In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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REBECCA RESKE and TIMOTHY RESKE, parents and natural guardians of J.R., a minor,	*	
	*	No. 19-131V
Petitioners,	*	Special Master Christian J. Moran
v.	*	
	*	Filed: September 20, 2021
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement, RotaTeq, intussusception
Respondent.	*	
* *		

Bridget McCullough, Muller Brazil, LLP, Dresher, PA, for petitioners;
Meghan Murphy, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT TO COMPENSATION[1]

Mr. and Ms. Reske allege that the third dose of rotavirus vaccine caused their daughter, J.R., to suffer intussusception. They seek compensation pursuant to the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa–10 to 34 (2012). Because various epidemiological studies have not detected an increase of intussusception after the third dose of a rotavirus vaccine and because petitioners have not otherwise presented a persuasive theory to explain a causal

[1] The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this decision on its website. Anyone will be able to access this decision via the internet (https://www.uscfc.uscourts.gov/aggregator/sources/7). Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

connection between the third dose of a rotavirus vaccine, they are not entitled to compensation.

I. Facts[2]

J.R. was born in [redacted] 2016. She did not have any significant medical problems in her first six months. During this time, she received various vaccines, including two doses of rotavirus vaccine. Exhibit 1 at 1 (vaccination record).[3]

At her six-month well baby appointment, J.R. had cough and congestion, symptoms of an upper respiratory infection. The pediatrician at Pikesville Pediatrics did not note any unusual health problems. The pediatrician also ordered additional vaccinations, including a third dose of a rotavirus vaccine. Exhibit 4 at 33.

The medical records do not specify the brand of the rotavirus vaccine given to J.R. See id. However, the doctors retained to provide opinions in this case agree that she received RotaTeq. Exhibit 10 at 3; exhibit A at 2; exhibit C at 2; see also Germaine v. Sec'y of Health & Human Servs., No. 18-800V, 2020 WL 8992815, at *4 (Fed. Cl. Spec. Mstr. Mar. 9, 2020) (finding a third dose of a rotavirus vaccine means the vaccine was RotaTeq).

J.R. returned to Pikesville Pediatrics on January 3, 2017, which is 14 days after vaccination. J.R. was fussy and vomiting for one day. The pediatrician diagnosed J.R. as suffering from a viral gastrointestinal illness and instructed her parents to take her to an emergency room if she became dehydrated. Exhibit 4 at 18-19.

The following day, J.R.'s parents brought her to a local emergency department due to abdominal pain, vomiting, and bloody diarrhea. Exhibit 2 at 32. The doctors considered that J.R. might have intussusception and transferred her to another hospital, Sinai Hospital of Baltimore.

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[2] The parties' recitations of fact are relatively similar. Thus, the events in J.R.'s early medical history are presented relatively summarily. See Pet'rs' Br., filed Feb. 23, 2021, at 1-2; Resp't's Br., filed Apr. 24, 2021, at 2-3.

[3] Ms. Reske averred that J.R. spit out portions of the first two doses of the rotavirus vaccine. Exhibit 9 ¶ 4. However, the petitioners do not advance this assertion in their brief. Regardless, the degree of the vaccine that J.R. swallowed appears not to be a material issue. See exhibit C (Dr. Romberg's report) at 9.

In Sinai Hospital, an ultrasound confirmed the intussusception. Exhibit 3 at 11. After an enema only partially reduced the intussusception, J.R. underwent an operation in which the surgeons repaired the intussusception. Id. at 110-11. J.R. was discharged on January 6, 2017.

In a follow-up appointment, J.R.'s exam was normal, except for a scar from the operation. Exhibit 4 at 16-17. A medical record from August 2018 indicates that she was doing well and developmentally normal. Exhibit 7 at 4-8.

II. Procedural History

Mr. and Ms. Reske initiated this action on January 28, 2019, by filing their petition, which was assigned to the Chief Special Master's Special Processing Unit. They filed medical records with the petition.

The Secretary reviewed the material and recommended that compensation be denied. The Secretary maintained that the Reskes did not qualify under the Vaccine Injury Table because the Table associates intussusception with only the first two doses of a rotavirus vaccine. Resp't's Rep., filed July 16, 2019, at 4 (citing 42 C.F.R. § 100.3(a) ¶ XI). The Secretary further argued that Mr. and Ms. Reske did not support a claim for an off-Table case because they did not present sufficient evidence to show that the third dose of RotaTeq was the cause-in-fact of J.R.'s intussusception. Id. at 4-5. In response to the Secretary's report, the case was re-assigned, out of the Special Processing Unit.

To assist the parties in presenting reports from experts, a set of proposed instructions were issued. After the parties did not submit any comments about the instructions, they became final on October 28, 2019.

Mr. and Ms. Reske submitted a report from Thomas Sferra, a pediatric gastroenterologist. Exhibit 10. They later added a supplemental report. Exhibit 25.

Dr. Sferra graduated from the Northeast Ohio Universities College of Medicine in 1986. He had a residency in pediatrics. After this residency, Dr. Sferra participated in a research fellowship at the University of Michigan Medical Center from 1990 to 1993. He then had a clinical fellowship in pediatric gastroenterology at the Ohio State University from 1993 to 1996. Dr. Sferra taught pediatric gastroenterology at various institutions. He is currently the Martin and Betty Rosskamm Chair in pediatric gastroenterology at University Hospitals Rainbow Babies & Children Hospital in Cleveland, Ohio. He is board-certified in pediatrics and pediatric gastroenterology. His curriculum vitae includes a long list

of honors, presentations, and authorships. However, none appear to relate to intussusception specifically. Exhibit 11. Dr. Sferra has cared for approximately 250 patients with intussusception. Exhibit 10 at 1.

The Secretary submitted reports from two doctors. The initial set of reports were filed on June 4, 2020, and then supplemented on November 3, 2020. The doctors whom the Secretary retained are Chris A. Liacouras, whose reports are exhibits A and F, and Neil Romberg, whose reports are exhibits C and E.

Dr. Liacouras is currently a professor of pediatrics at Children's Hospital of Philadelphia, University of Pennsylvania School of Medicine. He graduated from Harvard University Medical School in 1985. He has had a residency and fellowship. He has been teaching in some capacity at medical schools since 1988. Like Dr. Sferra, Dr. Liacouras is board-certified in pediatrics and pediatric gastroenterology. Dr. Liacouras has a similarly lengthy list of honors, presentations, and authorships. He, too, appears not to have written about intussusception. Exhibit B. He has evaluated more than 100 children with intussusception. Exhibit A at 2.

Like Dr. Liacouras, Dr. Romberg currently works at the Children's Hospital of Philadelphia. Dr. Romberg's area of specialization is pediatric immunology for which he is board-certified. Dr. Romberg, too, has written many articles and received many honors. Exhibit D.

After the parties appeared to complete the process of filing reports from experts, a status conference was held during which the Secretary indicated that he was not interested in attempting to resolve this case. Accordingly, the parties were directed to file briefs regarding entitlement. Order, issued Dec. 29, 2020.

The parties submitted briefs as required. The Reskes filed their primary brief on February 23, 2021. The Secretary responded on April 24, 2021. Mr. and Ms. Reske replied on June 23, 2021. With the submission of the reply brief, the case is ready for adjudication.

III. Standards of Adjudication

Petitioners are required to establish their case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "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 v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations

omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (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 & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

In looking at record as whole, special masters may draw upon their accumulated expertise. Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996) (quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)).

IV. Analysis

A. Prong One

The evaluation of the evidence in Mr. and Ms. Reske's case begins, preliminarily, with a recognition that special masters have considered claims that the third dose of the RotaTeq vaccine can cause intussusception in previous cases. Special masters have found that the evidence in those cases does not preponderate in favor of finding that petitioners have met their first Althen prong. See Germaine, 2020 WL 8992815, at *7; Carda v. Sec'y of Health & Human Servs., No. 14-191V, 2017 WL 6887368, at *19-20 (Fed. Cl. Spec. Mstr. Nov. 16, 2017) (petitioners failed to establish that RotaTeq can cause a transient intussusception). While those decisions do not constitute binding precedent, see Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351, 1358 (Fed. Cir. 2019), they remain a legitimate source of information pursuant to Whitecotton and Hughes.

The persuasiveness of those non-binding decisions is enhanced because the evidence in those cases overlaps, at least in part, with the evidence presented in

Mr. and Ms. Reske's case. The similarity in evidence is particularly notable with respect to the epidemiologic evidence.

For a lengthy discussion of the value of epidemiologic studies in the Vaccine Program, see Tullio v. Sec'y of Health & Human Servs., No. 15-51V, 2019 WL 7580149, at *5-8 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448, 475 (2020). Epidemiological studies carry greater weight in the context of rotavirus vaccines causing intussusception because researchers have actively searched for an association. Cf. Taylor v. Sec'y of Health & Human Servs., 108 Fed. Cl. 807, 819-21 (2013) (pertussis vaccines leading to infantile spasms); Hennessey v. Sec'y of Health & Human Servs., 91 Fed. Cl. 126, 138-40 (2010) (hepatitis B vaccine leading to type one diabetes).

In support of their assertion that the third dose of the RotaTeq vaccine can cause intussusception, Mr. and Ms. Reske point to four epidemiologic studies. See Pet'rs' Br. at 4-5. These are: Murphy (exhibit 16), Parashar (exhibit 17), Escolano (exhibit 23), and Kassim (exhibit 24). The Secretary adds more epidemiologic studies, including Yih (exhibit A, tab 6), Koch (exhibit A, tab 7), Haber (exhibit A, tab 8), Lu (exhibit C, tab 5), and Soares-Weiser (exhibit C, tab 8). Resp't's Br. at 10-12.[4]

The evidence on which Mr. and Ms. Reske rely carries relatively little weight. Murphy, for example, studied an older rotavirus vaccine, RotaShield. Exhibit 16 at 564. Given that the RotaTeq vaccine was designed in response to problems associated with RotaShield (see exhibit 17 (Parashar)), studies about RotaShield are not particularly useful in determining whether RotaTeq can cause similar problems. See Parsley v. Sec'y of Health & Human Servs., No. 08-781V, 2011 WL 2463539, at *13 (Fed. Cl. Spec. Mstr. May 27, 2011) (stating in a RotaTeq-intussusception case that "[t]he RotaShield experience provides little support for petitioner's causation case" because RotaShield and RotaTeq are "biologically distinct").

Kassim evaluated RotaShield (the older and withdrawn rotavirus vaccine) as well as RotaTeq (the vaccine J.R. received) and Rotarix (another more modern vaccine). Based upon six cohort studies and five case-controlled studies, the researchers found "a higher risk of developing intussusception within the first 7 days after the first dose of vaccine." Exhibit 24 (Kassim) at 4280. An increased risk of intussusception was also found "after receiving the first dose and all the

[4] The appendix contains complete bibliographic information.

doses of the rotavirus vaccine." Id. As a possible limitation to their study, the Kassim group acknowledged that including "the date of the revoked [RotaShield] vaccine . . . may have favoured the final pooled results, thus not showing the full effects on the currently available [Rotarix] and [RotaTeq] vaccines alone." Id. at 4284.

Parashar and colleagues summarized the benefits and risk of vaccination with RotaTeq and Rotatrix. In discussing the risk that RotaTeq might cause intussusception, the researchers did not differentiate among different doses. Moreover, Parashar and colleagues cited studies (references 19-23 in the article) that include Haber and Yih, discussed below. Exhibit 17 (Parashar) at D56.

Finally, Escolano is the most pertinent of the quartet of articles on which petitioners rely. Escolano analyzed the risk of intussusception after RotaTeq. "The risk of intussusception occurring in either of the 0- to 2-day, 3- to 7-day or 8- to 14-day risk periods, was compared to the risk in the 15- to 30-day period." Exhibit 23 at 1017 (abstract). The researchers found "Rotavirus vaccination with RV5 increases the risk of intussusception 3-7 days following vaccination, mainly after the first dose and marginally after the second and third doses. The risk is small and restricted to a short time window." Id. The authors further detailed: "After doses 2 and 3, the risk increase was small (about 1.5 during both the 0- to 2- and 3- to 7-day periods) and did not reach statistical significance." Id. at 1019. The researchers summarized their work: "while not providing definitive evidence, our study suggests that vaccination with [RotaTeq] is associated with an increase in risk of intussusception after the first dose." Id.[5]

The value of these three studies must be weighed against the studies the Secretary presented. Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (noting the Secretary may present evidence to undermine a

[5] Dr. Liacouras makes a mistake in how he quoted this summary. He wrote: "In summary, while not providing definitive evidence, our study suggests that vaccination with RV5 is associated with an increase in the risk of intussusception (only) after the first dose." Exhibit F at 2. The Secretary repeated this statement in his brief. Resp't's Br. at 15 (quoting exhibit F at 2).

However, the Escolano authors did not use the word "only." While "only" is consistent with the findings of the paper, Dr. Liacouras should not have changed the text of the article. It may be the case that Dr. Liacouras intended to place the word "only" in brackets (rather than parenthesis) to show his alteration.

petitioner's case). The undersigned has previously considered the Yih, Haber, and Koch studies. Germaine, 2020 WL 8992815, at * 6-7.

Yih primarily concluded that "subsequent doses of the [the RotaTeq vaccine] were not associated with a significant increase in the risk of intussusception." Exhibit A, tab 6, at 509. Yih did qualify that conclusion adding that "an increased risk associated with [the second and third] doses cannot be ruled out, given the overlapping confidence intervals of the risk estimates for doses 1, 2, and 3." Id.

Haber concluded that "there was no significant increase in reporting after dose 2 or dose 3 [of the RotaTeq vaccine]." Exhibit A, tab 8, at 1042. Haber concluded that there was only a small increase in intussusception events for three to six days after the first dose of the RotaTeq vaccine.

Koch concluded that "[t]here is no increase in risk after the third dose of the [RotaTeq] vaccine." Exhibit A, tab 7, at 260. Koch does not list any attributable risk for the third dose in a table of calculations. Id., Table 2. In the "Key Messages" section, Koch does not mention any risk of intussusception from the third dose of the RotaTeq vaccine. Id. at 261.

The Secretary and the experts he retained expanded the set of relevant epidemiologic articles by adding Lu (exhibit C, tab 5), and Soares-Weiser (exhibit C, tab 8). In Lu, the researchers undertook a meta-analysis of approximately 31 studies involving different rotavirus vaccines, including RotaTeq. They found "no association of vaccination with increased risk of intussusception compared with placebo among infants for up to 2 years after vaccination." Exhibit C, tab 5, at 10.

For Soares-Weiser, the authors examined 15 studies involving RotaTeq with nearly 90,000 participants. Exhibit C, tab 8, at 1. "There were 16 cases of intussusception in 43,629 children after [RotaTeq] vaccination and 20 cases in 41,866 children after placebo (RR 0.77, 95% CI 0.41 to 1.45; low-certainty evidence)." Id. at 2.

Overall, the weight of the epidemiological evidence is not consistent with a finding that the third dose of the RotaTeq vaccine causes intussusception. Two of the studies on which Mr. and Ms. Reske rely (Murphy and Kassim) examined the RotaShield vaccine, which is not the vaccine that J.R. received. Thus, those studies are less meaningful.

The remaining study (Escolano) did not find a meaningful increase in risk after the third dose. While the Escolano's detection of a slight increase warrants

consideration, Yih, Haber, and Koch also did not find any statistically significant increase in risk. Koch goes so far as to state: "[t]here is no increase in risk after the third dose of the [RotaTeq] vaccine." Exhibit A, tab 7, at 260. For these reasons, the epidemiologic studies do not support a finding that a third dose of RotaTeq can cause intussusception.

While epidemiologic studies are relevant in evaluating the petitioners' theory that a vaccine can cause an injury, they are not dispositive. Thus, the medical theory Dr. Sferra proposes will be assessed.

In their brief, Mr. and Ms. Reske summarize Dr. Sferra's theory as one in which the vaccine induces an acute immune response that leads to hyperplasia of the lymph nodes near the bowel or Peyer's patches of the bowel wall. ("Hyperplasia" means an "abnormal multiplication or increase in the number of normal cells in normal arrangement in a tissue." Dorland's Illust. Med. Dictionary (33d ed.) at 882.) The hyperplasia, in turn, serves as the lead point to trigger the intussusception. Pet'r's Br. at 4 (citing exhibit 10 at 4-5).

The problems, however, with this theory are at least two-fold. First, the theory is overly general. Although doctors do not understand what causes intussusception, the "prevailing view is that idiopathic intussusception is caused by hypertrophy lymphoid tissues within the bowel." Exhibit C (Dr. Romberg's report) at 3.[6] Thus, Dr. Sferra's theory resembles saying "the vaccine causes the cause of intussusception." But, Dr. Sferra provides no suggestion as to how a vaccine leads to hyperplasia or hypertrophy in the bowel's lymph nodes. Thus, Dr. Sferra's opinion contains a gap and is, therefore, unpersuasive. See Langland v. Sec'y of Health & Human Servs., 109 Fed. Cl. 421, 441 (2013) (stating a persuasive medical theory "may require an explanation of the steps by which the vaccination was believed to result in the harm").

Second, Dr. Sferra cites no articles presenting the theory that vaccines can cause hyperplasia or hypertrophy. At best, Dr. Sferra cites articles indicating that viral infections are associated with intussusception. See exhibit 10 at 5.[7] While

[6] "Hypertrophy" means "the enlargement or overgrowth of an organ or part due to an increase in size of its constituent cells." Dorland's at 886. Thus, while it appears that "hyperplasia" (an increase in the *number* of cells) and "hypertrophy" (an increase in the *size* of cells) differ in meaning slightly, the parties seem to have overlooked any distinction.

[7] As discussed, the risk for intussusception following the first dose of a rotavirus vaccine is increased. However, the epidemiologic studies cited by petitioner do not identify hyperplasia or hypertrophy as the cause of these intussusception cases.

petitioners are not required to demonstrate the "specific biologic mechanism," Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994), "a scientific theory that lacks any empirical support will have limited persuasive force." Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 134 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012).

Accordingly, for these reasons, Mr. and Ms. Reske have failed to present a reliable and persuasive opinion that the third dose of the RotaTeq vaccine can cause intussusception. While this finding means that they are not entitled to compensation, the remaining two Althen prongs are briefly reviewed.

B. Prong Three

To the extent that studies have detected an increased risk for intussusception, the risk is increased after the first dose and the increased risk appears to be highest in the first week following vaccination. See Exhibit 23 (Escolano) at 1017 (abstract); exhibit A, tab 8, (Haber) at 1042.

Dr. Sferra acknowledges that the risk "is clustered during the first 7 days after the vaccination." Exhibit 10 at 5. This recognition did not prevent Dr. Sferra from maintaining that the risk extends to 21 days and Dr. Sferra cited the Carlin article (exhibit 22) for this proposition. Id. However, Carlin's extension to 21 days is in the context of "first vaccine dose." Exhibit 22 at 1431; see also exhibit 25 (Dr. Sferra's supplemental report) at 2.

Accordingly, whether an onset of intussusception 13 days after the third dose of RotaTeq is appropriate for inferring causation is not clear. Because Dr. Sferra has not described the process by which the third dose of RotaTeq can cause intussusception, evaluating the appropriate temporal interval is difficult. "With no reputable theory as to how the vaccination could cause the injury, this exercise [of determining the appropriate temporal interval] is not possible." Langland, 109 Fed. Cl. at 443. Thus, due to the lack of a coherent medical theory, the undersigned finds that Mr. and Ms. Reske have not met their burden of establishing that 13 days is an appropriate temporal relationship for intussusception to occur after the third dose of RotaTeq.[8]

[8] Given that the Vaccine Table associates the first two doses of rotavirus vaccine with intussusception within 1 to 21 days, 42 C.F.R. § 100.3(a) ¶ XI, the claim that 13 days is an appropriate interval is not facially unreasonable. However, even if the Reskes established that J.R.'s intussusception developed within an appropriate time after the vaccination, merely

C. Prong Two

Given that Mr. and Ms. Reske have not met their burden on prongs one and three, it follows as a matter of logic that they have not met their burden on prong two, which requires petitioners to present a "logical sequence of cause and effect." With respect to this prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Here, Mr. and Ms. Reske essentially argue that: (1) J.R. was healthy before the vaccination, (2) J.R. received the vaccination, (3) J.R. developed intussusception, and (4) no other cause for the intussusception has been determined. See Pet'r's Br. at 5-6. The Federal Circuit has rejected this paradigm. Moberly, 592 F.3d at 1323.

Furthermore, although they were directed to identify any doctors who linked a vaccination to J.R.'s intussusception, see order, issued Dec. 29, 2020, at 7, petitioners did not identify any such instances. This lack of evidence undermines the argument that the RotaTeq vaccine caused J.R.'s intussusception.

V. Ruling on the Record is Appropriate

Special masters may rely on their accumulated knowledge in the Vaccine Program to make entitlement decisions on the papers. Thus, special masters, "based upon their accumulated expertise in the field, judg[e] the merits of individual claims." Whitecotton, 81 F.3d at 1104. Additionally, special masters retain wide discretion in determining whether an evidentiary hearing is necessary. Kreizenbeck v. Sec'y of Health & Human Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2020) (citing 42 U.S.C. § 300aa-12(d)(3)(B)(v) ("In conducting a proceeding on a petition a special master . . . may conduct such hearings as may be reasonable and necessary.")). The special master must only determine "that the record is comprehensive and fully developed before ruling on the record." Id. at 1366 (citing Simanski v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1385 (Fed. Cir. 2012)).

A hearing to determine whether the third dose of RotaTeq caused J.R.'s intussusception in this case is not needed. The parties have had ample opportunity to develop the record both in terms of the facts presented, as well as the expert

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establishing a sequence of events does not show causation. Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

opinions in the case, lengthy submissions of evidence, multiple expert reports, and thorough briefing.

Mr. and Ms. Reske's claim fails for reasons that a hearing could not cure given the strength of epidemiologic evidence and lack of development of a theory to explain how the third dose of RotaTeq can cause intussusception. They have had a full and fair opportunity to present their case. Thus, a disposition on the papers is appropriate. See Kreizenbeck, 945 F.3d at 1365.

VI. Conclusion

J.R.'s development of intussusception approximately two weeks after receiving a rotavirus vaccine may have led Mr. and Ms. Reske to believe the vaccine caused the intussusception. However, a vaccine does not cause all medical problems that follow it. In this case, evidence shows that the rotavirus vaccine that J.R. received (RotaTeq) is unlikely to cause intussusception after the third dose. Accordingly, Mr. and Ms. Reske are not entitled to compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information regarding the deadline for filing a motion for review can be found in the Vaccine Rules of the Court of Federal Claims, which can be found on the Court's website.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master

Appendix

John B. Carlin et al., *Intussusception Risk and Disease Prevention Associated with Rotavirus Vaccines in Australia's National Immunization Program*, 57 Clinical Infectious Diseases 1427 (2013), filed as exhibit 22.

Sylvie 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 exhibit 23.

Penina Haber et al., *Intussusception After Rotavirus Vaccines Reported to US VAERS, 2006-2012*, 131 Pediatrics 1042 (2013), filed as exhibit A, tab 8.

Priya Kassim & Guy D. Eslick, *Risk of intussusception following rotavirus vaccination: An evidence based meta-analysis of cohort and case-control studies*, 35 Vaccine 5276 (2017), filed as exhibit 24.

Judith Koch et al., *Risk of Intussusception After Rotavirus Vaccination*, 114 Deutsches Arzteblatt Int'l 255 (2017), filed as exhibit A, tab 7.

Hai-Ling Lu et al., *Association Between Rotavirus Vaccination and Risk of Intussusception Among Neonates and Infants: A Systematic Review and Meta-analysis*, 2 JAMA Network Open 1 (2019), filed as exhibit C, tab 5.

Trudy V. Murphy et al., *Intussusception among infants given an oral rotavirus vaccine*, 344 New England J. Med. 564 (2001), filed as exhibit 16.

Umesh D. Parashar et al., *Value of post-licensure data on benefits and risks of vaccination to inform vaccine policy: The example of rotavirus vaccines*, 33 Vaccine D55 (2015), filed as exhibit 17.

Karla Soares-Weiser et al., *Vaccines for preventing rotavirus diarrhoea: vaccines in use*, 10 Cochrane Database of Systematic Revs. 1 (2019), filed as exhibit C, tab 8.

W. Katherine Yuh et al., *Intussusception Risk after Rotavirus Vaccination in U.S. Infants*, 370 New England J. Med. 503 (2014), filed as exhibit A, tab 6.