s gastrointestinal symptoms in this early-November timeframe. Second Supplemental Petitioners' Declaration, dated July 21, 2023, filed as Exhibit 33 (ECF No. 39-2). In this declaration, Petitioners report that T.R. displayed colicky pain, irritability, crying, loose bowel movements of yellowish stool and mucus, and that he had been "insidiously vomiting' after every feeding between those dates, with the vomit ranging from moderate to projectile. Ex. 33 at 1 ¶2. They further report that this information was excluded from their first declaration due to an "unintentional deletion" by their attorney's office, and that they did not mention any of these symptoms to medical professionals when T.R. was admitted due to tiredness and anxiety. *Id.* at 2, 3.

On November 18, 2017 (thirty days post-vaccination), T.R. was brought to the emergency room at Torrance Memorial Medical Center. Ex. 7 at 1. This record memorializes that Petitioners reported T.R. had been projectile vomiting with bile, bloody and watery stool, abdominal pain, and prolonged crying.

Ex. 2 at 1–2. Treaters noted in these records that it was reported that T.R.'s symptoms began *two days* prior to his presentation (meaning November 16, 2017—28 days post-vaccination), and no mention is made herein of any earlier symptoms. Ex. 7 at 12. An abdominal ultrasound and barium enema indicated possible intussusception. *Id*. at 21. Two additional attempts at barium enema reduction were performed. *Id*.

That same day, Dr. Daniel DeUgarte provided a surgical consultation. Ex. 7 at 19. Although Dr. DeUgarte concluded that a good amount of reduction had been achieved, he could not rule out the possibility of a residual ileal edema or a residual ileal-ileal intussusception. *Id*. at 20. At that time, he did not recommend surgery, but ordered ongoing abdominal examinations to monitor T.R.'s condition and a Pedialyte feeding schedule of an ounce every three hours, spread over two feedings. *Id*. If T.R. tolerated these feedings, he would be switched to his normal formula. *Id*. However, the Pedialyte feedings prompted cramping, pain, and bilious vomiting, leaving treaters to re-evaluate. *Id*. at 4.

After pediatric surgery was notified of T.R.'s change in condition, a repeat abdominal x-ray was performed. Ex. 7 at 4. The x-ray revealed a distal small bowel obstruction, and small bowel thickening secondary to probable intussusception. *Id*. An abdominal ultrasound revealed free fluid and fluid-filled loops, reaffirming the probability of a small bowel obstruction or ischemia. *Id*. T.R. then underwent exploratory surgery, wherein surgeons reduced a small-bowel intussusception, released a bowel obstruction, performed an 8-10 centimeter small bowel resection, and removed the appendix. *Id.* at 23. An ultrasound the following day confirmed there was no remaining intussusception. *Id*. at 6. T.R. was monitored post-surgery with no issues, and discharged on November 24, 2017. *Id*. at 5.

T.R. subsequently underwent normal six and fifteen-month-old checkups in March and December 2018. Ex. 3 at 6, 12. He received his second and third Rotavirus vaccines and additional vaccinations without issue. Ex. 4 at 2.

II. Expert Reports and Treater Evidence

A. Petitioners' Expert – Dr. Hillel Janai

Petitioners submitted three expert reports from Dr. Janai. First Janai Report, dated June 9, 2022, filed as Ex. 19 (ECF No. 30) ("First Janai Rep."); Second Janai Report, dated February 17, 2023, filed as Ex. 27 (ECF No. 34-2) ("Second Janai Rep."); Third Janai Report, dated July 21, 2023, filed as Ex. 34 (ECF No. 39-3) ("Third Janai Rep.").

Dr. Janai received his medical degree from the Israel Institute of Technology. Janai CV, dated June 9, 2022, filed as Ex. 23 (ECF No. 30-7). He completed his residency in pediatrics and neurology at Lady Davis Carmel Hospital in Haifa, Israel. *Id*. at 1. He then completed fellowships in pediatric infectious disease and pediatric pulmonary medicine in the United States. *Id*. at 2. He has 37 years of experience as a general pediatrician and pediatric infectious disease consultant, and has diagnosed many cases of intussusception. First Janai Rep. at 1.

First Report

Dr. Janai opined overall that T.R.'s intussusception was directly correlated with the Rotavirus vaccine he received the month before. First Janai Rep at 1. Intussusception, he observed, is a known risk of the vaccine, leading to its removal from the market at one point. Ex. 20 at 1–2. The vaccine is understood to be capable of causing lymph node hyperplasia, due to an exaggerated lymphatic tissue response to immune system activation. First Janai Rep. at 1. This creates a "lead point," causing the gut loops to become inflamed. This in turn leads to intestinal blockages, which can be fatal if left untreated. Irene M. Shui et al., *Risk of Intussusception Following Administration of a Pentavalent Rotavirus Vaccine in US Infants*, 207 Journal of the American Medical Association 598 (2012) ("Shui"), filed as Ex. A, Tab 8 (ECF No. 32-9); Catherine Yen et al., *Rotavirus Vaccination and Intussusception- Science, Surveillance, and Safety: A Review of Evidence and Recommendations for Future Research Priorities in Low and Middle Income Countries*, 12 Human Vaccines and Immunotherapies 2580 (2016), filed as Ex. 22, Ref. 3 (ECF No. 30-6).

In Dr. Janai's construction of the medical history, T.R. began to have initial symptoms of intussusception two weeks after receiving the vaccine, including fussiness, colic, abdominal pain, and decreased appetite. First Janai Rep. at 1. This later led to his admission at Torrance Memorial Hospital, where he eventually underwent surgery after several unsuccessful attempts to correct the intussusception. *Id*. Although lymph node hyperplasia can also occur after infection, Dr. Janai opined that T.R.'s status as a breastfed infant would have protected him from community-acquired diseases. *Id.*

Dr. Janai did not propose a specific onset date for the symptoms that preceded T.R.'s hospitalization by two weeks, noting that their course and nature can differ due to "virus, immune system, age, genetic[s], type of feeding." First Janai Rep. at 1. However, he emphasized that T.R. was a healthy infant prior to receiving the vaccine. Otherwise, in his view T.R.'s "progression of symptoms was very typical for many of the cases that I have seen during my career as a pediatrician." *Id.* at 2.

Second Report

Dr. Janai's supplemental report mostly attempted to respond to arguments of Respondent's expert, Dr. Christopher Liacouras. First, he criticized some of the literature Respondent cited, stating that "in all of the references cited by the Respondent, there is no information that refutes the claims of T.R.'s family." Second Janai Rep. at 1. In fact, several of the articles list presenting symptoms of intussusception that T.R. is documented to have displayed, such as pain, vomiting, drawing up of the legs, and colicky pain. *Id*. at 1; *see, for example,* A. Manning & D. Little, *Intussusception in Infants and Children*, in PEDIATRIC GASTROINTESTINAL AND LIVER DISEASE (5th ed. 2016) ("Manning & Little"), filed as Ex. A, Tab 1 (ECF No. 32-2). Another item noted a "five-fold" increase in intussusception after a second dose of Rotateq vaccine (as compared to a "30-fold" risk from the initial vaccine), with other articles observing an increased risk associated with any version of the vaccine. *Id*. at 1–2; Manning & Little at 613; S. Jain & M. Haydel, *Child Intussusception*, filed as Ex. 3, Tab A (ECF No. 32-4). In fact, Dr. Janai maintained

that one study proposed that all newer Rotavirus vaccines, including Rotateq, "were associated with a possible 700% increase in intussusception"—although no reference is offered for this contention. Second Janai Rep. at 2. And Dr. Janai emphasized the text of the Rotateq vaccine package insert, which warned of the association between Rotavirus vaccines and intussusception within 21 days of vaccination. *Id.*; *CDC Package Insert, Rotateq*, filed as Ex. 28, Ref. 2 (ECF No. 34-3).

Second, Dr. Janai criticized Dr. Liacouras's discounting of representations contained in witness statements (which purport that T.R.'s symptoms began two weeks *before* he was hospitalized). Second Janai Rep. at 3. Dr. Janai deemed these statements worthy of greater evidentiary weight than the information in medical records, as it is "generally the most accurate information that we as clinicians receive." *Id*. He also argued that in his experience with intussusception patients, the pain will "come and go," leading to periods of fussiness and lethargy interspersed with periods without symptoms. This would be a basis for lending more credence to the statements by the family that T.R.'s intussusception developed over a period of nearly a month after his vaccine. Although Dr. Janai could point to no medical or scientific support for the view that intussusception would likely progress over a week or more before becoming so acute that a surgical response was warranted, he maintained that "[e]very patient has a different presentation," and "[r]eview[s] [or] studies do not always document individual cases." *Id*. at 4.

Dr. Janai acknowledged that the exact biologic mechanism leading to intussusception is still unknown. Second Janai Rep. at 3. But even if no studies have shown that lymphoid hyperplasia causes intussusception, "the theory is biologically plausible and widely accepted as valid among pediatric critical care physicians and pediatric surgeons." *Id.* He interpreted Dr. Liacouras's statement that this causal theory is "speculated" to be accurate to mean that Dr. Liacouras acknowledges the opinion is shared by many. *Id*.

Dr. Janai also took issue with the extent of Dr. Liacouras's clinical experience with intussusception. By contrast, Dr. Janai emphasized that "in my decades of clinical practice, and all of the intussusception cases that I have managed, been consulted, or even read about, a pediatric gastroenterologist has never been involved in the acute care of an infant with intussusception." Second Janai Rep. at 4. Thus, he deemed Dr. Liacouras's assertion that he has evaluated many intussusception cases to be "perplexing." *Id*.

Third Report

Dr. Janai authored a final report that specifically addressed a number of additional points made by Dr. Liacouras. For example, he disputed Dr. Liacouras's proposal that the initial, early-November symptoms T.R. is alleged to have experienced could have been infectious in origin (and in turn could provide an alternative explanation for the later intussusception). Third Janai Rep. at 1. In so arguing, Dr. Janai observed that T.R. had no indicators of an infection in his medical records—none of his treaters noted a concern for infection, or ordered laboratory testing on stool or blood samples. *Id*. And he took issue with Dr. Liacouras's statement that "intussusception does not cause persistent, severe, foul-smelling diarrhea, vomiting, and fever." *Id*. In fact, in Dr. Janai's experience, intussusception can cause blood in

stool (leading to a foul smell) and vomiting. *Id*. Additionally, one of Dr. Liacouras's cited sources lists fever as a symptom. Manning & Little at 4.

Dr. Janai also maintained that the "intermittent" presentation in T.R.'s medical history—with less-acute initial symptoms later progressing to an acute event—were not, as Dr. Liacouras proposed, so uncommon that an intervening infection was a better causal explanation. Third Janai Rep. at 3. Thus, even if most filed literature in this matter suggested the post-vaccination intussusception risk was highest within seven days of vaccination, a 29-day onset remained "medically reasonable given the genetic variability between individuals." *Id*. at 2–3. The very fact that T.R. needed surgical intervention to treat his intussusception was actually "further evidence that this was a more advanced case of intussusception," from a temporal standpoint. *Id*. at 2. And T.R. was younger than the average intussusception patient. While the condition most commonly develops in children between 6 and 18 months, T.R. was barely three months at the time of his illness—lending "further support that T.R.'s intussusception was caused by the Rotavirus vaccine, not an infection," (although Dr. Janai's report does not explain why a young age would make a longer post-vaccination onset more likely). *Id*.

Ultimately, Dr. Janai emphasized that the fact of vaccination was undisputed, whereas the infection Dr. Liacouras proposes as potentially causal was unconfirmed. As a result, "the known causative agent, the vaccine, should be weighted more heavily than the unknown agent that may have caused some unknown infection." Third Janai Rep. at 2. Thus, there was no other plausible cause for T.R.'s intussusception besides the Rotavirus vaccine. *Id*. at 3. And T.R.'s subsequent receipt of the Rotavirus vaccine on two occasions with no comparable symptoms was not evidence against causation by the first dose. *Id.*

B. Respondent's Expert – Dr. Christopher Liacouras

Respondent submitted two expert reports in this case from Dr. Liacouras. Liacouras First Report, dated October 26, 2022, filed as Ex. A (ECF No. 32-1) ("Liacouras First Rep."); Liacouras Second Report, dated September 29, 2023, filed as Ex. C (ECF No. 42-1) ("Liacouras Sec. Rep."). Dr. Liacouras opined that T.R.'s intussusception was unrelated to the Rotavirus vaccine.

Dr. Liacouras is a pediatric gastroenterologist at the Children's Hospital of Philadelphia ("CHOP"), and a Professor of Pediatrics at the Perelman School of Medicine at the University of Pennsylvania. Liacouras CV, dated October 26, 2022, filed as Ex. B (ECF No. 32-13). He received his medical degree from Harvard University, and completed a residency and fellowship in pediatrics and pediatric gastroenterology at CHOP. *Id.* at 1. He serves in leadership roles for several professional societies, including the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition, and the American Society for Gastrointestinal Endoscopy. Liacouras First Rep. at 1. He has published extensively in the field of pediatric gastroenterology. Liacouras CV at 9–26. He has over 30 years of clinical practice experience, and has personally evaluated over 100 patients with intussusception in the past seven years. Liacouras First Rep. at 1.

First Report

Dr. Liacouras began his initial report by emphasizing that (at least from the perspective of medical science, as opposed to the Vaccine Program), the current versions of the Rotavirus vaccine are not strongly linked to intussusception. Liacouras First Rep. at 4. An earlier version, Rotashield, was pulled from the market after a "small but significant number" of intussusception cases occurred, but Rotateq (the vaccine at issue in this case) and Rotarix are now the primary versions utilized. *Id*. Since then, numerous studies have been performed on these new versions, and studies specific to Rotateq have found either no risk of intussusception, or a risk only within seven days of the first dose of the vaccine, with no real risk for subsequent doses. *Id.*; S. Escolano et al., *Intussusception Risk After Rotateq Vaccination: Evaluation From Worldwide Spontaneous Reporting Data Using a Self-Controlled Case Series Approach*, 33 Vaccine 1017 (2015), filed as Ex. A, Tab 9 (ECF No. 32-10). He thus opined that Dr. Janai was mischaracterizing the risk as related to the current versions of the Rotavirus vaccine.

Dr. Liacouras also criticized the core of Dr. Janai's causal theory: that the Rotavirus vaccine could cause lymphonodular hyperplasia leading to intussusception. Liacouras First Rep. at 6. Dr. Liacouras maintained there were no definitive reports in the literature showing that the vaccine causes this clinical progression (even if some researchers have hypothesized it), characterizing it as "speculation and theory." *Id*. Another article discussed intestinal "lead points," but noted they had never been associated with the Rotavirus vaccine, and concluded no associated risk. Shui at 598. Further, the medical record itself was not consistent with the theory. There was, for example, no evidence that T.R. had lymphonodular hyperplasia when he underwent surgery. Liacouras First Rep. at 6. And none of T.R.'s treaters even attributed his illness to the Rotavirus vaccine. *Id.* In fact, T.R. received the second and third doses of the Rotavirus vaccine without issue, showing no signs of rechallenge complications that would support an adverse reaction occurred in the first place. *Id.*

The onset timeframe for T.R.'s intussusception was also not in keeping with what valid medical science proposed was the likely post-vaccination onset period. Liacouras First Rep. at 5. One study had observed an increased risk of intussusception only within the first seven days of vaccination, diagnosed within two days of the onset of symptoms. J. Koch et al., *Risk of Intussusception after Rotavirus Vaccination: A Systematic Literature Review and Meta-Analysis*, 114 Deutsches Arzteblatt International 255 (2017), filed as Ex. 26 (ECF No. 30-10). In Dr. Liacouras's experience, intussusception would more commonly progress rapidly, one to two days after onset, before diagnosis could be made. First Liacouras Rep. at 6. It would therefore be "very unusual" for symptoms to progress over one to two *weeks. Id.*

But T.R.'s onset occurred several weeks after vaccination. First Liacouras Rep. at 6. And Dr. Janai's effort to link the acute onset event in mid-November 2017 with purported symptoms beginning between then and the vaccination date in October were not deemed persuasive by Dr. Liacouras. Dr. Janai had relied on witness declarations rather than the treater notes from Torrance Memorial, which confirmed a closer-in-time onset. Ex. 7 at 3. While T.R.'s family members had reported (often in second iterations of witness statements prepared years after the fact) that his symptoms began two weeks before he was diagnosed, the medical records did not corroborate their contentions. Further, some of the

symptoms Petitioners had described (persistent diarrhea, vomiting, and fever) were to Dr. Liacouras evocative of an infection—and he deemed that a more likely cause of T.R.'s intussusception. First Liacouras Rep. at 7.

Second Report

Dr. Liacouras's supplemental report reacted to some of Dr. Janai's contentions in his later reports. First, he fleshed out the argument that T.R.'s intussusception was more likely caused by infection. Liacouras Second Rep at 2. Dr. Liacouras observed in the record distinct differences between the symptoms reported in the November 5-14, 2017 timeframe (almost exclusively described in witness statements) and those noted in treater records from T.R.'s hospital admission. *Id*. Those witness statements noted that between November 5th and 14th, T.R. displayed "subtle gastrointestinal symptoms" which would "subside after loose bowel movements." Ex. 33 at 2. They also reported that T.R. vomited after every feeding, and the vomit was the consistency of formula milk, as well as that he was running a "low grade fever." *Id.*

However, when T.R. was brought to Torrance Memorial's emergency room on November 18th, the records indicate reports that T.R. had (only a day or two prior to his appearance at the hospital) been projectile vomiting, vomiting with bile, experiencing sudden onset of cramping abdominal pain, significant decrease in oral intake, and dark blood in his stools. Ex. 7 at 3. Such symptoms as reported in T.R.'s hospital records were typical of intussusception—but contrasted with those reported in subsequent witness statements, which were far more consistent with gastrointestinal enteritis. Second Liacouras Rep. at 3. In Dr. Liacouras's experience, children with gastrointestinal enteritis typically have a viral infection, which resolves without treatment in two weeks. All of the above was supportive of Dr. Liacouras's opinion that T.R.'s intussusception was likely infectious in origin. *Id.*

Second, Dr. Liacouras rejected Dr. Janai's claim that intussusception is more common in children a bit older than T.R. Certain literature actually observed that peak incidents of intussusception actually occur in children between the ages of *three to nine* months. Manning & Little at 608; H.M.L. Carty, *Pediatric Emergencies: Non-Traumatic Abdominal Emergencies*, 12 European Radiology 2835, 2839 (2002), filed as Ex. A, Tab 2 (ECF No. 32-3) ("Carty"). In addition, although Dr. Janai had cited some items of literature that suggested a vaccine-intussusception link, that association was not confirmed consistently in all filed items in this case. Second Liacouras Rep. at 4; Shui at 598 ("[a]mong US infants aged 4 to 34 weeks who received RV5, the risk of intussusception was not increased compared with infants who did not receive the [R]otavirus vaccine"). Other studies underscored that any associations with vaccination occurred in a tighter timeframe. K. Kim and D. Kim, *Relationship Between Pentavalent Rotavirus Vaccine and Intussusception: A Retrospective Study at a Single Center in Korea*, 58 Yonsei Medical Journal 631 (2017), filed as Ex. A, Tab 10 (ECF No. 32-11) ("Kim"). And Dr. Janai's claim that the Rotateq vaccine causes a "possible 700% increase in intussusception" was "incorrect, unexplained, and unreferenced." *Id.* at 5.

Dr. Liacouras concluded by responding to Dr. Janai's criticisms of his clinical experience with intussusception. Second Liacouras Rep. at 5. Dr. Liacouras reiterated that he had been involved in the care of children with many different types of intussusception, including intermittent intussusception,

intussusception from feeding tubes or "lead points," and intussusception after intestinal surgeries. *Id*. at 5. He sees urgent patients in his office, and is often called to the emergency room to evaluate patients eventually diagnosed with intussusception. He also reviews cases with fellows and nurse practitioners, and attends weekly hospital conferences where cases may be discussed. Thus, he proposed that his decades of clinical practice included ample experience with the condition.

C. Treater Support

Petitioner filed a letter from Dr. Steven Lee, who operated on T.R. to reduce his intussusception. Letter of Steven Lee, dated June 9, 2022 (ECF No. 30-2) ("Lee Ltr.").

Dr. Lee opined in his letter that T.R. exhibited symptoms of intermittent intussusception for 13 days prior to his presentation for surgery. Lee Ltr. at 1. He based this, however, solely on the declarations of T.R.'s parents and grandmother, which both state that T.R. developed symptoms such as pain, crying, vomiting, loose bowel movements, and loss of appetite seventeen days after vaccination. *Id.* Dr. Lee also maintained that T.R. experienced "sudden worsening" of these symptoms thirteen days after onset, and was subsequently hospitalized and diagnosed with intussusception. *Id.* He based his conclusion on witness statements, however, coupled with his "observations of the child at the time of surgery." *Id.*

III. Procedural History

This claim was initiated in May 2020. Respondent filed his Rule 4(c) Report in November 2020, and I ordered Petitioner to file an expert report in support of the claim. This report was filed in June 2022. Respondent then filed their responsive expert reports in October 2022. This was followed by two additional expert reports from Petitioner, in February and July of 2023. I then set a schedule for a Ruling on the Record, to be completed in October 2023. The matter is now fully briefed and ripe for resolution.

IV. Parties' Arguments

A. *Petitioners*

Petitioners first argue (despite self-evident deficiencies discussed below) that T.R.'s intussusception onset occurred within 1-21 days of receiving the Rotavirus vaccine, meeting the requirements for a Table claim. Mot. at 27. They base this on filed witness statements detailing symptoms of diarrhea, colicky pain, fever, and gas. *Id*. at 27–28. T.R.'s symptoms continued over the next week, until he developed the bilious vomiting and bloody stools leading to his hospital admission. *Id*. Based upon this course, at least one treater proposed that T.R. had suffered intermittent intussusception for 13 days prior to the admission. *Id*. at 30, *citing* Lee Ltr. Thus, since the onset of these symptoms themselves occurred in the Table's defined post-vaccination timeframe, the claim was tenable *as* a Table claim.

Petitioners further maintain that the intussusception was not caused by an infection, despite Dr. Liacouras's argument to the contrary. The symptoms T.R. displayed starting on November 5th (foul-smelling stools, vomiting, and fever) are symptoms of intussusception, and are reported in the relevant

literature. Mot. at 31. The preexisting, known occurrence of vaccination should be weighed more heavily than the possibility of an infection that is not otherwise corroborated by the record.

Next, Petitioners contend that even if a Table claim could not succeed on these facts, the test for causation set by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005) can be met. The "can cause" prong is satisfied because the Table lists intussusception as an injury caused by the Rotavirus vaccine. Mot. at 36. Additionally, they note that Dr. Janai's theory—that the vaccine caused swelling of the lymphatic tissue lining the gastrointestinal tract, leading to the bowel telescoping on itself—is credible, especially in conjunction with other items of literature observing an increased risk of intussusception after the Rotavirus vaccine. *Id*. at 36, 37.

The "did cause" prong is also satisfied by Dr. Janai's explanation of a logical sequence of cause and effect, based on the record. Mot. at 39–40. And a timeframe of a 29-day, post-vaccination onset (assuming a Table onset was not found, and thus relying on the date T.R. was taken for emergency care, based on his condition at the time) fits into a timeframe supported by medical literature. *Id*. at 38. Indeed, since the causes and mechanisms of intussusception are not fully understood, it is impossible to rule out that T.R.'s onset (which only fell a few days outside of the Table timeframe) could still be "medically acceptable"—especially since some studies even allowed a timeframe of 30 days. *Id*.[4]

B. *Respondent*

Respondent denies a Table claim can succeed under the facts of this case. Contemporaneous medical records, he argues, establish an onset well outside of the Table timeframe, and under Program law that evidence warrants more weight than testimony, especially since the two conflict. Opp. at 16; *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d at 1528 (Fed. Cir. 1993). The only evidence Petitioners present that T.R.'s symptoms started earlier than November 17th is found in their own witness statements, filed over the course of six years after T.R.'s hospitalization. *Id*. at 17–18. These statements themselves contain conflicting facts and inconsistencies that Respondent attributes to litigation concerns. *Id*. at 20. The letter from Dr. Lee gives these statements no additional weight, as it was prepared for litigation over four years after he treated T.R., and relies solely on witness statements. Thus, because the contemporaneous records show onset of T.R.'s intussusception occurred on November 17, 2017, a Table claim is precluded. *Id*. at 21–22.

In addition, Respondent maintains that the facts of this case do not support a showing of causation-in-fact. *Althen* prong one cannot be satisfied simply because intussusception is a Table claim, Respondent contends, noting that "[s]imple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner." *Grant v. Sec'y of Health & Hum. Servs.,* 956 F.2d 1144, 1147-48 (Fed. Cir. 1992); Opp. at 27. Nor does Dr. Janai's opinion establish a preponderant theory. He fails, for example, to distinguish between Rotateq and earlier versions of the Rotavirus vaccine throughout all three of his reports, relying on vaccine associations not pertinent herein. Opp at 28–29. Dr. Janai also proposes that the vaccine could cause swelling of the lymphatic tissue lining the bowel, a

[4] Petitioner cites several studies filed by Respondent that use a 30-day window, yet fails to note that these studies concluded that there was no association between the Rotavirus vaccine and intussusception (during any window). *See,* e.g., Kim at 631.

mechanism that remains unproven by definitive studies. In fact, they note, up to 90% of cases of intussusception in children are idiopathic or have other causes like infection. *Id*. at 30. Even Dr. Janai admits to the speculative nature of his theory. Ex. 27 at 3; *Id.* at 29.

Second, Respondent argues that Petitioners have failed to make an *Althen* Prong Two showing. Opp. at 32. The 29-day onset proposed is too long, and unsupported by medical literature, the majority of which places vaccine-caused intussusception risk within a shorter, seven-day period. *Id*. Dr. Janai's argument to the contrary is conclusory, relying heavily on the temporal association between vaccination and onset. Second Janai Rep at 4; Opp. at 33. And similar problems, Respondent proposes, condemn a favorable *Althen* prong three finding. Opp. at 35. Dr. Janai provides no support for his assertions about the timing and progression of intussusception, while prevailing medical literature supports only a seven-day timeline. In fact, the Table timeframe is larger simply because of the desire "to allow for a generous timeframe that will capture any cases related to the vaccine after day 7." National Vaccine Injury Compensation Program: Addition of Intussusception as Injury for Rotavirus Vaccines to the Vaccine Injury Table, 80 Fed. Reg. 35848 (June 23, 2015) (codified at 42 C.F.R. pt. 100), cited in Opp. at 36. And prior cases have rejected timeframes longer than 21 days. *Carda v. Sec'y of Health & Hum. Servs*., No. 14-191V, 2017 WL 6887368, at *21 (Fed. Cl. Spec. Mstr. Nov. 16, 2017).

Petitioners' Reply

On reply, Petitioners argue that medical records should not automatically be given more weight than testimony, nor should they be presumed to be accurate and complete under Program case law. *See Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021); Reply at 2. And to the extent there are discrepancies between versions of the declarations, they have reasonable explanations—accidental deletions, exhaustion at the time of T.R.'s admission, and miscommunication with doctors and nurses. Reply at 3–5.

Petitioners further defend their success in meeting the *Althen* prongs. Regarding Prong One, they maintain that they are not required to offer evidence specific to establishing an association between the Rotateq vaccine and intussusception. Reply at 6. Thus, the literature they present studying earlier versions of the Rotavirus vaccine should not be discounted. They also note that intussusception was added to the Table *after* the introduction of the Rotateq vaccine, without qualification about the specific version of vaccine. And they reiterate the view that it is fair for claimants to rely on Table elements (in particular specific to causation) even when a claim "falls out" of the Table for other reasons. *Id*. at 7.

In addition, Petitioners contend that there are no other reasonable explanations for T.R.'s intussusception, with Dr. Liacouras unable to establish an intervening infectious cause. Reply at 8. This, plus temporal proximity and the fact that the Rotavirus vaccine can cause intussusception, was enough of a basis for Dr. Janai to find an existence of a "logical sequence of cause and effect" between vaccination and T.R.'s injury. *Id.* at 8. And 29 days is an acceptable timeframe for onset, since "there is not a universally accepted biological understanding of the mechanism by which the Rotavirus vaccine causes intussusception." *Id*. at 9. Cases like *Carda* rejecting an onset longer than 21 days are distinguishable, since (a) the injured child therein experienced an even longer onset timeframe, and (b)

the case involved a second dose of the vaccine as allegedly causal. *Id.* at 8–9; *Carda*, 2017 WL 6887368 at 19.

V. Applicable Law

A. *Standards for Vaccine Claims*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[5] Petitioners allege a causation-in-fact claim (and could not otherwise allege a Table claim of encephalopathy or encephalitis after receipt of the flu vaccine: there is no such claim).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of

[5] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen,* 35 F.3d at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed,* No. 23-1816 (Fed. Cir. Apr. 28, 2023). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

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

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied,* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for

inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

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

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

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

proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Hum. Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Hum. Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not every filed item factors into the outcome of this Decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the

preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Treatment of Intussusception in the Vaccine Program

Intussusception is defined as the invagination, or telescoping, of one segment of the intestine within another. Manning & Little at 607. This leads to two distinct clinical issues: obstruction of the bowel, and progressive vascular compromise. *Id*. It accounts for up to 50% of pediatric small bowel obstructions. *Id.* The "classic triad" of symptoms includes abdominal pain, vomiting, and red "currant jelly" stools. *Id*. at 608. Infants commonly draw their legs up to the abdomen in pain. Carty at 2839. Treatment is first attempted with an air or barium enema, which is expected to be successful in 70% of cases. *Id*. at 2840. Surgery is rarely necessary. *Id*.

Intussusception is included as a Table injury for the Rotavirus vaccine, with a listed onset period of 1-21 days post-vaccination. 42 C.F.R. § 100.3 (a)(XI)(A). (As discussed below, however, the relevant science relied upon to establish this claim *does not* support the conclusion that the risk of intussusception is consistent or equivalent throughout that entire period). Section (c)(4)(i) states that the illness is characterized by "a *sudden* onset of abdominal pain that may be manifested by crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus." (emphasis added) 42 C.F.R. § 100.3 (c)(4)(i). Factors that exclude Table intussusception cases are: onset after the third dose; onset within 14 days of an infectious disease; onset in a person with pre-existing condition identified as the lead point; abnormalities of the bowel; and underlying diseases associated with intussusception (such as cystic fibrosis, coeliac, or Kawasaki disease). *Id*. at Sections (4)(ii)(A)-(E).

Although the possibility of an "intermittent" form of intussusception seems to animate in part Petitioners' claim, it lacks identifiable support in filed literature.[6] At best, Respondent has referenced one case study of putative, intermittent intussusception in which a five year-old girl presented with symptoms beginning five days earlier. C. Mapagu et al., *Instructive Case: Intermittent Intussusception*, 39 Journal of Pediatric Child Health 147 (2003) filed as Ex. A, Tab 4 (ECF No. 32-5) ("Mapagu"). She then had intermittent episodes spanning ten days while hospitalized, which eventually resolved on their own. Evidence of mesenteric adenitis (inflamed lymph nodes in the terminal ileus) was found. Magapu

[6] Dr. Janai's only cited reference in his assertions about intermittent intussusception is derived from a Mayo Clinic web page, which he cites after saying that intermittent intussusception causes symptoms that "come and go." Janai Second Rep. at 3. But the page does not mention intermittent intussusception at all, and the "comes and goes" wording is specified to mean "usually every 15 to 20 minutes at first"—a far more limited timeframe than the four-week period between vaccination and T.R.'s ER presentation, with about two weeks separating onset from the purported initial symptoms. Intussusception, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/intussusception/symptoms-causes/syc-20351452 (last accessed May 28, 2024).

at 147. Mapagu's authors noted that "recurrent and spontaneously resolving" intussusception has been reported as a presenting feature in celiac disease. *Id.* at 148. The patient in this case study had recently been switched to a gluten-free diet after her sister was diagnosed with celiac disease. *Id*. Thus, to the extent intussusception could ever be intermittent, it appears from what has been filed in this case that the condition would *still* present in acute form, with intermittent symptoms only *following* an initial acute presentation, as opposed to leading *up to* it.

Non-Table cases in which intussusception is alleged to have been caused by a Rotavirus vaccine have resulted in dismissal of claims when onset occurred more than 21 days post-vaccination. *See,* e.g., *Carda*, 2017 WL 6887368. *Carda* also rejected a theory of "chronic or transient" intussusception, akin to the intermittent theory proposed in this case. *Id.* at 19. However, *Carda* is also somewhat distinguishable, since it involved a subsequent Rotavirus vaccine dose rather than the first, as here.

II. Petitioners' Claim Has Not Been Preponderantly Established

Petitioners' claim ultimately fails on *Althen* Prong Three, as they cannot establish that the timeframe between T.R.'s vaccination in October and his acute intussusception a month later was medically appropriate.[7] First, the record preponderantly supports the conclusion that T.R.'s onset occurred within *two days* of his hospitalization, as corroborated by the medical record.[8] Ex. 7 at 3. Nowhere in the medical record is a more unfolding and progressive course mentioned. The witness statements maintaining that T.R.'s symptoms began on November 5, 2017, lack corroboration, and do not gain reliability simply because a treater (Dr. Lee) offered an opinion (which in turn relied specifically on those same witness statements). It is true that medical records are not automatically entitled to more evidentiary weight than witness testimony. *Kirby*, 997 F.3d. But the latter needs to have some corroboration—especially when an existing record close-in-time to the relevant medical event expressly supports a *later* onset (and hence the statements are offered to vary what a record supports).

Second, theses onset issues would still exist even if I accepted Petitioners' witness statements despite their lack of corroboration, and determined that T.R. had been experiencing some kind of prior gastrointestinal issues in the weeks before his acute symptoms manifested. This is because it has not been demonstrated by Petitioners that there exists a kind of progressive, intermittent intussusception, in which the acute nature of symptoms specific to intussusception are preceded by a week or two of serious but less-alarming GI-level problems of the kind described in the witness statements. Such a condition goes unmentioned in the majority of filed literature sources (with the exception of Mapagu), but there the

[7] Although Respondent makes some convincing arguments regarding *Althen* Prong One, Petitioners fairly relied on the Table version of the claim for general causation in this instance (although the Table timeframe element cannot be met if onset exceeds 21 days—and therefore Petitioners were still obligated herein to prove a longer onset was consistent with the theory). And because dismissal of a claim is proper if only one of the *Althen* prongs is unmet, I do not discuss the second, "did cause" prong.

[8] This fact finding also precludes a favorable Table claim for intussusception as well. Indeed, a Table claim would not be supported even had I found onset occurred far closer in time to vaccination, since a period of 11 days (November 5, 2017 to November 16, 2017) separated the purported onset of T.R.'s GI symptoms and when his distress became acute, leading Petitioners to seek emergency care on November 18th. Nothing filed in this case (beyond Dr. Janai's say-so) supports the conclusion that an intussusception would be preceded by almost two weeks of less-acute symptoms, and this fact pattern is not consistent with the Table definition of the injury otherwise.

patient's waxing and waning symptoms occurred *after* an initial acute presentation, not before, with only a few days before the child's acute presentation, not weeks. (In addition, factors other than vaccination were deemed causal). *See* Mapagu at 147–148 (mesenteric adenitis and recent switch to gluten-free diet after celiac diagnosis in the family)).

Ultimately, T.R.'s presentation at the emergency room on November 18, 2017 is consistent with the rapid-onset nature of intussusception, which is noted as an "*abdominal emergency* in the pediatric population." Manning & Little at 607 (emphasis added). This injury is not something understood to progress, manifesting initially as generalized GI distress—despite Dr. Janai's conclusory assertions to the contrary. While I cannot on this record conclude (as Dr. Liacouras urged) that the purported initial symptoms T.R. experienced mean his injury had a viral cause, it has not otherwise been preponderantly established that a vaccine-caused case of intussusception would unfold in the manner alleged.

The nature of the Table claim for intussusception *itself* underscores the problem with timing in this case. The level of scientific/medical support for vaccine-caused intussusception was deemed by the Government strong enough for a Table claim—but mostly for an onset occurring *within a week* of vaccination. *See* Opp. at 35-37. Indeed, as Respondent points out, the Table timeframe was only extended to 21 days "to allow for a generous timeframe that will capture any cases related to the vaccine after day 7." *See National Vaccine Injury Compensation Program: Addition of Intussusception as Injury for Rotavirus Vaccines to the Vaccine Injury Table*, 80 Fed. Reg. 35848 (June 23, 2015) (codified at 42 C.F.R. pt. 100), cited in Opp. at 36. Thus, in the context of a non-Table claim, an onset falling well outside that period, and absent special factors not established herein, is simply lacking in sufficient medical/scientific support.

CONCLUSION

Having reviewed the medical records, expert reports, medical literature, and the parties' respective arguments, I do not find that Petitioners have met their preponderant burden of proof. Accordingly, they have established entitlement to an award of damages, and I must **DISMISS** the claim. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court SHALL ENTER JUDGMENT in accordance with the terms of this Decision.[9]

IT IS SO ORDERED.

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

[9] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.