In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-660V

UNPUBLISHED

PATRICIA KOAPKE, as parent and natural guardian of W.K., a minor, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 15, 2021 Special Processing Unit (SPU); Findings of Fact; Onset; Rotavirus Vaccine; Intussusception

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Adriana Ruth Teitel, U.S. Department of Justice, Washington, DC, for respondent.

ORDER (I) GRANTING IN PART MOTION TO DISMISS, AND (II) REQUIRING PETITIONER TO SHOW CAUSE[1]

On May 29, 2019, Patricia Koapke filed a petition for compensation on behalf of her minor child, W.K., under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that W.K. developed intussusception, a Table injury, as a result of a rotavirus vaccine administered on September 16, 2019. Petition at 1.

[1] Although I have not formally designated this Decision for publication, I am required to post it on the United States Court of Federal Claims' website because it contains a reasoned explanation for the action in this case, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

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

On October 2, 2020, Respondent filed a Rule 4(c) Report arguing that compensation is not appropriate in this case. Specifically, Respondent argues that W.K.'s injury occurred outside the timeframe set forth in the Table, and also meets one or more of the exclusionary criteria set forth in the Qualifications and Aids to Interpretation ("QAI") that govern Table claims. ECF No. 12, Respondent's Rule 4(c) Report ("Report") at 5-6.[3] Respondent concurrently filed a Motion to Dismiss for the reasons set forth in his Rule 4(c) Report. ECF No. 13, Motion to Dismiss, dated October 2, 2020 ("Mot.") at 1. Petitioner opposes the motion, arguing that she has established a prima facie case for causation and Respondent's motion is premature. ECF No. 15, Petitioner's Response to Respondent's Motion to Dismiss ("Opp.") at 1-3.

Now, having considered both parties' briefs as well as the medical records, I find that there is not preponderant evidence that Petitioner suffered a Table injury. Petitioner may be able to succeed on a causation-in-fact theory – although she will need to substantiate the contours of such a claim.

I. Factual Background

W.K. presented to his pediatrician for his two-month well check on September 16, 2019. Ex. 1 at 25. At that time, he received the pneumococcal and rotavirus vaccines. *Id.* at 26.

Less than a month later, on October 14, 2019, W.K. was seen at the emergency room for rectal bleeding and bloody vomit. Ex. 1 at 56. Petitioner and her husband reported that his symptoms began that day. Ex. 3 at 13.[4] W.K. had a fever at that time, fullness in the left lower quadrant, but did not appear tender on deep palpitation of his abdomen. *Id.* at 15. An abdominal x-ray indicated a possible obstruction of the left lower quadrant, and an ultrasound showed a colonic intussusception with marked edematous changes in the colonic wall. *Id.* at 40, 41. A barium enema was unsuccessful. *Id.* at 16.

W.K. was thereafter admitted to Sanford Bismark Medical Center under the care of Drs. Kimber Boyko and Tod Twogood on October 14, 2019. Ex. 4 at 12-15, 23. Upon admission, Petitioner reported that W.K. had vomited several times over the previous two days. *Id.* at 23. Further, that morning Petitioner noticed blood in W.K.'s diaper and coming out of his anus. *Id.*

[3] Respondent also argues that Petitioner has not established causation-in-fact. Report at 6-8.

[4] The petitioner states that W.K. presented with two days of vomiting and blood in his stool. Petition at 1. However, the medical records are not consistent with this.

W.K. did not have a fever upon admittance, and received IV fluids prior to emergency surgery on October 14, 2019. He had a large segment of ileum intussuscepted into the ascending and part of the transverse colon that was not able to be manually reduced and was nonviable. Ex. 4 at 12, 48-49. He also had a section of necrotic bowel due to intussusception, including 20 cm of small intestine and ascending colon, and a separate 5 cm segment of transverse colon. *Id.* at 48-49.

Dr. Boyko removed the necrotic bowel and connected the ileum to the transverse colon (an ileocolic anastomosis). Ex. 4 at 48-49. Pathology results revealed intussusception of the terminal ileum into the right colon, a prolapsed appendix, ischemic bowel and necrosis, severe acute inflammation and congestion, and an aggregate of five benign hypertrophic lymph nodes with severe congestion. *Id.* at 54-55. The pathologist noted in particular that "[d]irectly adjacent to the dusky portion of the bowel, there is a 1.7 x 1.2 x 1. cm dusky purple nodular lesion." *Id.*

Following surgery, W.K. had signs of shock with fever that was thought to be a response to his bowel injury and surgery. Ex. 4 at 13. He remained in the hospital for the following 15 days due to various complications, including abdominal distension, anemia, sepsis, and blood loss. *Id.* at 14-26. W.K. was discharged on October 29, 2019 without a fever, and a soft, non-tender and nondistended abdomen. *Id.* at 29.

On October 31, 2019, W.K. had a follow-up visit with his pediatrician and was noted as doing well. Ex. 1 at 23. W.K. was seen again on November 20, 2019, for a well visit and was reported as normal. *Id.* at 20. That same day, W.K. was seen for a follow-up by Dr. Boyko, who also noted he was doing well. Ex. 4 at 97.

II. Procedural History

The Petition was filed on May 29, 2020 and alleges a table injury of intussusception resulting from a rotavirus vaccine. ECF No. 1. The Petition also states that the intussusception injury "was caused by the rotavirus vaccine," indicating that a causation-in-fact non-Table claim is also alleged. *Id.* at 3.

Respondent filed a Rule 4(c) Report on October 2, 2020, arguing that W.K. did not suffer a Table injury because his intussusception occurred outside of the timeframe set forth in the Table. Report at 5. Respondent also argues that W.K. had a preexisting condition, identified as the lead point for intussusception and/or bowel abnormalities, which is an exclusion criterion under the Table. *Id.* at 6. Respondent concurrently filed a motion to dismiss for the reasons set forth in his report. Mot. at 1. Petitioner opposed the

motion, arguing that she has established a prima facie case for causation, and also maintaining that Respondent's motion is premature. Opp. at 1-3.

III. Analysis of Substantive Issues Raised by Respondent's Motion

A. Requirements of a Table Intussusception Claim

A petitioner may prevail on a claim if he has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). The most recent version of the Table, which can be found at Section 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a); 42 C.F.R. § 100.3.

Finding a petitioner is entitled to compensation cannot be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). Indeed, contemporaneous medical records are deemed trustworthy proof of petitioner's medical issues. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993, F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in question, by contrast, is considered less reliable, given the need for accurate explanation of symptoms at the time of treatment. *Reusser v. Sec'y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

"It must [also] be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991), aff'd, 968 F.2d 1226 (Fed. Cir. 1992); *see also Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (rejecting as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions).

However, in balancing these considerations, special masters in this Program have in most cases declined to credit later testimony over contemporaneous records. *See, e.g.*, *Stevens v. Sec'y of Health & Hum. Servs.*, No. 90–221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990); *Vergara v. Sec'y of Health & Hum. Servs.*, No. 08–882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. July 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recounted in later medical histories, affidavits, or trial testimony."); *see also Cucuras*, 993

F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight").

If a petitioner establishes that he has suffered a "Table Injury," causation is presumed. A Table injury following a rotavirus vaccine requires that intussusception occurs between 1 and 21 days after the vaccination. 42 C.F.R. § 100.3(a)(XI). The QAI provides additional guidance regarding intussusception, and in particular sets forth exclusionary criteria wherein an injury is not considered a Table intussusception. 42 C.F.R. § 100.3(c)(4)(ii). These include when an individual has a preexisting condition identified as the lead point for intussusception, such as intestinal masses and cystic structures, and when an individual has abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal hemorrhage, trauma, or abnormal intestinal blood vessels. 42 C.F.R. § 100.3(c)(4)(ii)(C), (D).

B. Adequacy of Petitioner's Table Claim

Petitioner alleges that W.K.'s symptoms first occurred, consisting of vomiting, on October 12, 2019. Petition at 1-2. However, the medical records indicate that W.K.'s symptoms first manifested *either* on October 12 or October 14. Ex. 1 at 56 (noting W.K.'s symptoms began on October 14, 2019); Ex. 4 at 23 (reporting on October 14, 2019 that W.K. had vomited several times over the previous two days). But neither date saves the Table claim – for in either case, W.K.'s first symptoms began either 28 or 26 days after his rotavirus vaccine, and thus outside the 21-day timeframe set forth in the Table. 42 C.F.R. § 100.3(a)(XI).

There are few cases that discuss the outside range of when intussusception can be attributed to a rotavirus vaccine. However, at least one case involving intussusception where the injury occurred outside twenty-one days resulted in dismissal of the Table claim. *Carda v. Sec'y of Health & Hum. Servs.*, No. 14-191V, 2016 WL 3571539, at *1 (Fed. Cl. Spec. Mstr. May 24, 2016) (motion to dismiss table claim granted in case where intussusception occurred fifty-seven days after the second rotavirus vaccine dose). Further, in *Carda* there was no medically acceptable timeframe suggesting an intussusception following a rotavirus vaccination would occur *more* than twenty-one days post-vaccination – casting doubt on any form of non-Table claim. *Carda v. Sec'y of Health & Hum. Servs.,* No. 14-191V, 2017 WL 6887368, at *21 (Fed. Cl. Nov. 16, 2017). Petitioner's inability to establish onset in the proper timeframe is thus by itself sufficient basis for the Table claim's dismissal.[5]

[5] With regard to the exclusionary criteria cited by Respondent, there is simply not enough evidence to establish that the prolapsed appendix or "dusky purple nodular lesion" in the bowl qualify as either a

C. Resolution of Non-Table Claim

Petitioner's failure to establish a Table claim still leaves the possibility that the matter could advance as a causation-in-fact non-Table claim. To establish entitlement for a Non–Table claim, a petitioner must satisfy all three of the elements set forth in by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Here, Petitioner *may* be able to show that a longer onset was still medically acceptable, under a causation-in-fact theory. But the admittedly-limited prior case law bearing on that kind of intussusception claim supports a short temporal connection between a rotavirus vaccine and acute intussusception. In *Carda*, for example, petitioners unsuccessfully attempted to establish an intussusception that occurred seven or eight weeks after receipt of a rotavirus vaccine was causally related to that vaccine. *Carda*, 2017 WL 6887368 at 23. In that case, I noted that there was no medically acceptable evidence to support the conclusion that intussusception would occur more than 21 days after a rotavirus vaccination (the timeframe allowed for in a Table claim). *Id.* at 21.

A non-Table version of an intussusception claim is of course not bound by the same 21-day timeframe (although Program petitioners cannot rely on how "close" they are to meeting it). *Rowan v. Sec'y of Health & Hum. Servs.*, No. 17-760V, 2020 WL 2954954, at *15 (Fed. Cl. Apr. 28, 2020) ("controlling and persuasive Program precedent does not permit claimants to rely on the Table requirements, or even the mere existence of a Table version of a claim, in proving a non-Table claim"). It is not certain to me based on the present record whether a non-Table claim *could* be persuasively advanced. I will, however, provide Petitioner the opportunity to file an amended claim, and then show cause why such a claim should be permitted to proceed, setting forth the evidence (and if possible, the science) that would support the claim. I will thereafter transfer the claim out of SPU for adjudication of the non-Table claim if it is evident that such a claim might be tenable.

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preexisting condition that was identified as a lead point for the injury, or an abnormality of the bowel. But the insufficiency of evidence supporting a Table onset is ample grounds for that claim's dismissal.

IV. Conclusion

Petitioner has failed to file preponderant evidence to establish W.K. suffered a Table claim.

Accordingly,

- **Petitioner's Table Claim for intussusception is dismissed;**
- **Petitioner may file an amended petition alleging a causation-in-fact claim by no later than September 29, 2021; and**
- **Petitioner shall show cause by October 14, 2021, why she should be permitted to advance this matter as a non-Table claim. Respondent may oppose on or before October 29, 2021.**

IT IS SO ORDERED.

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