

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-232V

UNPUBLISHED

VICTORIA LEMING and KEVIN
LEMING, Parents and Natural
Guardians of A.L., a Minor,

Petitioners,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: January 26, 2022

Special Processing Unit (SPU);
Decision on Remand; Diphtheria-
tetanus-acellular pertussis (DTaP)
Vaccine; Measles-mumps-rubella-
varicella (MMRV) Vaccine;
Haemophilus influenzae type b (Hib)
vaccine; Thrombocytopenic Purpura
(ITP); Severity Requirement

*Robert Joel Krakow, Law Office of Robert J. Krakow, P.C. New York, NY, for
Petitioners.*

Julia Marter Collison, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION ON REMAND¹

On February 14, 2018, Victoria and Kevin Leming, on behalf of minor A.L., filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq. (the “Vaccine Program”).² Petitioners alleged that the measles-mumps-rubella-varicella (“MMRV”), diphtheria-tetanus-acellular pertussis (“DTaP”), and/or Haemophilus influenzae type b (“Hib”) vaccines that A.L. received on September

¹ Because this Decision 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 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 The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter “Vaccine Act” or “the Act”). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

6, 2016, caused her to suffer from immune thrombocytopenic purpura (“ITP”), immune dysfunction, and immunodeficiency. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the “SPU”).

Special Master Dorsey (who was Chief Special Master at the time this matter was initially pending, and hence formerly responsible for SPU cases) previously determined that the claim met the exception to the Vaccine Act’s “severity” requirement, because A.L. underwent a “surgical intervention” as part of her ITP diagnosis, but that finding was reversed after Respondent’s Motion for Review. *Leming v. Sec’y of Health & Hum. Servs.*, 154 Fed. Cl. 325 (2021), Op. and Order, ECF No. 81 (hereinafter “Remand Order”). Now on remand, and in adherence to the Court’s reversal, I find that because this claim fails to meet the general severity requirement set forth in Section 11(c)(1)(D) of the Vaccine Act, it must be dismissed.

I. PROCEDURAL HISTORY

Because Petitioners alleged a Table claim (ITP after receipt of the MMRV), the matter was initially assigned to the SPU. On December 21, 2018, Respondent filed his Rule 4(c) Report, arguing (among other things) that Petitioners had not preponderantly established that A.L. had suffered “the residual effects or complications’ of a vaccine-related injury for more than six months after the administration of the vaccine,” and also that the injury had not “resulted in inpatient hospitalization and surgical intervention.” ECF 34 at 5 (citing § 11(c)(1)(D)(i), (iii)). Thereafter, the parties filed concurrent motions for a fact ruling on March 26, 2019. ECF Nos. 38-39.

On July 12, 2019, Special Master Dorsey issued a Ruling on Facts. *Leming v. Sec’y of Health & Hum. Servs.*, No. 18-0232V, 2019 WL 5290838 (Fed. Cl. Spec. Mstr. July 12, 2019), Ruling on Facts, ECF No. 41 (hereinafter “Severity Fact Finding”), *mot. for review granted*, 154 Fed. Cl. 325 (2021). Although she agreed with Respondent that the Petitioners had failed to establish six months of symptoms/sequelae severity (*Id.* at *3-5), she found they *had* established that “A.L.’s bone marrow aspiration and biopsy constituted a surgical intervention” (*Id.* at *6). Therefore, they met the Act’s exception to the requirement that claimants establish six months of injury-related symptoms or sequela, allowing the claim to proceed. *Id.* at *7.

Respondent next filed an Amended Rule 4(c) Report in November 2020, indicating that while he preserved his right to appeal the Severity Fact Finding, he agreed that Petitioners had “otherwise satisfied the legal prerequisites for compensation under the Vaccine Act.” ECF No. 65 at 2 (citing §§ 11(c)(1)(D) and 13(a)(1)). I therefore issued a

Ruling³ finding Petitioners entitled to compensation on November 4, 2020 (ECF No. 66), followed by a February 2021 Decision Awarding Damages (ECF No. 74), in accordance with Respondent's Proffer (ECF No. 73).

On March 18, 2021, Respondent filed a Motion for Review of the Severity Fact Finding, arguing that the bone marrow aspiration and biopsy performed to evaluate the propriety of A.L.'s ITP diagnosis (and to guide proper treatment thereafter) was not a surgical "intervention" under the Vaccine Act. ECF No. 75. The Court of Federal Claims agreed with Respondent, granting his Motion for Review and remanding the matter for further proceedings consistent with the determination. Remand Order, 154 Fed. Cl. at 327, 335.

I subsequently issued an Order to Show Cause giving Petitioners a final opportunity to demonstrate why their claim should not be dismissed for failure to establish the severity requirement. ECF No. 84. On August 30, 2021, Petitioners filed their brief in response, arguing that their claim should not be dismissed because new facts existed demonstrating that A.L. suffered residual effects or complications following her ITP for more than six months. ECF No. 88 at 1-3. Petitioners further challenged the Remand Order's surgical intervention finding (*Id.* at 3-4) - although unquestionably I am bound herein to apply that determination in addressing remand.

Respondent filed a Reply to Petitioners' Response on September 3, 2021, asserting that the Petition should be dismissed as a result of the Remand Order. ECF No. 89. Respondent maintains that the Petitioners have not offered any new evidence (but rather "speculation and conjecture") that A.L. suffered the residual effects of her injury for more than six months. *Id.* at 2-3. In reaction, Petitioners filed a Supplemental Response to my Order to Show Cause on September 5, 2021. ECF No. 90. Petitioners argued therein that they have submitted new and objective evidence which must be considered in determining whether dismissal is warranted. *Id.* at 1-2 (citing § 13(b)(1)⁴; *Cornelius-James v. Sec'y of Health & Hum. Servs.*, 984 F.3d 1374, 1380-81 (Fed. Cir. 2021) ("for many medical symptoms or events—such as a headache and other pain, dizziness,

³ In early October 2019, SPU cases were reassigned to me after my appointment as Chief Special Master.

⁴ The Vaccine Act reads:

In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of judgment of the special master or court.

Section 13(b)(1).

nausea, and vomiting—the patient's or a parent's testimony may be the best, or only, direct evidence of their occurrence”)).

I deferred acting on the Remand Order until the Federal Circuit Court of Appeals issued its recent ruling in *Wright v. Sec'y of Health & Hum. Servs.*, --- F.4th ----, 2022 WL 38987 (Fed. Cir. 2022), since (as Petitioners correctly observed) that matter (which touched more generally on severity in ITP cases) would “likely have some bearing on the determination of the issues in the present case.” ECF No. 88 at 2 n.1. This matter is now ripe for adjudication on remand.⁵

II. FACTUAL HISTORY

After a complete review of the record in this case, I find that factual history contained in section II of Special Master Dorsey's Severity Fact Finding (2019 WL 5290838, at *2) represents an accurate summary of the relevant facts in this matter. I hereby adopt, and incorporate herein, that aspect of her ruling (which was not contested or disturbed on review) in its entirety.

III. LEGAL STANDARD

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). “Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.” *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

⁵ My Show Cause Order (issued to provide Petitioners a full and fair opportunity to present their case), an extension of time requested by Petitioners to respond, and finally deferring the instant ruling until the issuance of the Federal Circuit's decision in *Wright* have collectively resulted in this matter being resolved in excess of the Vaccine Rules 90-day timeframe for special masters to act on remand from the Court. Vaccine Rule 28(b). However, the Court has noted that there is no literal sanction for acting outside the defined period. See *Paluck v. Sec'y of Health & Hum. Servs.*, 111 Fed. Cl. 160, 165–66 (2013); see also *Greene v. Sec'y of Health & Hum. Servs.*, No. 11-631V, Order at 3, ECF No. 119. The need to “bend” this rule was especially high here, since the extra time was required in order to allow the claimants the chance to fully make any arguments needed to defend their preferred outcome, and to ensure that I had the benefit of the Federal Circuit's binding precedent on this issue.

Accordingly, where medical records are clear, consistent, and complete, 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). However, this rule does not always apply. “Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” *Murphy v. Sec’y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991) (quoting with approval the standard used by the special master below), *aff’d per curiam*, 968 F.2d 1226 (Fed.Cir.1992). And the Federal Circuit recently “reject[ed] as incorrect the presumption that medical records are [presumed] accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined 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 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery v. Sec’y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

IV. ANALYSIS

In order to state a claim under the Vaccine Act, a petitioner must establish the “severity” requirement demonstrating that the vaccinee has 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).

As stated by Congress when amending the Vaccine Act in 1987, the six-month severity requirement was designed “to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine.” H.R. REP. 100-391(I), at 699 (1987), *as reprinted in* 1987 U.S.C.C.A.N. 2313–1, 2313–373. The only exception to proving a temporal post-vaccination condition is the alternative added in 2000: a showing that the vaccine injury required inpatient hospitalization *and* surgical intervention. Children’s Health Act of 2000, Pub. L. No. 106–310, § 1701, 114 Stat. 1101 (2000) (codified as amended at § 11(c)(1)(D)(iii) (emphasis added)). This exception was generated initially to allow compensation in intussusception cases which often required surgical intervention but then resolved in less than six months. 145 Cong. Rec. S15213–03 (Nov. 19, 1999); *Spooner v. Sec’y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *6-7 (Fed. Cl. Jan. 16, 2014) (detailing full history of this exception). It has since been applied to other injuries, like ITP (see, e.g., *Ivanchuk v. Sec’y of Health & Hum. Servs.*, No. 15-357V, 2015 WL 6157016, at *3 (Fed. Cl. Spec. Mstr. Sept. 18, 2015) (finding that bone marrow biopsy constitutes a surgical intervention)), although the Court’s holding herein calls into question whether those determinations were legally correct.

In regard to the six-month severity requirement, the Federal Circuit recently explained that the concept of “residual effects,” read in the context of Section 11(c)(1)(D)(i) of the Vaccine Act, “is focused on effects within the patient, particularly lingering signs and symptoms of the original vaccine injury.” *Wright*, 2022 WL 38987, at *6. Put another way “[a] residual effect must be a change within the patient that is *caused* by the vaccine injury.” *Wright*, 2022 WL 38987, at *1 (emphasis added).

The facts of *Wright* in certain respects run parallel to this matter. *Wright* also involved a minor child who suffered ITP following vaccination, and whose blood tests indicated that the ITP had resolved in less than six months, notwithstanding subsequent bruising. *Wright*, 2022 WL 38987, at *3 The Circuit deemed the child’s bruising not to have likely been caused by the ITP, since “the later tests ‘did not reveal the presence of ITP.’” *Wright*, 2022 WL 38987, at *5 (citing *Wright*, 146 Fed. Cl. 608, 614 (2019)). The Circuit further found that any subsequent non-invasive platelet count testing was not a “residual effect” within the meaning of the Vaccine Act as there was “no showing or argument that it was detrimental to [the minor’s] health such that it might qualify under § 300aa-11(c)(1)(D)(i) as a ‘residual effect’ or a ‘complication’ of thrombocytopenic purpura.” *Wright*, 2022 WL 38987, at *6.

A. A.L. Did not Experience A Surgical Intervention

Respondent's motion for review in this case raised the question of whether the surgical intervention severity exception had been met, based on the bone marrow aspiration A.L. underwent. The Court agreed that the bone marrow aspiration was a "surgical procedure" in a general sense, given its invasive quality and other factors. Remand Order, 154 Fed. Cl. 325, 332-33. But it did not constitute a "surgical intervention" under the *Vaccine Act*, because it was not "administered to directly treat" A.L.'s ITP. *Id.* at 333. Rather, it was performed for diagnostic purposes (to help treaters rule out the possibility that the ITP reflected a more concerning underlying bone marrow disorder), distinguishing it from procedures that were truly aimed at specifically ameliorating the illness or condition at issue. *Id.* at 333-35.

The Court therefore set aside the finding that the Act's severity requirement was met as inconsistent with the Vaccine Act. Remand Order, 154 Fed. Cl. at 335. As acknowledged by Petitioners, "Special Masters are bound by decisions of the Court of Federal Claims on remand in the same case." ECF No. 88 at 3 (citations omitted). Severity thus cannot be established in this case on the basis of a finding that the bone marrow aspiration and biopsy A.L. experienced was a "surgical intervention."

B. A.L. Has Not Established Six-Months of Severity

The Severity Fact Finding previously determined "that [P]etitioners have not established by preponderant evidence that A.L. suffered residual effects of her ITP for six months after her vaccination." Severity Fact Finding, 2019 WL 5290838, at *3-5. Petitioners have attempted to re-argue this point based on purportedly new evidence, but I do not find they have met their preponderant burden. Some discussion of that determination is required in order to explain why Petitioners' renewed showing is insufficient.

The record in this case establishes that a little more than three weeks after her September 6, 2016 vaccinations, A.L. was taken to the emergency room with a rash, bleeding gums, and black spots on her tongue. Ex. 8 at 209. On examination she was found to have a low platelet count, scattered bruising, and a generalized petechial rash. Ex. 8 at 211, 215.⁶ A.L. was subsequently diagnosed with acute ITP and received IVIG. Ex. 8 at 224. She was thereafter transferred to Children's Hospital in Omaha on September 30, 2016, and the aforementioned bone marrow biopsy and aspiration was

⁶ On September 16, 2016, Mrs. Leming had reported to A.L.'s pediatrician that A.L. suffered a fever and a rash beginning September 13, 2016 and was advised that it was likely roseola and would resolve on its own. Ex. 13 at 3.

conducted on October 4, 2018, to rule out cancer and other blood disorders. Ex. 4 at 21, 80-81, 111, 117.

A.L. was treated with IV steroids, and her platelet counts improved. Ex. 4 at 4. She was then discharged from the hospital on October 12, 2016. *Id.* at 3-5. On November 21, 2016 (less than three months post-vaccination), A.L. was seen by an outpatient treating hematologist at Texas Children's Hospital who found that her platelet count had normalized and she was otherwise asymptomatic. Ex. 9 at 51. A.L. was seen again by hematology on December 30, 2016. Ex. 9 at 61. A.L. remained asymptomatic with a normalized platelet count. *Id.* at 66. The treating hematologist noted that "patient[']s ITP] has likely resolved at this time, and is unlikely to recur." Ex. 9 at 66. The treater added that A.L.'s ITP would be monitored as needed and would be seen again in three months in combination with an immunology visit. *Id.* at 67. Thereafter (as the Severity Fact Finding observes), A.L. remained free of both obvious clinical symptoms, like bleeding, and had normal platelet counts when measured in June 2017. Severity Fact Finding, 2019 WL 5290838, at *2 (citations omitted).

Based on the above, Respondent argued that A.L.'s symptoms had resolved as of November 21, 2016.⁷ The Severity Fact Finding, however, recognized that "[a]lthough A.L. may have been symptom-free within three months of her September 6, 2006 vaccinations" it was necessary to examine the record with more care to determine whether any "residual effect or complication" of A.L.'s injury had persisted for six months or more. Severity Fact Finding at *3 (citing *Faup v. Sec'y of Health & Hum. Servs.*, 12-87V, 2015 WL 443802, *4 (Fed. Cl. Spec. Mstr., January 13, 2015) ("residual effects or complications" and 'symptomatic' are not synonymous" and the "ongoing need for medication" can constitute a residual effect of an injury).

The Severity Fact Finding engaged in such an inquiry – but did not find evidence that A.L.'s treatment after December 2016 reflected or established that her ITP had continued or manifested again. In particular, it focused on several nonspecific conditions that Petitioners argued were symptomatic of the ITP, even if they did not directly reflect it (in the form of either direct clinical manifestations or blood work evidence of lowered platelet counts). It thus rejected Petitioners' arguments that A.L.'s weight gain, bruising in June 2017, or purported immune dysfunction reflected ongoing sequelae. Severity Fact Finding at *4-5.

⁷ Respondent actually asserted in his Motion for a Fact Ruling that the date A.L.'s ITP resolved was November 12, 2016 (corresponding with A.L.'s hematology appointment). ECF No. 38 (Motion for Fact Ruling on Severity) at 3-4. However, this date appears to be a typographical error as A.L.'s hematology appointment was on November 21, 2016. Ex. 9 at 45-51.

I hereby adopt and incorporate Section IV(a) (Six Month Sequela) of the Severity Fact Finding (*Id.* at *3-5), as it remains undisturbed by the Remand Order and I concur with the reasoning behind it. Petitioners did not challenge this finding before the Court of Federal Claims,⁸ and the Court did not find any error in this specific finding either. However, in response to my Order to Show Cause, Petitioners now assert that the record in this case - supplemented with some additional items of evidence that Petitioners assert is “new,” and hence not considered previously - establishes severity. Having considered this contention and the evidence offered in its support, I do not find any grounds for reaching a severity conclusion contrary to the earlier one from the Severity Fact Finding.

First, Petitioners argue that Dr. Forbes, A.L.’s pediatric immunologist, now believes that A.L.’s “ITP and related immunodeficiency has *continued through the age of six*, requiring further testing,” and to that end A.L. had a pending appointment with Dr. Forbes at Texas Children’s Hospital on October 22, 2021 which “promises to yield further information confirming these facts.” ECF No. 88 at 3 (emphasis added).⁹ In support, Petitioners have offered a supplemental affidavit recounting Ms. Leming’s telephone conversations with Dr. Forbes in April and June 2017. See Ex. 23.¹⁰

But the medical record evidence is utterly contrary to this contention. A.L. has never been diagnosed with the chronic form of ITP that would be expected to persist. *Johnson v. Sec’y of Health & Hum. Servs.*, No. 14-113V, 2017 WL 772534 (Fed. Cl. Jan. 6, 2017) (discussing the differences between acute and chronic ITP). In addition, the Severity Fact Finding expressly considered, but rejected, similar contentions, and the determinations Special Master Dorsey reached on this point have ample record support. Severity Fact Finding, at *4-5. In particular, Dr. Forbes’s contemporaneous treatment records demonstrate that after reviewing the bloodwork ordered on June 29, 2017, she

⁸ Petitioners also did not seek review of this finding following the issuance of my February 23, 2021 Decision (issued before the Court’s Remand Order), nor did they file any Cross-Motion for Review in response to Respondent’s Motion challenging the prior surgical intervention determination. Respondent thus now argues (albeit in passing) that Petitioners’ new arguments regarding severity are untimely. ECF No. 89 at 2. However, this matter has never been reduced to a judgment (such that I could find arguments challenging aspects of the fact finding that were not previously directed to the Court on review have been waived), and it was *Respondent* who appealed surgical intervention. I therefore consider these points despite such waiver contentions

⁹ Petitioners assert that they had to move away from the Houston area, where Texas Children’s Hospital is located, but recently relocated back to Houston area, immediately scheduling an appointment with Dr. Forbes upon their return. I note, however, that it appears that Petitioners resided in Sulphur, Louisiana when A.L. treated with Dr. Forbes in 2017 (and hence were already in the practice of traveling to Texas for this treatment). Ex. 10 at 2. It is otherwise not clear why Petitioners could not locate another pediatric immunologist following their move.

¹⁰ These conversations were also detailed by Mrs. Leming in her Declaration filed on October 19, 2018. Ex. 15.

had *no concerns* that A.L.'s ITP and/or any related immunodeficiency persisted, and recommended only follow-up as needed.¹¹ No subsequent records establish platelet count drops after 2016. Finally, it has now been several months since A.L.'s purported appointment with Dr. Forbes, and no updated medical records or other evidence has been filed that alter this analysis.

Second, Petitioners argue that A.L. continues to bruise easily, as averred to by Mrs. Leming in her newly filed affidavit, thus suggesting her ITP is unresolved. ECF No. 88 at 2; ECF 90 at 2; Ex. 23 at ¶9. However, this argument was also addressed in the Severity Fact Finding, 2019 WL 5290838, at *5. As discussed, therein, Petitioners reported to Dr. Forbes at A.L.'s June 29, 2017 appointment their observation that A.L. bruised more easily than other children, and Dr. Forbes on exam noted bruises on A.L.'s left cheek and right ear pinna. Ex. 10 at 1, 4. But the Severity Fact Finding found that Dr. Forbes "did not attribute any June 29, 2017 bruising to A.L.'s previous ITP diagnosis." *Id.* at *5. And no other proof (such as evidence of platelet drops or bleeding) has been offered to corroborate Petitioners "new" contention that A.L.'s current propensity to bruise easily is caused by her ITP or is evidence that her ITP persists.

Additionally, as discussed above, there is no evidence that A.L. suffers chronic ITP, and Petitioners have filed no updated medical records from Dr. Forbes despite the fact that several months have passed since A.L.'s scheduled appointment with Dr. Forbes on October 22, 2021. Bruising *per se* is simply too nonspecific, even in the context of ITP, to amount to evidence of ongoing sequelae, in the absence of proof of accompanying platelet count drops. *Wright*, 2022 WL 38987, at *5 (concluding "the bruising itself cannot

¹¹ In sum, the progress notes of Dr. Lisa R. Forbes, A.L.'s pediatric immunologist, from her June 29, 2017 visit with A.L. details A.L.'s "recent history of ITP and mildly elevated transitional B cells on B cell subset typing" finding "A.L.'s [i]mmune work-up otherwise reassuring." Ex. 10 at 9 (internal medical coding omitted) (while the visit occurred on June 29, 2017, the progress notes corresponding to the visit from Dr. Forbes are dated July 5, 2017). Accordingly, Dr. Forbes stated her plan to

recheck B cell subsets today. - If trending toward normal the mild elevation is likely due to the immature immune system at her age and new B cell differentiation following the ITP episode *now resolved*. - *If* the level continues to increase there will be concern for immune dysfunction with potential for recurrence of autoimmune disease. We discussed this plan at length with mom and dad. They understood and will await the results and next steps for follow up.

Ex. 10 at 9 (emphasis added) (internal medical coding omitted). The June 29, 2017 record provides a "disposition" that Petitioners should "[f]ollow-up [as needed] as lab results are reassuring for *normal* B cell differentiation." *Id.* (emphasis added) (internal medical coding omitted). Dr. Forbes records from June 29, 2017 further document that she found that "all of [A.L.'s] labs were good" and advised Petitioners "we can cancel her appointment for September [2017]." Ex. 12 at 2.

be a ‘residual effect’” when the petitioner has not demonstrated or argued that the minor’s bruising after six months was caused by their ITP, and later tests did not demonstrate ITP).

Finally, I do not find Petitioners’ assertion that Dr. Forbes recommended that A.L. receive no further vaccines until age six (and then only after further testing), due to an increased risk of an adverse event, to constitute evidence that A.L.’s ITP and/or any related immunodeficiency persisted for more than six months. ECF No. 88 at 2; ECF 90 at 2; Ex. 23 at ¶¶7, 9. As a threshold matter, this does not constitute “new” evidence, since Ms. Leming asserts Dr. Forbes provided this guidance to her in *June 2017*. Ex. 23 at ¶7. But more importantly, the mere risk of a future associated problem that could be triggered a second time by vaccination cannot satisfy severity. *Parsley v. Sec’y of Health & Hum. Servs.*, 08-781V, 2011 WL 2463539, *5 (Fed. Cl. Spec. Mstr., May 27, 2011) (“an increased risk of a recurrence without an actual recurrence of a condition is not medically recognized as a ‘residual effect’ and is not a residual effect within the meaning of § 300aa-11(c)(1)(D)(i) of the Vaccine Act”). *But see Faup*, 2015 WL 443802, *4 (“‘residual effects or complications’ and ‘symptomatic’ are not synonymous” and the “ongoing need for medication” can constitute a residual effect of an injury).

I have fully considered Mrs. Leming’s affidavit and her observations discussed therein, but Petitioners’ arguments in response to my Order to Show Cause do not constitute “new evidence” sufficient to make a new determination on severity. Accordingly, I decline to revisit the prior fact finding that Petitioners have failed to establish that A.L. suffered the residual effects of her injury for more than six months.

Conclusion

For the reasons explained above, I find that Petitioners have failed to establish that A.L.’s alleged injury meets the severity requirement described in Section 11(c)(1)(D) of the Vaccine Act, and they have provided no persuasive or preponderant basis for a determination different from the Severity Fact Finding. Accordingly, this claim must be dismissed.

The Clerk of the Court is directed to enter judgment in accordance with this decision.¹²

IT IS SO ORDERED.

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

¹² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.