In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-0759V

TO BE PUBLISHED

SARAH FLORES and RYAN C. FLORES, on behalf of M.F., a Minor Child, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: October 26, 2020 Special Processing Unit (SPU); Findings of Fact; Statutory Six Month Requirement; Severity Requirement; Surgical Intervention; Measles Mumps Rubella (MMR) Vaccine; Thrombocytopenic Purpura (ITP)

Diana Lynn Stadelnikas, Maglio Christopher & Toale, PA, Sarasota, FL, for Petitioner.

Kyle Edward Pozza, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT[1]

On May 30, 2018, Sarah and Ryan C. Flores filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), on behalf of their minor daughter, M.F. Petitioners allege that following the June 23, 2016 administration of a measles, mumps and rubella ("MMR") vaccine, M.F. experienced immune thrombocytopenic purpura ("ITP"). *See generally* Petition. The case was assigned to the Special Processing Unit of the Office of Special Masters.

[1] Because this fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website 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 fact ruling 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).

For the reasons set forth below, and as I announced during the October 2, 2020 motions hearing,[3] I find that Petitioners have succeeded in producing preponderant evidence to satisfy the Vaccine Act's severity requirement. Accordingly, Respondent's request for dismissal of the petition is denied.

I. Relevant Procedural History

As noted above, the case was initiated in May 2018. After reviewing Petitioners' medical records and affidavit, Respondent filed a status report stating that he was not amenable to engaging in settlement discussions and requesting 60 days in which to file his status report pursuant to Vaccine Rule 4(c). ECF No. 26. This request was granted.

On July 19, 2019, Respondent filed the Rule 4(c) Report maintaining that the case was not appropriate for compensation under the terms of the Vaccine Act. ECF No. 29. Respondent specifically argued that "M.F.'s condition resolved around early November 2016, about three months after the July 2016 onset, and about four months after her June 2016 vaccination." *Id*. at 5. Respondent further argued that Petitioners "failed to establish that M.F. underwent a 'surgical intervention' as understood in the context of the Vaccine Act" and requested dismissal of the petition. *Id*.

Petitioners filed a response to Respondent's Rule 4(c) Report on January 20, 2020. Petitioners asserted that the Vaccine Act's severity requirement had been satisfied because M.F.'s bone marrow aspiration and biopsy constituted a "surgical intervention" (which, as discussed in greater detail below, is an alternative basis for finding severity). ECF No. 36. Nevertheless, on February 28, 2020 Respondent filed a status report indicating that he would continue to defend this claim. ECF No. 38.

The parties' arguments on the disputed severity requirement issue were based on briefing completed prior to the motions day hearing. Thus, on March 5, 2020, Petitioners filed a Motion for Findings of Fact and Conclusions of Law Regarding Entitlement. ECF No. 42. Respondent filed his response ("Response") on April 6, 2020. ECF No. 44. Petitioners filed a reply on April 13, 2020. ECF No. 45.

II. Issue

At issue is whether Petitioners have met the Vaccine Act's severity requirement by establishing either that M.F.'s bone marrow aspiration and biopsy constituted a surgical intervention for purposes of the Vaccine Act, and/or that she continued to suffer the residual effects or complications of ITP for more than six months.

[3] *See* Minute Entry dated October 2, 2020. The transcript of the hearing, which was not yet filed as of the date of this Ruling, is hereby incorporated into my Findings of Fact by reference.

III. Authority

> In order to state a claim under the Vaccine Act, a vacinee must have either:
>
> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and *surgical intervention.*

Section 11(c)(1)(D) (emphasis added).

There is no definition of "surgical intervention" within the Vaccine Act. *See* Section 33 (Definitions). Nor is there any Federal Circuit decision interpreting that term. As described in prior decisions by special masters, the "surgical intervention" language was added to the Vaccine Act primarily to allow for recovery for the injury of intussusception (a condition often experienced by infants in which a portion of the intestine telescopes into itself), which can require surgery but does not typically "persist" (in terms of injury-related sequelae) for six months. *See,* e.g., *Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728 (Fed. Cl. Spec. Mstr. Jan. 16, 2014); *Stavridis v. Sec'y of Health & Human Servs.*, No. 07-261V, 2009 WL 3837479 (Fed. Cl. Spec. Mstr. Oct. 29, 2009); *Ivanchuck v. Sec'y of Health & Human Servs*., No. 15-357V, 2015 WL 6157016 (Fed. Cl. Spec. Mstr. Sept. 18, 2015).

Special masters interpreting the "surgical intervention" language have disagreed somewhat as to its meaning, and have applied the term in different ways depending upon the circumstances that the injury in question poses. *Spooner*, for example, involved a petitioner who alleged that her minor child developed Guillain Barré syndrome ("GBS") after receiving a hepatitis A vaccine. 2014 WL 504278. The child was admitted to the hospital's neurological department five days after vaccination and, when concerns of GBS were raised, the minor underwent a lumbar puncture and received IVIG treatment. *Id*. at *1, 9. The special master (relying on medical dictionary definitions) interpreted the phrase to mean "the treatment of a disease, injury and deformity with instruments or by the hands of a surgeon to improve health or alter the course of a disease." *Id*. at *10. Using this definition, he determined that although a lumbar puncture conducted under general anesthesia was clearly surgical in nature, it did not constitute an "intervention," because it was diagnostic and not necessary for treatment. *Id*. at *12. Conversely, he determined that IVIG treatments were *not* surgical in nature. *Id*.

Subsequent cases more factually on point to the current matter have acknowledged *Spooner*'s holding, but have effectively applied a different interpretation of the disputed language, justifying the distinction due to the nature of the injury in question. *Ivanchuck*, for example, involved a minor who developed ITP after receiving several vaccinations, including MMR. The special master found that a bone marrow aspiration

and biopsy "to rule out myeloproliferative disease prior to starting oral steroids" constituted a surgical intervention. *Ivanchuck,* 2015 WL 6157016, at *1. As in *Spooner*, the *Ivanchuck* special master stressed that the procedure occurred in accordance with hospital policies for a surgical procedure and occurred under general anesthesia, but (unlike *Spooner*) was an intervention because it was performed as part of a protocol bearing on future possible treatments. *Id*. at *2-3.

A similar result, also involving bone marrow aspiration and biopsy in an ITP case, was reached in *Leming v. Sec'y of Health & Human Servs.*, No. 18-0232V, 2019 WL 5290838 (Fed. Cl. Spec. Mstr. July 12, 2019) – a case decided by the same special master that adjudicated the *Ivanchuck* matter. The *Leming* petitioners argued that their minor daughter developed ITP, immune dysfunction, and immunodeficiency after receiving three different vaccines. *Id*. As in *Ivanchuck*, the biopsy was conducted under general anesthesia, and the hospital followed surgical protocols involving consent and post-operative recovery, thus suggesting it was "procedural" in nature. *Id*. at *6. But the special master also noted that the procedure was conducted "to rule out bone marrow disorders for which steroid treatment would be contraindicated," and hence was also an "intervention." *Id*. The special master added that the medical record explicitly stated that the procedure was required to institute treatment rather than diagnose the minor's condition. *Id*.

Given the above, there is a slight divergence between the *Spooner* reading of the phrase (which requires the intervention ultimately to be more directly aimed at treating the underlying issue than in evaluating its nature) and *Ivanchuck/Leming* -- which, in a more factually-apposite context to the present, read "intervention" a bit more broadly, allowing procedures that are invasive but mainly aimed at making additional diagnostic determinations that may *later* impact treatment to be deemed to satisfy the severity requirement.

IV. Finding of Fact

I make the following finding regarding severity after a complete review of the record to include all medical records, affidavits, Respondent's Rule 4 report, Petitioner's response, and briefing by the parties. Specifically, I base the findings on the following evidence:

- M.F., a minor, received an MMR vaccination on June 23, 2016. She was fourteen months old at the time of vaccine administration. Ex. 1 at 1;

- On July 20, 2020, M.F. was brought to her pediatrician after her mother noticed bruising and "a few small red spots" on her child's body. M.F. was assessed with petechiae and was sent to the emergency room. Ex. 15 at 149-150;

- Labs taken on July 20, 2020 revealed that M.F. had a platelet count of two.[4] M.F. was assessed with a scalp contusion and severe ITP and was transferred to Memorial Hermann Texas Medical Center ("Memorial") for further evaluation and treatment. Ex. 9 at 33-34;

- M.F. underwent a hematology consultation on July 22, 2016. The medical note documenting this visit indicates that she received two doses of IVIG and that her platelet count had risen to seven. It was also noted that if there was no rise in M.F.'s platelet count, a bone marrow aspiration and biopsy would be the "next step in order to consider [her participation in a] steroid trial as long as bone marrow findings are consistent with ITP (increased megakaryocytes)." Ex. 10 at 9-13;

- M.F. was discharged home on July 23, 2016 with a platelet count of 23. Ex. 10 at 15;

- M.F. was brought to her pediatrician on July 25, 2016 for a follow-up visit. After noting that M.F.'s platelet count had again dropped to two, her pediatrician recommended M.F.'s return to Memorial's emergency department. Ex. 15 at 164;

- On July 25, 2016, M.F. was readmitted to the hospital for "bone marrow aspiration and biopsy to confirm the diagnosis." Ex. 10 at 216. After pre-surgery checklists were completed and M.F.'s mother signed surgical and anesthesia consent forms, M.F. underwent bone marrow aspiration and biopsy. The procedure was performed by Dr. Rodrick Zvavanjanja. *Id*. at 294-303, 312, 316-317;

- M.F. was transported to the post-anesthesia care unit ("PACU") following the bone marrow aspiration and biopsy. Ex. 10 at 313. A consult note indicates that the treating team's recommendations would be based upon the biopsy's results. *Id*. at 219;

- M.F. was discharged from the hospital on July 28, 2016 with a platelet count of 6. In addition to prescriptions for prednisone and Zantac, M.F.'s treatment plan included "weekly counts [and] weaning once platelets normalize-this could be weeks to months." Ex. 10 at 219-220, 226, 240-241;

- An August 12, 2016 chart note indicates that M.F.'s platelet count had risen to 10 and that she should "continue weekly labs." Ex. 2 at 71. By August 25, 2016, M.F.'s platelet count was reported to have risen to 31. Ex. 2 at 55;

[4] The number listed in the platelet count results is representative of the number of platelets in the thousands, *e.g.,* an account of three represents three thousand platelets. For children, the normal range is typically between 150-400, and for infants between 200-475. K. Pagana & T. Pagana, MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS (4th. ed. 2010) at 416.

- On September 1, 2016, M.F. had a platelet count of 131. M.F.'s mother was instructed to "cut the dose of [M.F.'s] prednisone in half . . . and repeat labs next Thursday 9/8/16." Ex. 2 at 41;

- On September 13, 2016, M.F.'s mother was informed that her daughter's platelet count had dropped to 31. The corresponding chart note indicates that M.F.'s pediatrician "wants [M.F.] to go back to twice a day on her medication and labs again this week." Ex. 2 at 39-40;

- The results of M.F.'s labs from September 19 and September 27, 2016 reveal that she had normal platelet counts of 213 and 176, respectively. M.F.'s parents were instructed to decrease their daughter's prednisone dosage. Ex. 2 at 33-35;

- On October 6, 2016, M.F.'s mother was informed that her daughter's platelet count dropped to 131. It was noted that this number "is a little down from last time . . . but is OK to go down again on the [p]rednisone." Ex. 2 at 28;

- Labs from October 26, 2016 showed that M.F. had a platelet count of 179, which was "completely within normal limits." M.F.'s mother was instructed to "begin to alternate [prednisone] every other day for a week, then stop." Ex. 2 at 19;

- On November 14, 2016, M.F.'s mother reported that her daughter had "basically been fully off the medication for a couple of days." Although a clinical staff note from this date indicates that M.F.'s physician believed it was "okay to 'take a break' from the lab," M.F.'s platelet count on November 21, 2016 was 218. Ex. 2 at 11-12;

- On February 10, 2017 (six months and 21 days after M.F. was first assessed with ITP), she had her final tests in the record, which showed a normal platelet count of 219. Ex. 2 at 6; and

- M.F. presented to a hematology clinic on August 10, 2017. The medical note documenting this appointment indicates that M.F. was "able to be weaned off steroids in the end of October and has been doing well since then." Ex. 12 at 7.

The above items of evidence establish that M.F. experienced hospitalization and surgical intervention within the meaning of Subsection 11(c)(1)(D)(iii) of the Vaccine Act. First, there is no question that M.F. underwent a surgical procedure in a literal sense. In order to perform the bone marrow aspiration and biopsy, M.F. was placed under general anesthesia and the procedure was performed by a physician. Ex. 10 at 212, 294, 317. A pre-surgery checklist was completed. *Id*. at 312. M.F.'s mother signed a consent for an operative procedure, which identified possible risks of heart failure, fever and infection. *Id*. at 296-303. Following the procedure, M.F. was transported to the PACU. *Id*. at 313.

Second, the circumstances of the present injury allow for the conclusion that M.F.'s bone marrow aspiration and biopsy constituted an "intervention." Admittedly, and as Respondent correctly observes, the aspiration biopsy was *somewhat* diagnostic – although not purely so, since (by the time a decision was made to perform it) M.F.'s platelet counts had already been determined to suggest ITP, and she had also manifested clinical indicia of the condition (bruising and petechiae). But the procedure also had a treatment orientation as well. The record clearly indicates that treaters believed a bone marrow aspiration might be necessary to guide further treatment (which had already featured IVIG infusions) if platelet counts declined again. Ex. 10 at 13.[5] Sure enough, they did decline – and the aspiration was deemed necessary to determine if the ITP was in fact symptomatic of a larger issue (in which case an alternative treatment involving steroids would be tried). Ex. 10 at 216-219. Thus, and consistent with *Ivanchuck* and *Leming,* the dual character of this invasive procedure supports a finding that it is a "surgical intervention" serious enough to satisfy the severity requirement.

In addition, other factors relevant to a claimed ITP Table injury after receipt of the MMR vaccine counsel in favor of my determination. First, I observe that bone marrow testing is recognized in the Vaccine Act's Qualifications and Aids to Interpretation (the "QAIs") as an evaluative tool for ITP. In defining this condition, it is noted in the QAIs that "[b]one marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow." 42 C.F.R § 100.3(b)(8). The inclusion of bone marrow examination in its definition of ITP reveals that this procedure is understood to be part of the reasonable standard of care (at least as of the time the Table claim was established), supporting the conclusion that for ITP (somewhat akin to intussusception), proof of an invasive procedure required as part of its treatment was envisioned to establish severity.

Second, I also note that (independent of whether a bone marrow aspiration and biopsy fits the Act's surgical intervention definition as construed in *Spooner*), Petitioners arguably can satisfy the *temporal* severity requirement under the facts of this case. Prior cases in the Program have found ongoing monitoring, or need for medication, to constitute a residual effect. In *Wright v. Sec'y of Health & Human Servs.,* 146 Fed. Cl. 608 (2019), a case with similar facts to the one at bar, it was found (in a Table ITP case) that subsequent platelet testing of a minor child was a "residual effect" of a vaccine injury. The court reasoned that "testing for a condition that could return ought to be compensated under the Vaccine Act when the testing is causally connected to the underlying vaccine-injury and triggered by subsequent symptoms of the conditions. The fact that those tests did not reveal the presence of ITP is not controlling." *Wright,* 146 Fed. Cl. at 614.

[5] It is common when dealing with ITP for treaters to employ bone marrow biopsies to confirm the scope and extent of the condition, since that impacts treatment choices. *See, e.g.*, S. Gerald Sandler, M.D., *Immune Thrombocytopenic Purpura, at* http://www.emedicine.com/med/topic1151.htm (last updated Jan. 11, 2020) ("[b]ecause corticosteroid administration may change marrow morphology, performance of a bone marrow aspiration and biopsy should be considered to confirm the diagnosis of ITP if the clinical presentation, patient age, or other findings are atypical for acute ITP before the patient is treated with corticosteroids.").

Respondent has acknowledged that Petitioners could satisfy the six-month severity requirement by demonstrating that "M.F. suffered the residual effects or complications of her ITP through at least December 23, 2016 (i.e., more than six months after the vaccine administration date of June 23, 2016)." Response at 7. Here, the medical record establishes this. Testing performed throughout this timeframe reveal several instances in which M.F.'s platelet count reached normal limits before dropping: Between September 1 and September 13, 2016, M.F.'s platelet count dropped from 131 to 31. Ex. 2 at 39-41. Then, between September 19 and September 27, 2016, M.F.'s platelet account dropped from 213 to 176. *Id*. at 33-35. Finally, on October 6, 2016, M.F.'s platelet count dropped to 131. *Id*. at 28. Two of these fluctuations caused M.F.'s physician to recommend an increase in her prednisone dosage. *Id*. at 33-35, 39-40. Testing subsequently continued into February 2017 – and although further fluctuations were not observed, M.F.'s pattern of platelet count drops had been inconsistent enough to be deemed to warrant observation. This fact pattern is thus consistent with what the *Wright* court deemed sufficient in an ITP case to establish severity.

V. Scheduling Order

Given the above finding of fact – specifically that Petitioners have succeeded in producing preponderant evidence to satisfy the Vaccine Act's severity requirement – Respondent's Motion to Dismiss is DENIED. Respondent shall instead evaluate and provide his current position regarding the merits of Petitioners' case.

Pursuant to my October 2, 2020 Docket Entry Order, Respondent shall file, by no later than **Friday, October 30, 2020**, a status report indicating whether he intends to defend this matter in any regard other than severity. Also by **Friday, October 30, 2020**, Petitioners shall file a status report indicating whether they have provided their demand to Respondent.

IT IS SO ORDERED.

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