In the United States Court of Federal Claims

VICTORIA LEMING and KEVIN LEMING, Parents and Natural Guardians of A.L., A Minor,	)	
Petitioners,	)	No. 18-232V (Filed Under Seal: August 12, 2022; Reissued for Publication: August 29, 2022)[*]
v.	)	
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

Robert J. Krakow, Law Office of Robert J. Krakow, P.C., New York, NY, for Petitioner.

Julia M. Collison, Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC, with whom were Alexis B. Babcock, Assistant Director, Heather L. Pearlman, Deputy Director, C. Salvatore D'Alessio, Acting Director, and Brian M. Boynton, Principal Deputy Assistant Attorney General, for Respondent.

OPINION AND ORDER

KAPLAN, Chief Judge.

This case, brought under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act" or "the Act"), is before the Court for the second time. The first time the Court heard the case was on a motion for review filed by respondent, the Secretary of Health and Human Services ("the Secretary"). See Leming v. Sec'y of Health & Hum. Servs., 154 Fed. Cl. 325 (2021) ("Leming I"). He sought review of the decision of then-Chief Special Master Nora Beth Dorsey that Petitioners' daughter, A.L., who experienced immune thrombocytopenic purpura ("ITP") within a few weeks of receiving the measles-mumps-rubella-varicella ("MMRV") vaccine, was eligible for compensation under the Act. Specifically, he argued that the then-Chief Special Master erred when she found that A.L.'s vaccine-related injury "resulted in inpatient hospitalization and surgical intervention" and so met the severity requirement set forth in 42 U.S.C. § 300aa-11(c)(1)(D)(iii). Id. at 329–30.

[*] Pursuant to Vaccine Rule 18(b), this opinion was initially filed on August 12, 2022, and the parties were afforded fourteen days to propose redactions. The parties did not propose any redactions and, accordingly, this Opinion is reissued in its original form for publication.

This Court granted the Secretary's motion for review and reversed the then-Chief Special Master's decision. It held that the bone marrow aspiration that A.L. had undergone before beginning a regimen of steroid treatment for her ITP was not a "surgical intervention" within the meaning of 42 U.S.C. § 300aa-11(c)(1)(D)(iii). Id. at 335.

The Court remanded the case to the Office of Special Masters. On remand, Petitioners resurrected an alternative argument that then-Chief Special Master Dorsey had rejected. They contended that A.L. suffered the residual effects of her ITP more than six months post vaccination and so satisfied the alternative severity criterion prescribed by 42 U.S.C. § 300aa-11(c)(1)(D)(i). Chief Special Master Corcoran, to whom the case had since been reassigned, ruled against Petitioners. They then filed a motion for reconsideration, which he denied.

Petitioners have now requested review of the Chief Special Master's decision on remand and his denial of their motion for reconsideration. They argue that he ignored or improperly rejected evidence in the record showing that "Giant platelets" were present in A.L.'s blood more than six months after she received the MMRV vaccine. According to Petitioners, these platelets, which they allege caused her to bruise easily, were a residual effect of the episode of ITP she suffered after her vaccination.

Alternatively, Petitioners argue that the Chief Special Master erred when he rejected their contention that one of A.L.'s treating physicians directed that she not receive any additional childhood vaccinations until the age of six, in light of her episode of ITP. This restriction, they allege, constituted another residual effect of her vaccine injury that lasted more than six months post vaccination as prescribed by 42 U.S.C. § 300aa-11(c)(1)(D)(i).

For the reasons set forth below, the Court concludes that the Chief Special Master's decision on remand and his decision denying reconsideration are neither arbitrary and capricious, an abuse of discretion, nor contrary to law. Petitioners' Motion for Review, ECF No. 102, must therefore be **DENIED**.

BACKGROUND

I. A.L.'s September 2016 Vaccination, Development of ITP, and Subsequent Successful Treatment

On September 6, 2016, during a scheduled well-child visit, fifteen-month-old A.L. received the MMRV vaccine, the diphtheria-tetanus-acellular pertussis vaccine, and the Haemophilus influenzae type b vaccine. Pet'rs' Ex. 1 at 37–39, ECF No. 5-1. Within the next week, A.L. developed a rash and fever. Pet'rs' Ex. 13 at 3, ECF No. 24-1.

A.L.'s mother reported the rash to the pediatrician on September 16, 2016. Id. By this time, A.L. no longer had a fever, and she was sleeping and eating normally. Id. The pediatrician told A.L.'s mother that the rash was likely roseola and that no treatment was needed. Id.; see also Pet'rs' Ex. 8 at 214, ECF No. 5-8.

By September 29, 2016, however, A.L. had developed a petechial[1] rash on her body and tongue, and was experiencing bleeding gums, prompting her parents to take her to the emergency room. Pet'rs' Ex. 8 at 214–15. A blood test was administered, and it revealed a platelet count of 3,000/mm^3. Id. at 211, 215. As a result, A.L. was diagnosed with ITP, id. at 215, "a disorder that can lead to easy or excessive bruising and bleeding . . . result[ing] from unusually low levels of platelets," Immune thrombocytopenia (ITP), Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/idiopathic-thrombocytopenicpurpura/symptoms-causes/syc-20352325; see also 42 C.F.R. § 100.3(c)(7) (stating that thrombocytopenic purpura "is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm^3").

A.L. was treated with one dose of intravenous ("IV") immunoglobulin. Pet'rs' Ex. 8 at 215. Nonetheless, she continued to exhibit bruising and petechia, and her platelet count in fact decreased. Pet'rs' Ex. 4 at 16, 19 (noting that A.L.'s platelet count was 1,000/mm^3 on September 30), ECF No. 5-4. The next day, she was transferred to Children's Hospital in Omaha, Pet'rs' Ex. 8 at 215, where she received a second dose of IV immunoglobulin but still showed no improvement, Pet'rs' Ex. 4 at 16, 19.

As described in greater detail in the Court's Opinion and Order on the first Motion for Review, see Leming I, 154 Fed. Cl. at 327–29, A.L. began receiving IV steroid treatments for her ITP on October 4, 2016, Pet'rs' Ex. 4 at 52, 153. This time, the treatment was successful. A.L.'s platelet count improved, id. at 4, and she was discharged from the hospital on October 12, 2016, id. at 3–5; see also id. at 4 (noting that A.L.'s platelet count at discharge was 19,000/mm^3 and that she "had no active bleeding and all petechiae and bruising were resolving"); Pet'rs' Ex. 9 at 11, ECF No. 5-9.

At A.L.'s first outpatient follow-up appointment on October 14, 2016, Dr. Amanda Grimes, a hematologist, noted that A.L.'s mother had reported "no significant further bruising," and that A.L.'s petechiae and oral purpura had resolved. Pet'rs' Ex. 9 at 11; see also id. at 13 ("Purpura . . . and rash noted. No petechiae noted."). A.L.'s platelet count was now 25,000/mm^3, a "minimal[] improve[ment]" over the level present two days earlier when she was discharged from the hospital. Id. at 14–15. She was reported to have "no further symptoms/active bleeding." Id. at 15.

Two weeks later, on October 28, 2016, A.L. underwent another round of blood tests which revealed that her platelet count had continued to improve. Id. at 33–34. Dr. Grimes directed that A.L. be weaned from steroid therapy "rapidly" over the following ten days, id. at 34, and the therapy ended by November 7, 2016, "with no symptom recurrence," id. at 46.

Three weeks later, on November 21, 2016, Dr. Grimes saw A.L. again. Id. at 45–53. Dr. Grimes reported that A.L. was "asymptomatic" and that her platelet count had "normalized" at

[1] Petechiae are small pinpoint skin rashes that can arise due to insufficient platelets. See Dorland's Illustrated Medical Dictionary 1401 (33d ed. 2020) (explaining that petechiae are "purplish red spot[s] caused by intradermal or submucous hemorrhage").

160,000/mm^3. See id. at 51. She noted that A.L.'s mother still believed that A.L. bruised and bled more easily than other children, id. at 45, but also observed that A.L. was "SIGNIFICANTLY improved," id. at 46; see also id. at 48 ("No petechiae and no rash noted. Purpura: few scattered evolving ecchymoses – but overall improved."). Dr. Grimes also recorded that A.L.'s mother was "still . . . concern[ed]" about "immune dysfunction, and hesitant to consider further immunizations for [A.L.]." Id. at 51 (noting that A.L. would be "refer[red] for Immunology evaluation").

Five weeks later, on December 30, 2016, A.L. had another follow-up examination, this time with a different hematologist, Dr. Michelle Ting. See id. at 60–69. Dr. Ting reported that A.L. "ha[d] been doing very well," and that she "continue[d] to remain free of bleeding symptomatology," with "[n]o easy bruising or petechiae." Id. at 61 ("Bruises/bleeds easily (now resolved)."); id. at 63 ("Purpura: few scattered evolving ecchymoses, but only on shins."). Dr. Ting also noted that A.L. was no longer receiving treatment and had a normal platelet count. Id. at 61–63, 66–67. She concluded that A.L.'s ITP "has likely resolved at this time, and is unlikely to recur." Id. at 66.

II. Follow-Up Exams in April and June 2017

On April 13, 2017, more than seven months after her MMRV vaccine, A.L. saw Dr. Grimes for a follow-up appointment, including blood tests. See Pet'rs' Ex. 9 at 94–97, 100–01. Dr. Grimes reported that A.L. was "asymptomatic . . . with normalized platelet count . . . and normalized platelet size/variance." Id. at 100. She concluded that A.L.'s "ITP [was] resolved," stated that she had "counseled [A.L.'s] family regarding possibility of [ITP] recurrence (<5%)," and opined that there was "no need for routine follow-up/surveillance (unless indicated by the development of signs/symptoms of bleeding)." Id. She again noted, as she had in her November 2016 report, that A.L.'s mother was "concern[ed]" about "immune disfunction, and hesitant to consider further immunizations for [A.L.]." Id.; see also id. at 51.

On the same day that she saw Dr. Grimes, A.L. was also seen by Dr. Lisa Forbes, a pediatric immunologist. Id. at 78–81. Dr. Forbes noted that A.L. had been referred for "consultation for ITP and concern for immunodeficiency," and that A.L.'s mother was "concerned that [A.L.'s] vaccination might have triggered the ITP." Id. at 78. She noted that A.L. had been "doing well with normal platelet count" since the conclusion of steroid therapy the previous December, id. at 79, and observed that A.L. had no "bruising [or] bleeding abnormalities," id. at 80.

At A.L.'s next follow-up appointment ten weeks later (on June 29, 2017), Dr. Forbes recorded that A.L.'s mother was expressing concerns "that [A.L.] is still bruising more easily than other children," but she also observed that "overall [she is] doing better." Pet'rs' Ex. 10 at 1, ECF No. 5-10; but see id. at 2 (noting that A.L.'s mother "denies . . . bruising [or] bleeding abnormalities"). Dr. Forbes also reported that A.L.'s mother was "concerned that [A.L.'s] vaccination might have triggered the ITP." Id. at 2.

During this appointment, Dr. Forbes recorded that A.L. had a bruise on her cheek and on her ear. Id. at 4. She stated, however, that A.L.'s "ITP episode" had "now resolved." Id. at 9.

In her report, Dr. Forbes observed that the blood tests that had been conducted in April, discussed above, had revealed the presence of "mildly elevated transitional B cells on B cell subset typing." Id. at 9 ("Immune work-up otherwise reassuring."). Therefore, Dr. Forbes stated, she would recheck B cell subsets that day. Id.; see also Pet'rs' Ex. 9 at 91 (documenting a platelet count of 321,000/mm^3 and a mean platelet volume of 9.0 femtoliters in April 2017). If the B cells were "trending toward normal," she opined, then the mild elevation was "likely due to the immature immune system at [A.L.'s] age and new B cell differentiation following the ITP episode now resolved." Pet'rs' Ex. 10 at 9. On the other hand, she observed, "[i]f the level continues to increase, there will be concern for immune dysfunction with potential for recurrence of autoimmune disease." Id.

The blood tests Dr. Forbes ordered that day revealed that A.L.'s platelet count was normal, id. at 6 (documenting a platelet count of 375,000/mm^3), and that her mean platelet volume was within the reference range (at 9.3 femtoliters), id. At the same time, in a box set aside for "comments" concerning platelets, the report stated that "Giant platelets" had been "noted on smear review." Id. at 7.[2]

Dr. Forbes reviewed the results and concluded that they were "reassuring for normal B cell differentiation." Id. at 9. In fact, the results were so reassuring that she cancelled any further testing and follow-up appointments with A.L. See Pet'rs' Ex. 12 at 2 ("Per Dr. Forbes, all of [A.L.]'s [June 29, 2017] labs were good so we can cancel her appointment for September."), ECF No. 19-1; see also Pet'rs' Ex. 23, ¶ 6 ("Dr. Forbes contacted me again by telephone to provide further advice regarding [A.L.]'s care and to report the June 2017 test results."), ECF No. 88-1. Dr. Forbes made no comments regarding the giant platelets present on the blood smear review.

III. The Vaccine Claim and the Special Master's Ruling on Facts

On February 14, 2018, A.L.'s parents, Petitioners Victoria and Kevin Leming, filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 to -34. Pet. for Comp. Under the Vaccine Act at 1, ECF No. 1. In their Petition, the Lemings alleged that the vaccines A.L. received on September 6, 2016, caused her to experience ITP, immune dysfunction, and immunodeficiency. See id. at 1.

The case was assigned to then-Chief Special Master Dorsey on February 15, 2018. ECF No. 4. On December 21, 2018, the Secretary filed a Vaccine Rule 4(c) report. ECF No. 34. In it, he asserted that Petitioners were not eligible for compensation because they could not satisfy the Act's severity requirement, codified at 42 U.S.C. § 300aa-11(c)(1)(D). Id. at 5–6. That provision requires a petitioner to prove that her alleged vaccine-related illness, disability, injury, or

[2] "Giant platelets" are "platelets the size of red blood cells." Pet'rs' Ex. 27 at 11 (David S. Rosenthal, Evaluation of the peripheral blood smear (Robert A. Brodsky & Jennifer S. Tirnauer, eds., Jan. 19, 2022), https://www.uptodate.com/contents/evaluation-of-the-peripheral-blood-smear), ECF No. 98-4. They "may be seen in patients with increased platelet turnover or a myeloproliferative neoplasm," as well as "a variety of congenital bleeding disorders." Id.

condition either: lasted longer than six months, 42 U.S.C. § 300aa-11(c)(1)(D)(i); resulted in death, id. § 300aa-11(c)(1)(D)(ii); or "resulted in inpatient hospitalization and surgical intervention," id. § 300aa-11(c)(1)(D)(iii).

On March 26, 2019, both parties filed motions for a ruling on the facts. ECF Nos. 38, 39. Then-Chief Special Master Dorsey issued such a ruling on July 12, 2019. See Ruling on Facts, ECF No. 41. As pertinent to the current motion for review, she agreed with the Secretary that Petitioners had failed to demonstrate that A.L. had suffered ITP-related sequelae for more than six months post vaccination as required to be eligible for compensation pursuant to clause (i) of 42 U.S.C. § 300aa-11(c)(1)(D). See id. at 5–7. Specifically, she found that the evidence did not support Petitioners' contentions that A.L. continued for more than six months to experience the adverse effects of immune dysfunction and/or bruising attributable to ITP. Id. at 6–7.

Then-Chief Special Master Dorsey observed that Petitioners' allegations that A.L.'s immune system "remained 'abnormal' for more than six months after vaccination" were based on Dr. Forbes' June 29, 2017 report. Id. at 6–7. As described above, Dr. Forbes had noted "mild elevation" in A.L.'s "transitional B cells," based on her April 2017 blood tests, Pet'rs' Ex. 10 at 9, and stated that—should the level continue to increase—it would create concerns about immune dysfunction with the "potential for recurrence of autoimmune disease," id.; see also Pet'rs' Ex. 9 at 91. But the June 29, 2017 tests Dr. Forbes conducted alleviated any potential concerns. As then-Chief Special Master Dorsey observed, Dr. Forbes characterized the results of the June 29, 2017 blood tests as "good," and she cancelled A.L.'s follow-up appointment without ordering any further treatment. Ruling on Facts at 6 (citing Pet'rs' Ex. 10 at 8–9; Pet'rs' Ex. 12 at 2). Relying on Dr. Forbes' observations, and the rest of the record, then-Chief Special Master Dorsey concluded that "A.L. did not suffer immune dysfunction or dysregulation persisting for more than six months after her September 6, 2016 vaccinations." Id. at 6–7.

Then-Chief Special Master Dorsey similarly rejected Petitioners' contention that A.L. "suffered continued ITP-related bruising more than six months after vaccination." Id. at 7. She acknowledged that, in the notes regarding the June 29, 2017 appointment, Dr. Forbes recorded that A.L.'s mother "fe[lt] that [A.L.] [was] still bruising easier than other children" and had also noted bruising on A.L.'s cheek and ear. Id. (citing Pet'rs' Ex. 10 at 1, 4). However, she explained, Dr. Forbes "did not attribute any . . . bruising to A.L.['s] previous ITP diagnosis." Id. She agreed with the Secretary that Petitioners had not proven that the bruising A.L.'s mother had observed was attributable to her vaccine injury, and therefore concluded that A.L. had not "suffered the residual effects or complications of [her] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine" as required for compensation under clause (i) of the Vaccine Act's severity requirement. See id.

IV. Proceedings on Remand

A. Order to Show Cause

On June 28, 2021, Chief Special Master Brian H. Corcoran, to whom the case had since been reassigned, issued an Order directing Petitioners to show cause why the case should not be dismissed given: (1) this Court's decision that A.L. had not undergone a surgical intervention

within the meaning of 42 U.S.C. § 300aa-11(c)(1)(D)(iii); and (2) then-Chief Special Master Dorsey's undisturbed finding that they "ha[d] not established by preponderant evidence that A.L. suffered residual effects of her ITP for six months after her vaccination" within the meaning of 42 U.S.C. § 300aa-11(c)(1)(D)(i). Order to Show Cause at 2 (quoting Ruling on Facts at 7), ECF No. 84.

Petitioners responded that the Chief Special Master should not dismiss the case given certain "new facts" set forth in an affidavit Petitioner Victoria Leming executed on August 30, 2021, Pet'rs' Resp. to Order to Show Cause at 1, ECF No. 88, as well as an upcoming appointment the Lemings had scheduled with Dr. Forbes for October, id. at 2. In the affidavit, Ms. Leming asserted that A.L. "continues to bruise easily" and "has suffered the effects and complications of her ITP until the present." Pet'rs' Ex. 23, ¶ 12. In addition, Ms. Leming stated that "[s]ometime" before June 2017 Dr. Forbes had informed her by phone "that [A.L.]'s B cell counts were high, consistent with the adverse effects of ITP," and that, while "the titers from [A.L.]'s earlier vaccinations came back in the normal range," "a second round of testing was necessary." Id. ¶ 4. Following that second round of testing on June 29, 2017, Ms. Leming asserted, "Dr. Forbes said that [A.L.]'s B cell count was still high" although lower than the first test conducted in April 2017. Id. ¶ 6. She stated that Dr. Forbes told her in June 2017 that, "based on the tests, [A.L.] was still experiencing the effects of the ITP but was nearing [the] end of the ITP healing process." Id.

"During the same June telephone conversation," Ms. Leming continued, "Dr. Forbes told [her] that because of [A.L.]'s vaccine reaction and resulting immune dysfunction, [Dr. Forbes] was ordering [A.L.] to avoid vaccinations until at least the age of six," allegedly citing "the risk, due to her ITP, of an adverse effect from vaccination." Id. ¶ 7. According to Ms. Leming, Dr. Forbes had told her that, "before [A.L.] resumed receiving vaccines, she would need to return for another round of testing." Id. ("Dr. Forbes recommended that we defer vaccination . . . ."). As a result, Ms. Leming stated, A.L. "ha[d] not had any vaccines since June 2017." Id. ¶ 9.

Citing these representations in Ms. Leming's affidavit, Petitioners argued that "Dr. Forbes believes that [A.L.]'s ITP and related immunodeficiency has continued through the age of six, requiring further testing." Pet'rs' Resp. to Order to Show Cause at 3. They further observed that A.L.'s upcoming October 22, 2021 appointment with Dr. Forbes "promises to yield further information confirming these facts." Id. In addition, in a footnote, Petitioners noted that the Federal Circuit had taken under consideration an appeal concerning "the interpretation by the Court of Federal Claims of the statutory meaning of the Vaccine Act's 'residual effects' requirement" in the context of ITP, and argued that "the outcome of the appeal will likely have some bearing on the determination of the issues in the present case." Id. at 2 n.1 (citing Wright v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 608, 614–15 (2019)).

B. Decision on Remand

Given the pendency of the appeal in the Federal Circuit in Wright, Chief Special Master Corcoran deferred his decision regarding the disposition of the case on remand. See Decision on Remand at 4, ECF No. 96. The court of appeals issued its decision on January 5, 2022. See Wright v. Sec'y of Health & Hum. Servs., 22 F.4th 999 (Fed. Cir. 2022). Three weeks later, and

without requesting additional briefs from the parties, the Chief Special Master dismissed the case. See Decision on Remand. He concluded that Petitioners had not proven that A.L. suffered from the residual effects or complications of her vaccine injury for longer than six months as required to establish severity under 42 U.S.C. § 300aa-11(c)(1)(D)(i). Id. at 7–11.

The Chief Special Master found that the "factual history contained in section II of Special Master Dorsey's [Ruling on Facts] represent[ed] an accurate summary of the relevant facts in this matter," and he adopted and incorporated that section into his decision. Id. at 4 (explaining that he agreed with "that aspect of her ruling (which was not contested or disturbed on review) in its entirety"). He also adopted section IV(a) of the Ruling on Facts ("Six Month Sequela"). Id. at 9 (explaining that section IV(a) "remains undisturbed by" Leming I and that he "concur[s] with the reasoning behind it").

Chief Special Master Corcoran was not persuaded by the "new evidence" Petitioners had submitted, id. at 7, 9, including Ms. Leming's affidavit, in which she represented that Dr. Forbes was of the view that A.L.'s "ITP and related immunodeficiency has continued through the age of six, requiring further testing," id. at 9 (quoting Pet'rs' Resp. to Order to Show Cause at 3). The Chief Special Master found this contention "utterly contra[dicted]" by the medical record. Id. He explained that "A.L. has never been diagnosed with the chronic form of ITP that would be expected to persist," and that "Dr. Forbes's contemporaneous treatment records demonstrate that after reviewing the bloodwork ordered on June 29, 2017, she had no concerns that A.L.'s ITP and/or any related immunodeficiency persisted, and recommended only follow-up as needed." Id. at 9–10 (discussing Pet'rs' Ex. 10 at 9). Further, he explained, no additional medical records had been provided to demonstrate that A.L.'s platelet count had been abnormal after 2016, despite the fact that several months had passed "since A.L.'s purported appointment with Dr. Forbes [in October 2021]." Id. at 10 (noting that "no updated medical records or other evidence has been filed that alter this analysis").

The Chief Special Master also found unpersuasive Petitioners' contention "that A.L. continues to bruise easily," noting that this assertion had been addressed in Special Master Dorsey's Ruling on Facts, where she observed that Dr. Forbes "did not attribute any June 29, 2017 bruising to A.L.['s] previous ITP diagnosis." Id. (quoting Ruling on Facts at 7). In the two years since that ruling, he continued, "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." Id. In any event, Chief Special Master Corcoran went on, "[b]ruising 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." Id. at 10–11 (citing Wright, 22 F.4th at 1005)).

"Finally," Chief Special Master Corcoran found, "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," could not support a finding "that A.L.'s ITP and/or any related immunodeficiency persisted for more than six months." Id. at 11 (citing Pet'rs' Resp. to Order to Show Cause at 2; Pet'rs' Suppl. Resp. to Order to Show Cause at 2, ECF No. 90; Pet'rs' Ex. 23, ¶¶ 7, 9). "[T]he mere risk of a future associated problem that could be triggered a second time by vaccination," he concluded, "cannot satisfy severity." Id. (citing

Parsley v. Sec'y of Health & Hum. Servs., 08-781V, 2011 WL 2463539, at *5 (Fed. Cl. Spec. Mstr., May 27, 2011)).

C. Petitioners' Motion for Reconsideration

On February 10, 2022, Petitioners filed a motion for reconsideration of the Chief Special Master's Decision on Remand pursuant to Vaccine Rule 10(e). See Pet'rs' Mot. for Recons. of the Decision on Remand Filed on Jan. 26, 2022 ("Pet'rs' Mot. for Recons."), ECF No. 97.[3] Along with their motion, Petitioners submitted additional medical records, including blood test results from October 2021 and a new November 2021 report from Dr. Forbes. Pet'rs' Ex. 38, ECF No. 99-1. They also submitted an expert report from Dr. Mark Levin, Pet'rs' Ex. 24, ECF No. 98-1, along with a number of items of medical literature, Pet'rs' Exs. 25–36, ECF Nos. 98-2 to -13.

In their Motion for Reconsideration, Petitioners complained throughout that the Chief Special Master had not solicited their views regarding the impact of the Federal Circuit's decision in Wright before he dismissed their case. See, e.g., Pet'rs' Mot. for Recons. at 2 (arguing that Petitioners were not given an opportunity "to show how their case meets the six-month severity statute, taking into consideration the Federal Circuit's new statutory construction [in Wright]").[4] They noted that, under Wright, the term "residual effects" in § 300aa-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." Id. at 14 (emphasis in original) (quoting Wright, 22 F.4th at 1006). They argued that the evidence showed that A.L. "experienced a demonstrable change within her body caused by the vaccine injury that persisted well past six months post vaccination." Id. at 3. That change was the presence of "Giant platelets" noted in her June 2017 blood test report. Id. Petitioners argued that the presence of giant platelets is "an abnormality—a 'residual effect or complication'—that was caused by her vaccine injury, immune thrombocytopenia purpura." Id.

[3] Vaccine Rule 10(e)(1) provides that "[e]ither party may file a motion for reconsideration of the special master's decision within 21 days after the issuance of the decision, if a judgment has not been entered and no motion for review under Vaccine Rule 23 has been filed." And Vaccine Rule 10(e)(3) gives the special master "the discretion to grant or deny the motion, in the interest of justice."

[4] See also Pet'rs' Mot. for Recons. at 3 (arguing that their claim "was not yet ripe for adjudication because the Petitioners had not had an opportunity to present their case considering the Federal Circuit's seminal Opinion in Wright"); id. at 4 (arguing that the Chief Special Master had issued his Decision on Remand "without the benefit of the Petitioners' input to consider the Wright Opinion's bearing . . . on their case"); id. at 16–17 (arguing that the Chief Special Master "did not give Petitioners a chance to present their case post-Wright"); id. at 17 (criticizing the Chief Special Master's issuance of his "Decision on Remand twenty-three days after the Federal Circuit issued its Opinion in Wright, without providing the Petitioners with an opportunity to present how the Federal Circuit's Opinion in Wright might bear on their case").

While the notation regarding giant platelets was not new evidence, and was not commented upon by any of A.L.'s treating physicians, Petitioners cited the newly submitted report of Dr. Levin in an effort to explain its significance. See id. at 10–12, 19–22. They noted his observation that "large platelets were present during the acute phase of [A.L.'s ITP] in October 2016," and that a blood test performed in June 2017 indicated elevated B cell levels plus "[t]he presence of large or Giant platelets." Id. at 11 (quoting Pet'rs' Ex. 24 at 8). Dr. Levin opined that "[t]he presence of large platelets in [A.L.]'s blood in June 2017 shows that she was continuing to experience the effects of her vaccine-caused ITP." Pet'rs' Ex. 24 at 8. ("The presence of Giant platelets in [A.L.]'s June 29, 2017, blood sample, is evidence of such a continuing thrombocytopenic process, the source of which is her ITP that began in September 2016."). Moreover, he observed, "Giant platelets are associated with detrimental effects on the patient" and "can result in certain kinds of excessive bleeding." Id.

Petitioners also argued that another residual effect of A.L.'s ITP was that she had not been able to receive any of her routine childhood vaccinations since 2016. Pet'rs' Mot. for Recons. at 24–29. They cited Dr. Forbes' purported "recommendation" to that effect in June 2017, and represented that she was "currently evaluating A.L. to determine an appropriate vaccination schedule, due to an increased risk of an adverse event." Id. at 27.

D. The Chief Special Master's Order Denying Reconsideration

On February 18, 2022, Chief Special Master Corcoran denied Petitioners' Motion for Reconsideration. See Order Den. Mot. for Recons. ("Recons. Order"), ECF No. 101. He observed that, while there was little case law interpreting the "interests of justice" standard, id. at 3, his practice was to "permit[] reconsideration when the movant provided new, relevant evidence that would have borne on [his] initial decision had it been previously available," id. at 4. Here, however, Petitioners had not supplied any "new medical findings or evidence." Id. at 5. Instead, he explained, they had relied almost entirely upon existing record evidence, in particular the June 2017 blood test findings. Id. at 5–6. The Chief Special Master noted that, while Petitioners were focusing for the first time on two particular aspects of A.L.'s test results, the blood test evidence itself had already been considered multiple times and been deemed insufficient to establish severity under § 300aa-11(c)(1)(D)(i) "by two special masters." Id. at 5 (noting that Petitioners were "emphasizing for the first time 'the giant platelets noted on smear review' in conjunction with [A.L.]'s bruising and B cell findings from this timeframe," but that Special Master Dorsey had already rejected a severity finding after considering these facts (citing Ruling on Facts at 4–5)).

The Chief Special Master further concluded that the new medical records documenting A.L.'s October 2021 blood test and follow-up visit with Dr. Forbes in November did not yield evidence that A.L. suffered from the residual effects or complications of her ITP more than six months after her vaccination. Id. at 5–6. He observed that A.L.'s October 2021 blood test results "were not interpreted by Dr. Forbes as suggesting A.L. was at risk for ITP or immune dysfunction." Id. at 5 (citing Pet'rs' Ex. 38). At best, Petitioners were "highlight[ing] a different aspect of the record (the giant platelets and/or B cell levels) that they did not previously reference." Id. at 6. But the medical studies submitted by Petitioners, he explained, did not demonstrate any "legitimate changes in the scientific understanding of ITP . . . [which] would

render this aspect of the record more significant today than it was in 2019." Id. It continued to be the case, he said, that "ITP is not present if a serum platelet count is normal" and that "bruising alone (and whatever might cause that) is not enough to prove [ITP-related] injury." Id. (citing Wright, 22 F.4th at 1002–03).

Finally, the Chief Special Master acknowledged that "[i]ntervening precedent can . . . provide grounds for reconsideration, if it in fact has the potential for altering a matter's prior resolution." Id. at 4. But he had already explicitly considered the impact of Wright on Petitioners' claim in his Decision on Remand. Id. at 6–7; see also Decision on Remand at 4, 6, 10. He acknowledged that he had not previously "invite[d] Petitioners to offer their parsing of Wright," but concluded that, even with "the benefit of their reading of it," their arguments were "wholly unpersuasive." Recons. Order at 6–7.

V. Petitioners' Motion for Review

On February 25, 2022, Petitioners filed the present Motion for Review of Chief Special Master Corcoran's Decision on Remand and his Reconsideration Order pursuant to 42 U.S.C. § 300aa-12(e)(1). See Pet'r's Mot. for Review of the Special Master's Decision Filed on Jan. 26, 2022, and Denial of Mot. for Recons. ("Pet'rs' Mot."), ECF No. 102; Pet'rs' Mem. of Numbered Objs. to the Decision on Remand Filed on January 26, 2022, and in Supp. of Pet'r's Mot. for Review ("Pet'rs' Mem."), ECF No. 104; see also Vaccine Rule 24 ("Memorandum of Objections").

The Secretary filed a response to Petitioners' Motion on March 28, 2022, in which he urged the Court to affirm the Chief Special Master's determination. Resp. to Mot. for Review ("Sec'y's Resp."), ECF No. 106. The Court held oral argument on Petitioners' Motion via videoconference on August 4, 2022.

DISCUSSION

I. Jurisdiction and Standard of Review

Congress established the National Vaccine Injury Compensation Program in 1986 to provide a no-fault compensation system for vaccine-related injuries and deaths. Figueroa v. Sec'y of Health & Hum. Servs., 715 F.3d 1314, 1316–17 (Fed. Cir. 2013). The Act is "[r]emedial legislation" which "should be construed in a manner that effectuates its underlying spirit and purpose." Id. at 1317 (alteration in original) (citing Cloer v. Sec'y of Health & Hum. Servs., 675 F.3d 1358, 1362 (Fed. Cir. 2012)).

A petition seeking compensation under the Vaccine Act must be filed in the Court of Federal Claims, after which the Clerk of Court forwards it to the Office of Special Masters for assignment. 42 U.S.C. § 300aa-11(a)(1). The special master to whom the petition is assigned "issue[s] decision on such petition with respect to whether compensation is to be provided under the [Vaccine Act] and the amount of such compensation." Id. § 300aa-12(d)(3)(A).

The Vaccine Act grants the Court of Federal Claims jurisdiction to review the decisions of special masters (subject to further review in the Federal Circuit). Mahaffey v. Sec'y of Health & Hum. Servs., 368 F.3d 1378, 1383 (Fed. Cir. 2004) (citing 42 U.S.C. § 300aa-12(d)(3)(A)). On review, the Court has several options. It may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); see also Vaccine Rule 27.

The Court reviews a special master's legal determinations de novo, applying the "not in accordance with law" standard. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278–79 (Fed. Cir. 2005); see also Carson v. Sec'y of Health & Hum. Servs., 727 F.3d 1365, 1368 (Fed. Cir. 2013) (instructing the reviewing court to "give no deference to the . . . Special Master's determinations of law").

By contrast, review of a special master's factual determinations is limited to whether such determinations are arbitrary, capricious, and/or reflect an abuse of discretion, Moberly, 592 F.3d at 1321, which is a "uniquely deferential" standard, Milik v. Sec'y of Health & Hum. Servs., 822 F.3d 1367, 1376 (Fed. Cir. 2016) (quoting Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)). The Court does not reweigh the evidence nor examine its probative value or the credibility of the witnesses; those "are all matters within the purview of the fact finder." Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1349 (Fed. Cir. 2010)). Therefore, if a special master "'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision,' then reversible error is 'extremely difficult to demonstrate.'" Milik, 822 F.3d at 1376 (quoting Hines v. Sec'y of Health & Hum. Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

II. Merits

Under the Vaccine Act, "[a] petitioner seeking compensation must establish by a preponderance of the evidence that the injury or death was caused by a vaccine." Wright, 22 F.4th at 1001 (citing 42 U.S.C. §§ 300aa-11(c)(1)(C), -13(a)(1)). There are two ways a petitioner may make this showing. "First, the petitioner may prove that the injury is one listed in the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a) (2020), and occurred within the time provided within the Table, establishing a presumption of causation." Id. (citing Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1319–20 (Fed. Cir. 2006)). Second, where an injury is not listed in the Vaccine Injury Table, the petitioner must prove causation in fact. Id. at 1001–02.

Whether the case involves a Table Injury (as here) or requires specific proof of causation, compensation is only available for injuries that reach a specified threshold of severity. A petitioner seeking compensation under the Act must therefore also prove that she: (1) suffered the residual effects of her vaccine-related illness, disability, injury, or condition for more than six months, 42 U.S.C. § 300aa-11(c)(1)(D)(i); (2) suffered a vaccine-related illness, disability, injury or condition that resulted in death, id. § 300aa-11(c)(1)(D)(ii); or (3) suffered a vaccine-related illness, disability, injury or condition that "resulted in inpatient hospitalization and surgical intervention," id. § 300aa-11(c)(1)(D)(iii).

The motion for review presently before the Court concerns the Chief Special Master's determination under clause (i) of the severity provision that A.L. did not "suffer[] the residual effects or complications" of her ITP for more than six months after she received the MMRV vaccine. Id. § 300aa-11(c)(1)(D)(i). Petitioners contend that this determination was arbitrary and capricious and/or an abuse of discretion, alleging that there exist two alternative bases on which the Chief Special Master could have and should have found 42 U.S.C. § 300aa-11(c)(1)(D)(i) satisfied. Pet'rs' Mem. at 1–2.

First, Petitioners rely on a June 29, 2017 laboratory report showing that on that day a blood test revealed both elevated levels of B cells and the presence of "Giant platelets" in A.L.'s blood. See id. at 24–36. Petitioners contend that A.L.'s ITP caused the formation of the giant platelets and that they affected the ability of her blood to clot, which explained why A.L. allegedly continued to bruise easily. Id. at 27, 33. Therefore, Petitioners argue, the giant platelets were residual effects of A.L.'s ITP. Id. at 26, 29.

Alternatively, Petitioners argue that, at the direction of her doctor, and because of the risk of adverse effects, A.L. did not receive routine childhood vaccinations for over four years. Id. at 37–43. They contend that the doctor's direction was a course of treatment she prescribed for A.L.'s vaccine injury and therefore a "residual effect" of that injury. Id. at 42.

The Chief Special Master rejected both arguments. See Recons. Order. For the reasons set forth below, his determinations were neither arbitrary and capricious, an abuse of discretion, nor contrary to law. Petitioners' Motion for Review must therefore be denied.

A. Whether the "Giant Platelets" Noted in a June 2017 Blood Smear Represented a Residual Effect of A.L.'s Vaccine Injury

Petitioners contend that the Chief Special Master did not give sufficient weight to the results of a blood smear taken on June 29, 2017, which, as noted, revealed the presence of "Giant platelets" in A.L.'s blood. Pet'rs' Mem. at 26 (citing Pet'rs' Ex. 10 at 7). They argue that the medical literature and the report of their medical expert, Dr. Mark Levin, show that the giant platelets were caused by and therefore were a residual effect of A.L.'s vaccine-injury—i.e., ITP. Id. at 26–27, 30–31. Further, Petitioners observe, giant platelets interfere with the blood's ability to clot. Id. at 33 (citing Pet'rs' Ex. 24 at 8). Therefore, they posit, the bruises Dr. Forbes recorded in June 2017 were caused by "a continuing ITP process as revealed by the medical evidence of the presence of giant platelets." Id. at 30. They argue that when the Chief Special Master denied their Motion for Reconsideration, he "improperly ignored or rejected [this] unambiguous

evidence of a detrimental somatic condition within A.L. that was medically caused by and a 'residual effect' of A.L.'s vaccine-caused ITP." Id. at 2 (citing Wright, 22 F.4th at 1005–06). These arguments lack merit.

First, there is ample support in the record for the finding of the Chief Special Master (and that of his predecessor, former Chief Special Master Dorsey) that A.L. was not suffering from ITP at the time she allegedly experienced unusual bruising in June 2017. Recons. Order at 5–6. In fact, the great weight of the medical evidence, which both of them credited, showed that A.L.'s vaccine injury—i.e., ITP—was resolved in December 2016. Id. at 2, 5–6; Ruling on Facts at 5–7; see also Pet'rs' Ex. 9 at 66 (hematologist's December 30, 2016 statement that A.L.'s ITP "has likely resolved at this time and is unlikely to recur"); id. at 45–46 (documenting that A.L. was weaned off of steroids in November 2016 with "no symptom recurrence"); id. at 95 (April 13, 2017 report of hematologist stating that A.L. remained "completely free of bleeding symptomatology").

These conclusions are based on a series of blood tests, which showed a normal platelet count. See Pet'rs' Ex. 9 at 55, 79, 100; Pet'rs' Ex. 10 at 6; Pet'rs' Ex. 12 at 2. The blood test results are dispositive because, as the Chief Special Master observed, and as is consistent with the medical literature Petitioners themselves submitted, "platelet count drops" are "the sine qua non for diagnosing ITP." Recons. Order at 2; see also Pet'rs' Ex. 36 at 2 (defining ITP as the condition of having a platelet count of less than 50,000/mm^3 or a higher count but "accompanied by severe or mucosal bleeding"), ECF No. 98-13; Pet'rs' Ex. 29 at 1 (defining ITP as a "platelet count [of less than] 100,000/[mm^3]"), ECF No. 98-6; Pet'rs' Ex. 32 at 1 (noting that ITP "is defined as a platelet count of <150,000/[mm^3]"), ECF No. 98-9.

Petitioners argue nonetheless that, even if A.L.'s ITP had in some sense been "resolved" in December 2016, in June 2017 she was still suffering from its "residual effects," as the court of appeals interpreted that term in Wright. Pet'rs' Mem. at 25–28. In Wright, a two-year-old child (B.W.) was diagnosed with ITP about two weeks after he received an MMRV vaccine. 22 F.4th at 1003. Although his platelet count was normal within a few months, he continued to experience bruising over the next two years and had to return for blood tests on several occasions. Id. at 1003–04. Each blood test revealed a normal platelet count, reflecting that B.W. no longer suffered from ITP. See id. The petitioners in Wright argued nonetheless that the severity requirement was met because the blood tests B.W. had been required to undergo were themselves the residual effect of the now-resolved ITP. See id. at 1004.

The Federal Circuit rejected Petitioners' argument. Id. at 1004–07. While it agreed that the language of 42 U.S.C. § 300aa-11(c)(1)(D)(i) "dictates that a residual effect must be caused by the vaccine injury," id. at 1004–05, it observed that "vaccine injuries are somatic conditions defined by their signs and symptoms within the patient," and "their residues are similarly defined," id. at 1005–06 (citing 42 C.F.R. § 100.3(c)). The phrase "residual effects," the court said, "is focused on effects within the patient, particularly lingering signs and symptoms of the original vaccine injury." Id. at 1006. In addition, the court of appeals held, "[t]he words 'suffered' and 'complication,' used in association with 'residual effects' in § 300aa-11(c)(1)(D)(i)," indicate that "Congress contemplated residual effects to be detrimental conditions within the patient, such as lingering or recurring signs and symptoms." Id. Moreover,

the use of the word "suffered," the court explained, "suggests something detrimental, especially something painful." Id.; see also id. at 1007 (observing that the legislative history showed that Congress "intends the word 'suffered' to require painful or otherwise detrimental effects").

The court concluded that the blood tests B.W. had undergone, which it characterized as "relatively non-invasive," had not been shown to be detrimental to his health. Id. Therefore, the court of appeals held, they did not qualify as "residual effects" or "complications" of his thrombocytopenia. Id.

The Chief Special Master's decision is entirely consistent with the court of appeals' approach in Wright. As noted above, Petitioners argued that the presence of giant platelets in A.L.'s blood smear, noted in a comment in the June 29, 2017 blood test report, was—if not evidence that she still suffered from ITP—at least evidence that she was suffering its residual effects. Pet'rs' Mem. at 28–31. According to Petitioners, "[t]he presence of large or Giant platelets is abnormal," id. at 17 (quoting Pet'rs' Ex. 24 at 8), and constitutes the kind of "somatic change" described in Wright, id. at 25. They contend that the giant platelets were a "direct product of immune thrombocytopenia," "have a detrimental effect on A.L.'s ability to clot," and "thus [are] likely related to A.L.'s continued bruising." Id. at 33 (citing Pet'rs' Ex. 24 at 8).

Petitioners charge that the Chief Special Master ignored these arguments because they were raised for the first time in their Motion for Reconsideration. See, e.g., id. at 21–22, 35–37. They note that he several times pointed out that the arguments were not based on new evidence but rather on evidence that either was or could have been in the record before both Special Master Dorsey and himself. Id. at 35 (arguing that he "presumably" rejected their claim "because it is based on 'evidence that existed at the time of the [Ruling on Facts]'" (quoting Recons. Order at 4)); see also id. at 35–36.

In the Court's view, the Chief Special Master would not have abused his discretion had he in fact decided not to consider Petitioners' arguments based on the presence of giant platelets. As the Chief Special Master observed, the information that giant platelets were present on the 2017 blood smear was not "new" evidence for purposes of deciding whether to grant Petitioners' Motion for Reconsideration. Recons. Order at 5. The underlying report that included the blood smear results was part of the record before Special Master Dorsey in 2019 when she issued her Ruling on Facts. Id. And, as the Chief Special Master observed, the opinions Dr. Levin expressed were not based on changes in the scientific understanding of ITP. Id. at 6. All that was new was Petitioners' argument: that the results of the 2017 blood smear are relevant, indeed critical, to the proof of their claim. And this argument could have been made as early as the time that Special Master Dorsey issued her Ruling on Facts in July 2019.

In any event, the Chief Special Master did, in fact, address Petitioners' argument regarding the presence of giant platelets, including the observations in Dr. Levin's report and accompanying medical literature. See id. at 5–6. Dr. Levin was asked "to evaluate and provide [his] medical opinion regarding the question of whether or not [A.L.] had recovered fully or continued to experience residual effects of her ITP after the six-month mark after her MMR and other vaccinations she received on September 6, 2016, which would have been after April 5, 201[7]." Pet'rs' Ex. 24 at 1–2. Dr. Levin stated that, in his view, A.L. "had not fully recovered

after April 5, 201[7], although she had made good progress toward recovery." Id. at 2. "Specifically," he stated, "there is clear medical evidence, based on the testing of her platelets that [A.L.] still had the effects of her ITP after April 5, 201[7]." Id. That medical evidence, according to Dr. Levin, consisted of the June 29, 2017 blood smear reflecting the presence of giant platelets, which Dr. Levin opined "show[ed] that the effects of her ITP were present as of 6/29/17 and she had not fully recovered from her ITP." Id. at 4.[5]

Moreover, he stated, the notation in the record that A.L. was "'bruising more easily than other children' reported by [her] mother and documented in the Texas Children's Hospital record . . . was likely the clinical manifestation of the residual ITP process." Id. at 8 (citing Pet'rs' Ex. 10 at 1). "Large or Giant platelets," he explained, "are associated with detrimental effects on the patient because such large platelets do not adhere to the walls of injured blood vessels, and are not as effective in clotting, which can result in certain kinds of excessive bleeding." Id. "Thus," he concluded, "the presence of large platelets in [A.L.]'s body in June 2017 explains why [she] continued to experience bruising at that time, even considering that the acute phase of her ITP had passed, and she was recovering." Id.

Dr. Levin's report, of course, was drafted exclusively for purposes of this litigation. In addition, Dr. Levin wrote the report some three years after Special Master Dorsey had already found the existing record did not show that A.L. continued to suffer residual effects of her ITP beyond the six-month threshold, and also after the Chief Special Master issued his decision on remand. The focus of Dr. Levin's report was the presence of giant platelets in the blood smear results, a topic about which none of A.L.'s treating physicians—including Dr. Forbes, who ordered the tests—thought worthy of even mentioning.

The Chief Special Master reasonably declined to give Dr. Levin's views much weight, finding that the medical literature cited in Dr. Levin's report did not show that an acute episode of ITP "lingers" in a patient after his or her platelet count increases to the normal range. See Recons. Order at 6 (noting that Petitioners' Exhibits "merely discuss the role that B cells or platelet size play in ITP's pathogenesis (and what in turn that says about treatment of ITP while it is occurring) – not that B cells or giant platelets establish ITP's lingering presence, in the absence of evidence of platelet count drops" (citing Pet'rs' Exs. 31, 34, ECF Nos. 98-8, 98-11)).

Equally significant, even if the giant platelets were a residual effect of A.L.'s ITP, there is no evidence in the record that established that their presence was detrimental to her. Dr. Levin

[5] Dr. Levin explained that "[t]he body can compensate for ITP (the autoimmune destruction of peripheral platelets) for an extended period." Pet'rs' Ex. 24 at 8. It "responds to a low or fluctuating level of platelets by the bone marrow producing platelets to compensate for increased peripheral destruction of platelets, which occurs in the condition we call ITP," and "does so by breaking off fragments of megakaryocytes earlier than normal, resulting in immature and larger platelets." Id. "The presence of Giant platelets in [A.L.]'s June 29, 2017, blood sample," he opined, "is evidence of such a continuing thrombocytopenic process, the source of which is her ITP that began in September 2016." Id. And, he observed, "the finding of elevated immune function subsets" in the June 2017 blood tests, "including elevated B cells," also "points to and is consistent with the ongoing effects of [her] ITP." Id. at 9.

stated that the presence of the giant platelets in A.L.'s body in June 2017 "explains why [she] continued to experience bruising at that time, even considering that the acute phase of her ITP had passed." Pet'rs' Ex. 24 at 8. But Dr. Levin did not personally observe the bruises mentioned in Dr. Forbes' June 2017 report. See Pet'rs' Ex. 10 at 4. And, as Special Master Dorsey observed, although Dr. Forbes noted bruises on A.L.'s left cheek and left ear pinna (outer ear) during her June 29, 2017 exam, she "did not attribute [that] bruising to A.L.'s previous ITP diagnosis," even as she noted that A.L.'s mother believed that A.L. was still bruising more easily than other children. Ruling on Facts at 7.

The Chief Special Master was also not persuaded by Dr. Levin's observation that the presence of "elevated B cells[] points to and is consistent with the ongoing effects of [A.L.]'s ITP." Pet'rs' Mem. at 28 (emphasis in original) (quoting Pet'rs' Ex. 24 at 9); see also id. at 14 (observing that A.L.'s June 29, 2017 blood tests showed "immune dysregulation," based on "elevated B cell subset levels" (citing Pet'rs' Ex. 10 at 4–6, 7)). Dr. Forbes ordered the June 2017 blood tests and, after reviewing the results, concluded that they were "reassuring for normal B cell differentiation." Pet'rs' Ex. 10 at 9. For that reason, she cancelled any further testing and follow-up appointments with A.L. See Pet'rs' Ex. 12 at 2 ("Per Dr. Forbes, all of [A.L.'s] [June 29, 2017] labs were good so we can cancel her appointment for September.").

The Chief Special Master, in short, concluded neither the presence of giant platelets described in the June 2017 blood test report, nor the reported elevated B cell levels constituted "residual effects" of ITP within the meaning of 42 U.S.C. § 300aa-11(c)(1)(D)(i), as interpreted in Wright. His conclusion was based on a review of the record as a whole and on his determination that the opinions expressed in Dr. Levin's report were entitled to little weight. Because it is his responsibility to weigh the evidence and assess its reliability, and because his conclusions are supported by the record, the Court will not disturb the Chief Special Master's findings that neither the presence of giant platelets nor A.L.'s temporarily elevated B cell count constituted residual effects of A.L.'s ITP.

B. Alleged Restrictions on Further Vaccinations Until A.L. Turned Six

Petitioners' second challenge to the Chief Special Master's decision is based on his rejection of their contention that another residual effect of A.L.'s ITP was that A.L. was restricted from receiving any childhood immunizations until her sixth birthday. Pet'rs' Mem. at 37–38. The Chief Special Master rejected this argument because, among other reasons, the medical records in the case were inconsistent with Ms. Leming's assertion in her affidavits that Dr. Forbes told her that A.L.'s vaccinations should be delayed until after her sixth birthday. See Recons. Order at 5 n.5. Petitioners contend that the Chief Special Master's factual finding "is erroneous and contrary to the totality of the record." Pet'rs' Mem. at 39 n.18. The Court disagrees.

Petitioners' proof that Dr. Forbes told them not to vaccinate A.L. is based entirely on Ms. Leming's several affidavits. See Pet'rs' Mem. at 38, 38–39 n.18. In the first, which is dated October 19, 2017, Ms. Leming states that, during a telephone call in June 2017, Dr. Forbes "order[ed] [A.L.] to avoid vaccinations until the age of 6." Pet'rs' Ex. 15, ¶ 11, ECF No. 31-1. Further, she asserted, Dr. Forbes also told her that, "before [A.L.] resumed receiving vaccines,

she would need to return for another round of testing and possibly follow a delayed schedule of vaccination while being closely watched." Id.

Similarly, in her subsequent affidavit, dated February 14, 2018, Ms. Leming stated that Dr. Forbes informed her during this same June 2017 phone call that A.L. "will need further testing down the road if she is to receive her booster vaccines," that she "should not receive any vaccines until she is at least 6 years of age," and that she should only receive "one vaccine at a time." Pet'rs' Ex. 11, ¶ 23, ECF No. 6-1. Ms. Leming states that she was "also advised that during the next 4 years [A.L.] has a higher chance than other children of having ITP." Id.

Finally, Ms. Leming referenced her June 2017 telephone call with Dr. Forbes in an affidavit dated August 30, 2021, in which she again stated that Dr. Forbes "order[ed] [A.L.] to avoid vaccinations until at least the age of six because of the risk, due to her ITP, of an adverse effect from vaccination," and that she had "said that before [A.L.] resumed receiving vaccines, [A.L.] would need to return for another round of testing." Pet'rs' Ex. 23, ¶ 7. Dr. Forbes, she said, "recommended that we defer vaccination and watch [A.L.] closely for any symptoms of ITP or immune dysfunction." Id.

Ms. Leming's description of the advice she received in June 2017 is not supported by the medical record. As the Chief Special Master observed, the comprehensive medical records that document A.L.'s treatment for ITP, including the follow-up exams conducted after December 2016, do not reflect that Dr. Forbes or any other provider advised Ms. Leming to delay vaccinating A.L. again until she was six years old (or for any period of time). In fact, the records contain no mention of any restriction on vaccinations, which one might expect to find given that Ms. Leming had on several occasions raised concerns about the risks of A.L. having an adverse reaction to vaccines. See Pet'rs' Ex. 9 at 51, 78, 100; Pet'rs' Ex. 10 at 2. To the contrary, as discussed above, the contemporaneous treatment records reflect that Dr. Forbes cancelled any follow-up appointments after reviewing the results of A.L.'s June 2017 blood tests, without any indication that there was need for any further testing. Pet'rs' Ex. 12 at 2.

Petitioners argue that the records of A.L.'s November 2021 visit with Dr. Forbes support their contention that Dr. Forbes had advised that A.L. not receive vaccines due to the risk of another episode of ITP. Pet'rs' Mem. at 39 (citing Pet'rs' Ex. 38 at 29). The notes of that visit state that Ms. Leming had been seen that day "to revisit vaccination and decide how to move forward" and "to discuss [A.L.'s] reaction risks for vaccine reaction." Pet'rs' Ex. 38 at 26, 29. They further reflect that Dr. Forbes recommended that A.L. begin a catch-up vaccination schedule which would start with the COVID-19 vaccine, to be followed by "inactivated vaccines including the flu shot," with the "live vaccine[s]" to be "address[ed]" "separately," by starting with the Varicella vaccine and, three months later, the MMR vaccine. Id. at 29. The notes of the visit also record that Dr. Forbes and Ms. Leming "discussed signs of ITP and that should [A.L.] develop symptoms post vaccination she should be seen and a [complete blood count] obtained." Id.

Petitioners contend that it is significant that, during this visit, "Dr. Forbes recommended a delayed catch-up schedule with the live vaccines delayed even further." Pet'rs' Mem. at 39. According to Petitioners, this "shows that Dr. Forbes was in accord with the restriction on

vaccination, with focus on the MMR vaccine that caused A.L.'s ITP." Id. (citing Pet'rs' Ex. 38 at 29).

The inference Petitioners would have had the Chief Special Master indulge is not an especially compelling one. Dr. Forbes' recommendation that A.L. begin a "catch-up schedule" was an instruction that A.L. catch up on the vaccinations she had not received on schedule. See, e.g., Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, Centers for Disease Control and Prevention (Feb. 17, 2022), https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html#table-catchup. The fact that the recommendation was made does not suggest anything about why A.L. stopped getting her vaccinations. It is entirely possible, given her mother's concern about the risks of vaccination, that A.L.'s parents made the decision to avoid them on their own.

It was not unreasonable for the Chief Special Master to give weight to the fact that the medical record did not reflect the advice Dr. Forbes supposedly gave Ms. Leming not to have A.L. vaccinated until she turned six. And doing so does not reflect any lack of sincerity or bad faith on Ms. Leming's part in reporting what she understood Dr. Forbes' advice to be. Medical records are afforded weight because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," and are "generally contemporaneous to the medical events." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). With respect to the advice given by a physician, it is fair to assume that medical records will generally be more reliable than the recollection of lay persons.

It was therefore not unreasonable for the Chief Special Master to conclude that, had Dr. Forbes advised Petitioners that A.L. not receive any of her childhood immunizations for a period of several years, she would have documented that advice in A.L.'s medical records. The Court therefore declines to disturb his finding that A.L. was not restricted from receiving her childhood vaccinations as a residual effect of her ITP.[6]

CONCLUSION

On the basis of the foregoing, Petitioners' Motion for Review and Memorandum of Numbered Objections to the Decision on Remand, ECF Nos. 102 and 104, are **DENIED**, and the Decision of the Chief Special Master on Remand dismissing Petitioners' claim, as well as his Reconsideration Order, ECF Nos. 96 and 101, are **SUSTAINED**. The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

[6] The Chief Special Master also held that any alleged restriction on vaccination would not in any event be a residual effect of A.L.'s ITP because "the mere risk of a future associated problem that could be triggered a second time by vaccination cannot satisfy severity." Remand Decision at 11. Given the Court's conclusion upholding the Chief Special Master's factual finding that Dr. Forbes never directed that A.L. pause her vaccinations, it is unnecessary to decide whether, had she done so, the vaccine restriction would constitute a residual effect of A.L.'s ITP.

s/ Elaine D. Kaplan
ELAINE D. KAPLAN
Chief Judge