In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-811V

(to be published)

TASHA LOYD, *Parent and next Friend of* C.L., *a minor*,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: May 20, 2021
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Chronic Immune Thrombocytopenic Purpura (ITP); Prevnar; Hib; Pneumococcal Vaccine; *Althen*; Onset.
Respondent.	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for Petitioner.

Mary E. Holmes, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On July 8, 2016, Tasha Loyd filed a Petition as next friend of C.L., a minor, under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Petitioner alleges that C.L. experienced immune thrombocytopenic purpura ("ITP") caused-in-fact by the haemophilus influenza type b ("Hib") and/or pneumococcal conjugate (also referred to herein as "PCV" or "Prevnar") vaccines administered on August 30, 2013. Petition at 1 (ECF No. 1).

[1] This Decision will be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

A hearing in this matter was held (via remote/video participation) on October 29, 2020. ECF No. 64. After consideration of the filings in this case plus the testimony provided at hearing, I deny entitlement. As set forth in greater detail below, there is reliable scientific evidence associating *some* vaccines with certain forms of ITP—but insufficient evidence regarding the pneumococcal vaccine (which Petitioner's expert focused upon in his opinion) to deem it also likely causal. More significantly, there was an almost nine-month gap from the August 2013 vaccination to the most likely onset—and Petitioner's causation theory cannot reliably explain or overcome this timeframe. The record does not otherwise preponderantly establish that C.L.'s chronic ITP had an onset closer-in-time to vaccination, but then had a largely subacute course over many months.

I. *Factual Background*

Early History and Receipt of PCV Vaccine

C.L. was born on January 25, 2013. Ex. 2 at 4, filed Oct. 24, 2016 (ECF No. 10-3). She was a generally healthy baby and was developing normally. Ex. 2 at 4, 9, 13, 16, 22. During her two-week well-child visit at Westchase Pediatrics in Tampa, Florida, C.L.'s pediatrician, Dr. Laura Heimback-Graham, M.D., noted that Petitioner was requesting a staggered vaccination schedule. *Id.* at 4. Thus, it was not until April 5, 2013 (during her ten-week well-child visit) that C.L. received her first set of vaccinations, including the PCV, Hib, inactivated polio ("IPV"), and diphtheria-tetanus-acellular pertussis ("DTaP") vaccines. Ex. 2 at 9, 11. No adverse reactions were documented. *Id.* at 9.

C.L. returned to Dr. Heimback-Graham on August 7, 2013, for her six-month well-child visit. Ex. 2 at 18. Following a physical examination that reported nothing abnormal, C.L. received the second dose of the DTaP vaccine as well the Rotavirus vaccine. *Id.* at 18–23. Again, no adverse reactions to the vaccinations were documented. *Id.* at 22–23.

On August 30, 2013, C.L. returned to her pediatrician's office to receive the second doses of the PCV and Hib vaccines. Ex. 2 at 25. During the visit, Petitioner reported having seen "white patches" on C.L.'s tongue, and she was fussier than normal with a decreased appetite. *Id.* at 24. Dr. Heimback-Graham diagnosed C.L. with a candidiasis of the mouth and prescribed an antifungal medication. *Id.* at 25. No other complaints were documented during the visit. *Id.* at 25–26.

C.L. was next seen by her pediatrician over three months later—on December 2, 2013—for treatment of an infected earlobe piercing. Ex. 2 at 29. The record from this visit documents no other health complaints, and a physical examination was otherwise normal. *Id.* at 30–31. C.L. was

prescribed Augmentin—an antibiotic—and Petitioner was instructed to continue cleaning C.L.'s earlobe with alcohol swabs. *Id.* at 31.

2014 Treatment Incidents

By the beginning of 2014, a little more than four months had passed since the vaccination at issue in this case deemed by Petitioner causal of C.L.'s ITP injury. Even more time would pass before any manifestation of injury in the medical records would occur (although, as discussed below, Petitioner maintains that clinical evidence of ITP had by this point already appeared).

Thus, on January 15, 2014, C.L. returned to Dr. Heimback-Graham for a sick visit. Ex. 2 at 32. Petitioner reported a five-day history of fever, cough, congestion, and decreased appetite. *Id.* A physical examination revealed symptoms consistent with an acute upper respiratory infection. *Id.* at 33. No complaints of abnormal bruising were documented during this visit, no bruising was observed during the physical examination, and no blood testing that could have revealed platelet levels (a significant diagnostic tool for ascertaining the presence of ITP) was deemed necessary by Dr. Heimback-Graham. *Id.*

The next month, C.L. was again seen at her pediatrician's office on February 3, 2014, for her one-year well-child visit. Ex. 2 at 35. During this visit, Dr. Heimback-Graham noted that C.L. was again behind on her immunizations. *Id.* Petitioner indicated that she wished to delay further vaccination because C.L. "has fever after shots and 'is not herself' for 3 weeks afterwards" and she wished to stay home with C.L. following her next round of vaccinations. *Id.* at 35, 38. It was also noted that C.L. was suspected to have swallowed a piece of gravel or glass at a birthday party ten days before, but no mouth or stool bleeding had been observed. *Id.* at 35.

No other concerns were documented during the visit, and C.L.'s physical examination was normal. Ex. 2 at 35–38. At this visit, however, a same-day complete blood count ("CBC") test was performed, although the record does not reveal why such testing was deemed necessary. *Id.* The blood test revealed normal white blood cell (9.2 K/cumm), hemoglobin (11.4 gm/dL), hematocrit (35.1%), and platelet levels (340,000),[3] but slightly low mean corpuscular volume and slightly

[3] A CBC is a test of the peripheral blood which provides information about the hematologic system and organ system functions. K. Pagana & T. Pagana, *Mosby's Manual of Diagnostic and Laboratory Tests* 156 (6th ed. 2018) (hereinafter "*Mosby's*"). C.L.'s CBC results were compared against the following reference ranges: normal white blood cell count (5–11 K/cumm), normal hemoglobin level (10.5–12 gm/dL), normal hematocrit level (33–36%). Ex. 2 at 40. A reference range was not provided for platelet counts, but *Mosby's* proposes a normal platelet count range of 200,000–475,000/µL for infants. *Id.*; *see also Mosby's* at 362. Based upon literature filed by Petitioner, vaccine-associated ITP is diagnosed when platelet levels measure below 100,000/µL. V. Cecinati et al., *Vaccine Administration and the Development of Immune Thrombocytopenic Purpura in Children*, 9 Hum. Vaccines & Immunotherapeutics 1, 2 (2013), filed as Ex. 16 on July 14, 2017 (ECF No. 26-8) ("Cecinati").

elevated lymphocytes—though even these were deemed within normal limits. *Id.* at 38, 40; Tr. at 112–13, 159, 167–68.

On March 21, 2014, C.L. was seen again by Dr. Heimback-Graham for a sick visit. Petitioner reported that C.L. was irritable and pulling at her diaper, and also that she was more "clingy" and not very playful, and had experienced a 101-degree fever earlier that morning. Ex. 2 at 42. But there were no complaints of abnormal bruising, and C.L.'s physical examination was unremarkable except for mild erythema around her genitals. *Id.* at 42–43. Dr. Heimback-Graham diagnosed C.L. with an unspecified fever and dysuria[4], and she recommended Petitioner administer Tylenol for fevers above 101 degrees. *Id.* at 43–44. A same-day urine culture was normal without signs of infection. *Id.* at 44–45.

First Record Evidence of ITP – June 2014

Over two months later (and now approximately nine months after receiving the PCV vaccine at issue), C.L. returned to Dr. Heimback-Graham on June 2, 2014—and it was at this visit that the record sets forth the first instance in which anything associated with ITP is formally documented. At this time, Petitioner reported to Dr. Heimback-Graham that C.L. had experienced a two-week history of excessive bruising (although the record also references C.L. as presenting with a rash). Ex. 2 at 46. Petitioner specifically noted that C.L. had developed small red dots on various parts of her body approximately one week prior to the visit. *Id.* Such reporting suggests an onset of no earlier than the middle of May 2014.

Two CBCs performed at this time now revealed significantly decreased platelet counts of 34,000 and 23,000, leading Dr. Heimback-Graham to diagnose C.L. with severe ITP of unknown etiology. Ex. 2 at 47–48, 52. C.L. was thereafter referred to Dr. Hardeo Panchoosingh, a hematologist at Baycare Pediatric Hematology. *Id.* at 47–48; Ex. 4, filed Oct. 24, 2016 (ECF No. 10-5). Dr. Panchoosingh evaluated C.L. that same day, at which time Petitioner reported a two or three-week history of bruising (along with a fact not contained in the record from the pediatric visit—that C.L. had experienced a viral illness approximately two weeks earlier). Ex. 4 at 5. Dr. Panchoosingh also made noted that C.L. was behind on her immunizations, in accordance with her parents' wishes. *Id.* A physical examination revealed mild, scattered ecchymosis[5] and petechia[6]. *Id.* at 7. Based on these observations and the CBC results, Dr. Panchoosingh agreed that C.L.'s

[4] Dysuria describes painful or difficult urination. *Dorland's Illustrated Medical Dictionary* 579 (33d ed. 2020) (hereinafter "*Dorland's*").

[5] Ecchymosis is a "small hemorrhagic spot, larger than petechia, in the skin or mucus membrane forming a nonelevated, rounded or irregular, blue or purplish patch." *Dorland's* at 582.

[6] A petechia is "a pinpoint, nonraised, perfectly round, purplish red spot caused by intradermal or submucous hemorrhage." *Dorland's* at 1401.

clinical picture was most consistent with post-viral ITP. *Id.* at 8. It was recommended that C.L.'s condition be monitored, and that she return for a follow-up appointment in three days, but no other interventions were proposed or adopted at that time. *Id.*

A repeat platelet count was conducted on June 5, 2014 and showed another even lower result of 9,600. Ex. 4 at 11. C.L. was now admitted to Baycare Pediatric Hematology for further evaluation, and a repeat CBC showed an increased platelet count of 18,000. *Id.* C.L. was discharged home with instructions to return a few days later for a follow-up platelet count. *Id.*

On June 9, 2014, C.L.'s platelet count was documented as 1,000 and 8,000, and she was again admitted to Baycare Pediatric Hematology intravenous immunoglobulin ("IVIG").[7] Ex. 4 at 14; Ex. 115 at 8. Following this IVIG treatment, C.L.'s platelet counts improved to 184,000 on June 12, 2014, but then continued to decline to 33,000 on June 19th and 21,000 on June 26, 2014. Ex. 4 at 17, 21, 25. C.L. was admitted for another round of IVIG on July 7, 2014 after presenting with a platelet count of 12,000. *Id.* at 32; Ex. 115 at 16, 29. During this admission, C.L.'s family history was noted as significant for "ITP in paternal [grandmother] and von Willebrand disease[8] in paternal aunt who experienced thrombocytopenia during pregnancy." Ex. 115 at 14. C.L. was discharged from July 8th, and on July 17th C.L.'s platelet count had improved to 35,000. Ex. 4 at 30–31; Ex. 115 at 19–22. Petitioner was advised, however, that C.L.'s recurrent ITP would likely require other therapies in the future. Ex. 4 at 26, 30–31.

C.L.'s next platelet count on July 22, 2014 showed continued improvement at 42,000, but those levels again decreased to 15,000 on August 4th and 11th, and 11,000 on August 25, 2014. Ex. 4 at 34, 41, 48. At her follow-up visit on August 4, 2014, Dr. Dana Obzut, M.D., another one of C.L.'s treating hematologists, noted that C.L. seemed to require IVIG treatment on a monthly basis, but she was only experiencing improvements in her platelet count for two weeks before her condition deteriorated again. *Id.* at 36. Dr. Obzut noted that Ms. Loyd was concerned about the chronic nature of C.L.'s condition and wanted to know more about future treatment options. *Id.* at 36, 41. Petitioner and C.L.'s treating hematologists opted for an observational approach, and no further treatments were administered during these visits. *Id.* at 41, 48, 52.

[7] IVIG is a blood product that is used to treat patients with antibody deficiencies and autoimmune conditions. American College of Rheumatology, *Intravenous Immunoglobulin (IVIG)*, https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Treatments/Intravenous-Immunoglobulin-IVIG (last visited Apr. 30, 2021).

[8] Von Willebrand disease is "a congenital bleeding disorder caused by mutation in the VWF gene . . . resulting in deficiency of von Willebrand factor, with prolonged bleeding time and often impairment of adhesion of platelets . . . increased bleeding after trauma or surgery, menorrhagia, and postpartum bleeding. *Dorland's* at 538.

Subsequent Care: 2014 – Present

The remaining records filed in this case detail efforts to treat C.L.'s ITP, as well as other treatment evaluations, but none shed significant light on possible explanations for her condition (although some do rule out possible alternative explanations).

For the remainder of the 2014 fall, C.L. continued to require IVIG treatment, and saw fluctuation in her platelet count levels, although she evidenced no return to the higher, normal levels she had displayed earlier in 2014. *See, e.g.*, Ex. 4 at 55, 58, 60, 63, 69; Ex. 115 at 32–34, 38–40 (September platelet count of 2,000, then up to 28,000, before decreasing to 3,000 by November). C.L. returned to Baycare Pediatric Hematology on February 3, 2015, for a follow-up appointment. Ex. 4 at 72. Petitioner reported that C.L.'s ITP symptoms occurred in cycles. *Id.* She declined a platelet count at that time, however, because "[C.L.] is so traumatized by all the blood draws." *Id.* She also indicated that she was seeking opinions from a homeopathic doctor to determine whether dietary changes would help alleviate C.L.'s symptoms. *Id.* Another platelet count from March 2015 (obtained after an ER visit due to an accident) was low again (7,000), resulting in further IVIG treatment. Ex. 115 at 57, 59, 67, 71.

On May 4, 2015, C.L. was evaluated by Dr. Calvin Lee, M.D., a hematologist at North Pinellas All Children's Hospital. Ex. 3 at 17, filed Oct. 24, 2016 (ECF No. 10-4). During this evaluation, Dr. Lee noted that C.L.'s family history included a maternal great-aunt who also suffered from ITP and possible sarcoidosis,[9] requiring a splenectomy and lung biopsy respectively. *Id.* at 18. A physical examination revealed "numerous small petechial lesions, too numerous to count, on her chest, back, neck and a few on her face and eyelids…numerous small bruises in various stages of healing diffusely on her back and lower extremities." *Id.* at 19. Based on this examination and the last known platelet count, Dr. Lee confirmed that C.L. suffered from chronic ITP. *Id.* Dr. Lee emphasized that the etiology of ITP remains largely unknown, though he also acknowledged that it may be precipitated by an infectious agent. *Id.* Petitioner agreed to continue monitoring C.L.'s symptoms and to follow-up with her treating hematologists at Baycare Pediatric Hematology. *Id.* at 19–20.

By the fall of 2015, Petitioner began seeking treatment for C.L.'s ITP from holistic providers. *See generally* Ex. 5, filed Oct. 28, 2016 (ECF No. 12-1). C.L.'s family history of a prior ITP occurrence, along with other autoimmune illnesses, was again noted. *Id.* at 2. A number of immune-modulating treatments were proposed, and it was also recommended that C.L. be tested for an *H. pylori*[10] infection because it is associated with the development of ITP (although it was

[9] Sarcoidosis is "a chronic, progressive, systemic granulomatous reticulosis of unknown etiology, characterized by hard tubules . . . It can affect almost any organ or tissue." *Dorland's* at 1641.

[10] *H. pylori* is a species of *Helicobacter*, gram-negative, microaerophilic bacteria that "causes gastritis and peptic ulcers and is also associated with gastric cancer." *Dorland's* at 819.

not detected). *Id.* at 13. C.L. was similarly tested for a MTHFR gene[11] mutation. Ex. 5 at 9. The results showed that C.L. possesses one copy of the c677T variant of the MTHFR gene—a mutation that occurs frequently in the general population. *Id.* These studies also showed that C.L. now had a platelet count of 10,000. *Id.* at 10. The genetic testing results were deemed potentially suggestive for contributing to a folate deficiency, so it was proposed that C.L. take supplements to address that problem. *Id.* at 16–17.

On February 1, 2016, C.L. returned to North Pinellas All Children's Hospital for a follow-up with a hematologist, Dr. Erin Cockrell, D.O. Ex. 4 at 76. The follow-up was a year-delayed, due to Petitioner's concerns about the trauma of blood draws plus her desire to pursue alternative treatments. *Id.* It was reported at this time that C.L. was continuing to easily bruise, although a physical examination conducted during the visit did not reveal bruising. *Id.* at 78. Dr. Cockrell noted at this time that ITP "is a benign condition with…extremely low risk of serious, spontaneous bleeding," and that many children with ITP do not require in-home health services and can instead attend daycare and school as normal. *Id.* at 79.

C.L. returned to North Pinellas All Children's Hospital at the end of March for treatment of abdominal pain, and non-tender bruising of the lower left abdomen and arms were noted, along with a platelet count of 9,000. Ex. 3 at 50–51. The following month, a repeat CBC conducted on April 20, 2016 showed that C.L.'s platelet level had decreased further, to 7,000. *Id.* at 55–56. By the summer, C.L.'s holistic treater observed greater bruising and petechiae. Ex. 5 at 33.

Since then, C.L. has continued to obtain treatment for her chronic ITP, with levels remaining persistently low. Ex. 28 at 50 (August 2017 treatment). At times, IVIG treatment has been discontinued because C.L. developed aseptic meningitis from the treatment and its effects were otherwise short-lived. *Id.* She has tested positive for an anti-platelet antibody,[12] and treaters have proposed a "possible underlying immune dysregulation" to explain C.L.'s persistent chronic ITP. Ex. 28 at 41, 46. She has received treatment and evaluation many times in this regard, but no conclusive determinations have been made. *See, e.g.*, Ex. 28 at 36–39 (October 2018 visit to Johns Hopkins Immune Dysregulation Clinic), 33–35 (follow-up visit to Johns Hopkins in July 2019), Ex. 113 at 33–34, 43–44, 65–66, 69–71 (Johns Hopkins visit in September 2019). It has also been proposed by some treaters that (based on other lab findings establishing the existence of other

[11] The MTHFR gene mutation is "a common autosomal recessive, inborn, error of folate metabolism caused by mutation in the MTHFR gene…which encodes the enzyme….Clinical manifestations, age of onset, and severity are highly variable, characteristics include signs of neurologic damage, ranging from psychiatric symptoms to fatal developmental delay, microcephaly, ectopia lentis, and thrombosis. Some patients are asymptomatic." *Dorland's* at 1136.

[12] Anti-platelet antibodies are those antibodies that are "directed against or destructive to blood platelets." *Dorland's* at 106.

autoimmune biomarkers) C.L. might be in the early stages of development of lupus erythematosus, although she did not meet the precise diagnostic requirements. Ex. 28 at 13–14, 18–30.

II. *Testimony at Hearing*

A. Ms. Tasha Loyd

Petitioner—C.L.'s mother—provided an affidavit and also testified at the entitlement hearing. Tr. at 6–54; Affidavit, filed as Ex. 7 on June 22, 2017 (ECF No. 24-2). Ms. Loyd described C.L. as an active, sweet, bubbly baby during the first six months of her life. Tr. at 7. C.L. appeared to be developmentally ahead and was reaching milestones ahead of schedule. *Id.* at 8.

Petitioner recalled that C.L. was fussy after receiving the August 30, 2013 vaccines, and that later that evening, C.L. developed a fever—though Ms. Loyd did not remember how long the fever lasted (and this assertion is not corroborated by a medical record). Tr. at 8–9, 50 (Petitioner noting that C.L. had a history of developing fevers after vaccination). *Id.* at 40. She purported to have first noticed C.L.'s abnormal bruising approximately two weeks later, appearing "out of nowhere." Tr. at 9–10; Affidavit at 1. Petitioner also alleged that C.L. "wasn't herself" during this time, although only in a vague sense. Affidavit at 1; Tr. at 9. The medical records discussed above do not record any bruising or behavior changes from this immediate post-vaccination period, but Petitioner alleged she did raise concerns with C.L.'s pediatrician, Dr. Heimback-Graham, who dismissed them. Tr. at 17–19.

Ms. Loyd took C.L. for her one-year well-child visit on February 3, 2014. Tr. at 18. At that time, she purportedly told Dr. Heimback-Graham about the fever C.L. had purportedly developed after receiving the Hib and Prevnar vaccines. Tr. at 18–19. There was no mention of abnormal bruising documented in this contemporaneous medical record, but Dr. Heimback-Graham agreed (at Petitioner's request) to order a blood panel. *Id.* at 18–20; *see also* Ex. 2 at 35–38. Ms. Loyd was unable to recall ever receiving the results of that blood panel. Tr. at 20. Regardless, she declined further vaccinations for C.L. *Id.* at 18–19, 45. Meanwhile, she continued to dress C.L. in long sleeves and pants to hide her bruises (even though the family lives in Florida) because she did not want to appear irresponsible. *Id.* at 16–17.

The record-documented discovery of C.L.'s ITP was the result of an accident. As Petitioner recalled, in June 2014 C.L. stumbled and fell into a baby gate, causing injuries that appeared more severe than she would have expected from such a fall. Tr. at 21. In particular, C.L. developed a unique bruising pattern reflective of the gate slats. *Id.* at 47. This bruising did not subside, and approximately two weeks later, Ms. Loyd took C.L. to be evaluated by Dr. Heimback-Graham. *Id.* at 22, 27, 51. Dr. Heimback-Graham now noted the bruising. *Id.* at 22–24. By this point, Ms. Loyd

testified, she had taken several photographs of C.L.'s bruising in the preceding months, but she did not discuss them with Dr. Heimback-Graham during the visit given the pediatrician's prior rejection of the concerns. *Id.* at 51–52. But C.L.'s bruising was now "no longer deniable," and the slatted-gate pattern on C.L.'s face was so obviously concerning that Dr. Heimback-Graham ordered another CBC. *Id.* at 23. Dr. Heimback-Graham immediately referred C.L. to hematology after receiving the CBC results, which revealed low platelet counts. *Id.* at 23, 47.

When C.L. was evaluated by Dr. Panchoosingh in hematology, Ms. Loyd was asked if C.L. had recently received the measles, mumps, and rubella ("MMR") vaccine, which she has not. Tr. at 25–26. Although the medical record from this visit indicates that C.L.'s bruising had started "two to three weeks ago," Ms. Loyd alleged that this notation likely referred only to the more recent "excessive" bruising, rather than what she maintained C.L. had been experiencing all fall. Tr. at 26–27. It was at this point that C.L. received her ITP diagnosis, and it is the first time that Ms. Loyd was made aware of the condition. *Id.* at 28.

Since then, C.L. has undergone several IVIG treatments, but due to the chronic and refractory nature of her condition, she was unable to sustain a positive response to those treatments. Tr. at 27–28. She also has experienced negative side effects to the IVIG treatments, including aseptic meningitis. *Id.* at 29. Other holistic treatments have been similarly ineffective in managing C.L.'s chronic ITP. *Id.* at 28. C.L. has also undergone genetic testing in an effort to identify the root cause of her condition, but no abnormalities have been identified. *Id.* at 30.

Ms. Loyd ultimately stopped taking C.L. to see Dr. Heimback-Graham due to her failure to "catch" C.L.'s ITP. *Id.* at 46. Instead, Ms. Loyd opted for an observational approach, and they have since discontinued treatments. *Id.* at 29. According to Ms. Loyd, the bruises C.L. develops do not appear to cause her pain, but consistent blood draws and treatments were traumatic and caused significant distress for both her and C.L. *Id.* at 52–53. Ms. Loyd now pays attention to certain behavioral cues, such as fussiness, clinginess, fatigue, and sadness, that seem to indicate when C.L. may be experiencing low platelet levels. *Id.* at 30–31. In her experience, Ms. Loyd has noticed that C.L. exhibits these behaviors just before she starts to develop bruising, and they are the same types of behavior that C.L. demonstrated in September 2013, when Ms. Loyd believes her ITP began. *Id.*

B. Petitioner's Expert – M. Eric Gershwin, M.D.

Dr. Gershwin, an immunologist, testified on behalf of Petitioner and offered four expert reports in the case. Tr. 55–115, 182–86; Gershwin Report, filed as Ex. 17 on Aug. 7, 2017 (ECF No. 28-1) ("First Gershwin Rep."); Second Gershwin Report, filed as Ex. 19 on Dec. 29, 2017 (ECF No. 35-1) ("Second Gershwin Rep."); Third Gershwin Report, filed as Ex. 21 on Feb. 7,

2018 (ECF No. 38-1) ("Third Gershwin Rep."); Fourth Gershwin Report, filed as Ex. 27 on May 23, 2018 (ECF No. 42) ("Fourth Gershwin Rep."). Dr. Gershwin opined that the Prevnar vaccine C.L. received in August 2013 caused her chronic ITP. Tr. at 84–85.

Dr. Gershwin received his bachelor's degree from Syracuse University in Syracuse, New York, followed by his medical degree at Stanford University. Dr. Gershwin Curriculum Vitae, filed as Ex. 18 on Aug. 7, 2017 (ECF No. 41) ("Gershwin CV"). He then completed his internship and residency at Tufts–New England Medical Center in Boston, Massachusetts. *Id.* at 2. After completing a fellowship in immunology with the National Institute of Health, Dr. Gershwin became an assistant Professor in Rheumatology and Allergy at the University of California, School of Medicine in Davis, California. *Id.* Dr. Gershwin is now semi-retired—though he continues to work on a "callback" basis at the University of California, School of Medicine in Davis providing consultations for rheumatology and immunology patients. Gershwin CV at 1–2; Tr. at 56–57, 88–91. Throughout his career, Dr. Gershwin has evaluated both pediatric and adult patients, though he now sees fewer pediatric patients than he did earlier in his career. *Id.* at 91. He currently serves as the editor-in-chief of the Journal of Autoimmunity as well as several other publications focusing on autoimmunity. Tr. at 57–58; Gershwin CV at 5–6.

Dr. Gershwin is not a hematologist, but he has had occasion to evaluate patients with ITP. Tr. at 56–58, 91–93. He estimates that he sees approximately five or six patients a year who have previously been diagnosed with ITP—although their ITP is incidental to the reasons for these patients being referred to him, who are to be primarily treated for other autoimmune problems like lupus. *Id.* at 91–93.

Dr. Gershwin defined ITP as an immune-mediated disease that causes platelet destruction and is characterized diagnostically by low platelet counts. Tr. at 59, 93–94. Indeed, a diagnosis of ITP can only be confirmed with a platelet count, as a person may be suffering from ITP without exhibiting bruising, although additional observations like those seen on a physical examination or documented in photos may be helpful in arriving at this diagnosis. *Id.* at 95–98. ITP's cause has been the subject of intense study, with a vast number of potential etiologies identified—quinine and other drugs, immune deficiencies, wild rotavirus, *H. pylori* bacterial infections, and even some vaccines. Tr. at 62, 69–70, 94–95, 103. Dr. Gershwin specifically highlighted reports of ITP following MMR, Diphtheria/Pertussis/Tetanus ("DPT"), Prevnar, and rotavirus vaccination. *Id.* at 70 (citing S. Akbayram et al., *Vaccination Associated Acute Immune Thrombocytopenia Purpura in Children*, 4 J. Vaccines Vaccination 1, 1 (2014), filed as Ex. 11 on July 14, 2017 (ECF No. 26-3)).

To explain how vaccines can cause ITP, Dr. Gershwin invoked the concept of molecular mimicry. Tr. at 103, *citing* J. Nagasaki et al., *Postinfluenza Vaccination Idiopathic*

Thrombocytopenic Purpura in Three Elderly Patients, Case Reports in Hematology 1, 3 (2016), filed as Ex. 13 on July 14, 2017 (ECF No. 26-5) ("Nagasaki"). As he explained, molecular mimicry can occur when a vaccine antigen looks like "something on the membrane of the platelet" and there is subsequent cross-reactivity between antibodies targeting the vaccine antigen and the platelets. Tr. at 63, 65. Dr. Gershwin emphasized, however, that the similarities between the vaccine antigen and platelet cells do not have to be identical, but instead require some combination of sequential, structural, and special homologies. *Id.* at 63–64. He also noted that T cells may play a role in the destruction of platelets, but studying their function in autoimmune disease is far more difficult than understanding what B cells do in manufacturing autoantibodies. *Id.* at 65 (citing Nagasaki at 3). Molecular mimicry is also considered a plausible explanation for the pathogenesis of ITP. First Gershwin Rep. at 9.

While Dr. Gershwin posited that any vaccine could potentially cause ITP, he deemed some vaccines—like MMR, DPT, and Prevnar—far more likely causal than others, such as Hib (and thus almost wholly focused his causation opinion on the second dose of PCV vaccine that C.L. received in August 2013). Tr. at 67–68, 84, 102–03; M. Böttinger et al., *Swedish Experience of Two Dose Vaccination Programme Aiming at Eliminating Measles, Mumps, and Rubella*, 295 Brit. Med. J. 1264, 1264–67 (1987), filed as Ex. 86 on Aug. 17, 2020 (ECF No. 57-6); J. Neiderud, *Thrombocytopenic Purpura After a Combined Vaccine Against Morbilli, Parotitis and Rubella*, 72 Acta Paediatrica Scandinavica 613, 613–14 (1983), filed as Ex. 85 on Aug. 17, 2020 (ECF No. 57-5); U. Nieminen et al., *Acute Thrombocytopenic Purpura Following Measles, Mumps and Rubella Vaccination. A Report on 23 Patients*, 82 Acta Paediatr 267, 267–70 (1993), filed as Ex. 87 on Aug. 17, 2020 (ECF No. 57-7); R. Wise et al., *Postlicensure Safety Surveillance for 7-Valent Pneumococcal Conjugate Vaccine*, 292 JAMA 1702, 1702–10 (2004), filed as Ex. 111 on Aug. 20, 2020 (ECF No. 60-1) ("Wise").

Dr. Gershwin admitted he could identify little direct evidentiary support in the medical literature for an association between *Prevnar* and ITP, but he attributed this to the fact that Prevnar has not been available for as long as vaccines more definitely recognized as causal, like the MMR vaccine. Tr. at 104. He did point to a prescriber reference in support of his opinion, arguing that it evidenced the manufacturer's awareness of an association between the Prevnar vaccine and relapses in previously stabilized ITP patients. *Id*. at 65–66, 103–04, 184 (citing Prescriber's Digital Reference, Pneumococcal Vaccine Polyvalent – Drug Summary, https://pdr.net/drug-summary/Pneumovax-23-pneumococcal-vaccine-polyvalent-373 (last visited Apr. 9, 2021), filed as Ex. 8 on June 22, 2017 (ECF No. 24-3) ("PDR")).

The PDR notes that treaters administering the PCV vaccine should do so with caution in patients with ITP, because the vaccine "has been associated with relapse of this condition." PDR at 5. This, according to Dr. Gershwin, suggests that some component of the Prevnar vaccine is a

mimic giving rise to cross-reactivity—though he later admitted that he would not advise against vaccination generally for individuals with chronic but stable ITP. Tr. at 66–67, 105. He otherwise acknowledged that he was not able to identify a specific homology, in terms of amino acid sequence, between the Prevnar vaccine and protein structures on a platelet cell's membrane, but argued that to require such specific evidence was "unfair" because there are many unknowns when it comes to even the most well-studied autoimmune conditions. *Id*. at 183.

Dr. Gershwin further attempted to fill this evidentiary "gap" on an association between Prevnar and ITP by applying what is known about how other vaccines—namely, the DPT vaccine—can cause ITP. Tr. at 67, 84. The Prevnar vaccine, he explained, is conjugated with a diphtheria carrier protein in order to increase immunogenicity against the vaccine's primary antigen—the polysaccharide capsule of *S. pneumoniae* bacteria. *Id*. Dr. Gershwin's theory is thus predicated on the assumption that because both the DPT and Prevnar vaccines contain diphtheria proteins, and because DPT is more credibly associated with ITP, the Prevnar vaccine could also be causal. *Id*.

In addition, Dr. Gershwin sought to rebut some of the evidence referenced by Respondent purporting to undermine an association between Prevnar and ITP. Thus, when questioned about the lack of any known association between ITP and the wild *S. pneumoniae* bacterium, Dr. Gershwin explained that unlike viral infections, pneumococcal infections are treated rapidly and aggressively with antibiotics, and thus the relevant infections do not run their full course (such that the association between the wild bacterium and condition would be discerned). Tr. at 183–84. Similarly, Dr. Gershwin attempted to address the fact that the Vaccine Adverse Events Reporting System ("VAERS")[13] (according to a 2016 article submitted by Respondent) had documented only *seventeen* instances of ITP following receipt of the Prevnar vaccine. Tr. at 151, 184–85 (referencing S. Gupta & D.C. Brennan, *Pneumococcal 13-Valent Conjugate Vaccine (Prevnar 13) – Associated Immune Thrombocytopenic Purpura in a Renal Transplant Recipient: A Case Report*, 48 Transplantation Proceedings 262, 262–64 (2016), filed as Ex. D on Jan. 26, 2018 (ECF No. 37-2) ("Gupta")). In Dr. Gershwin's view, VAERS likely undercounted relevant instances ("for every [adverse reaction] report, there's probably at least another tenfold or more that aren't reported" and "in a pediatric population, only about 5 percent ever get reported"), and therefore VAERS

[13] VAERS was created by the Vaccine Act to collect information concerning incidents in which a person suffers an adverse health event soon after receiving a vaccination. Section 25(b)(1); *E.S. v. Sec'y of Health & Hum. Servs.*, No. 17-480V, 2020 WL 9076620, at *13 n.40 (Fed. Cl. Spec. Mstr. Nov. 13, 2020). Under the VAERS system, vaccine administrators and manufacturers are required to report any adverse health event suffered by a person soon after a vaccination, without regard to whether there is reason to believe that the vaccination caused the injury. *Id*. VAERS reports, however, can be submitted by anyone, whether a medical or health official or not. *Id.*

reports do not "have the magnitude or the power calculations…to support the issue."[14] Tr. at 184–85.

To explain how the Prevnar vaccine could initiate *chronic* ITP (rather than a single, self-limiting case of acute ITP), Dr. Gershwin first noted that genetic diversity gives rise to variable immunologic responses, making it difficult to predict how *any* given individual will respond to infection or vaccination. Tr. at 60 (citing N. Dhiman et al., *Immune Activation at Effector and Gene Expression Levels after Measles Vaccination in Healthy Individuals: A Pilot Study*, 66 Hum. Immunology 1125, 1125–36 (2005), filed as Ex. 91 on Aug. 17, 2020 (ECF No. 58-1)). In some individuals, the immune response may reach "an avidity or affinity" such that the production of certain antibodies becomes permanent. Tr. at 111. Alternatively, in the case of determinant spreading, the initial autoimmune cross-reaction will "mature and change," perpetuating an ongoing autoimmune response. *Id.* at 112.

Regardless of precise mechanism, Dr. Gershwin opined that C.L.'s diagnosed chronic ITP was perpetuated by the Prevnar vaccine—and in so maintaining he also relied on a review of her medical records to establish how his causation theory had occurred in actuality. He began by noting that C.L. did not appear to have any significant medical problems prior to receiving her August 2013 vaccinations. Tr. at 66, 70–73. Of course, the medical record in the immediate months thereafter also shows no evidence at all of any symptoms that might suggest ITP in an obvious clinical manner, like petechiae or abnormal bruising or low platelet levels, or even slight post-vaccination malaise—a fact Dr. Gershwin readily acknowledged. *Id.* at 73–80. The medical record for C.L.'s January 2014 appointment with her pediatrician was similarly devoid of any documentation relating to abnormal bruising or low platelet levels, and instead focused on C.L.'s upper respiratory infection. *Id.* at 73–74. Dr. Gershwin nevertheless was persuaded by the photographs provided by Ms. Loyd (discussed below) that C.L. likely had experienced unexplained bruising long before—likely beginning in September 2013. *Id.* at 83–84.

Dr. Gershwin also focused on the specific record from C.L.'s February 3, 2014 pediatric visit. At that time, Ms. Loyd had reported that (as reflected in the relevant contemporaneous record) C.L. was "not herself" following vaccines generally, and thus she likely had felt similarly after her August 2013 vaccinations. Tr. at 74. Although post-vaccination fever and malaise are not uncommon, fatigue is also associated with ITP—though Dr. Gershwin provided no explanation for this associated symptom. *Id.* at 74–75. At most, he speculated that it could be the result of

[14] There is no small irony in a petitioner's expert arguing that VAERS data should be given minimal weight. Far more often than not, petitioners rely *heavily* on VAERS reports of vaccine reactions to bulwark their causation theories, even though as a general matter VAERS only establishes post-vaccination temporal reactions, and thus has little causal evidentiary value. *Flores v. Sec'y of Health & Hum. Servs.*, No. 10-489V, 2013 WL 5587390, at *13 (Fed. Cl. Spec. Mstr. Sept. 12, 2013).

immune-mediated inflammation, indicating that such an association has been described in scientific and medical literature. *Id.* at 76. Dr. Gershwin further contended that the CBC that was ordered during the February 3rd visit occurred because of Ms. Loyd's reports of abnormal bruising. *Id.* at 106. He again conceded, however, that the medical record does not include any documentation relating to bruising at this time—and in fact indicates that there were "[n]o parent concerns." *Id.* at 107 (referencing Ex. 2 at 36).

C.L.'s medical record from her next sick visit, in March 2014, lacks any documentation of ITP-related symptoms or concerns. Ex. 2 at 42–44. Dr. Gershwin opined that this omission was likely because C.L.'s pediatrician hadn't "figured [it] out yet," but he later acknowledged that C.L.'s ITP was not clinically obvious during this visit. Tr. at 79–80. Only in June 2014 did C.L.'s symptoms became apparent to her pediatrician, and it was shortly thereafter that she received her ITP diagnosis. *Id.* at 80–81. Though C.L. was initially diagnosed with "acute" ITP, Dr. Gershwin explained that her overall course—which has lasted for more than six months—is more consistent with chronic ITP. *Id.* at 109–10. Dr. Gershwin also emphasized the pediatrician's note indicating "patient cannot receive immunizations at this time," adding speculatively that Dr. Heimback-Graham likely would have identified Prevnar as the cause if the association was better known. *Id.* at 81–82.

Dr. Gershwin struggled to explain the normal CBC platelet count that C.L. displayed in February 2014—a little more than five months after vaccination, and then almost four months before any treater observed *both* clinical and lab evidence of any form of ITP. The record clearly established the CBC panel ordered at Ms. Loyd's request revealed a normal platelet level of 340,000. Id. at 112–13; Ex. 2 at 40. Dr. Gershwin contended, however, that ITP can have a waxing and waning course—especially if the patient is experiencing a concurrent infection or fever. Tr. at 76–79, 99 (citing A. Lateef & Y.K. Kueh, *Severe Intra-Abdominal Haemorrhage: A Consequence of Two Coinciding Events*, 48 Sing. Med. J. e237, e237–39 (2007), filed as Ex. 25 on Feb. 7, 2018 (ECF No. 38-5) ("Lateef"); J. Schaider et al., *Rosen & Barkin's 5-Minute Emergency Medicine Consult* 588–89 (4th ed. 2010), filed as Ex. 26 on Feb. 12, 2018 (ECF No. 39-1) ("Rosen & Barkin"); G.C. Wong & L.H. Lee, *A Study of Idiopathic Thrombocytopenic Purpura (ITP) Patients over a Ten-year Period*, 27 Annals Acad. Med. Sing. 789, 789–93 (1998), filed as Ex. 24 on Feb. 7, 2018 (ECF No. 38-4) ("Wong")).

Lateef describes a twenty-four-year-old woman who suffered from chronic ITP and subsequently developed internal bleeding due to a ruptured ovarian follicle. Lateef at e237. The authors of the report acknowledged that the severity of a patient's ITP can wax and wane. *Id.* at e238. Similarly, both Wong and Rosen & Barkin note that patients with chronic refractory ITP can experience a waxing/waning symptom pattern, and added that these patients do not typically respond to treatments. Rosen & Barkin at 588, Wong at 792. But Wong also emphasizes that

spontaneous remission of chronic ITP (i.e., platelet levels returning to a fully-normal range) is rare. Wong at 792.

Dr. Gershwin also noted that C.L.'s March 2014 pediatric visit was attributable to her having symptoms consistent with an upper respiratory infection. Tr. at 100–01. Remission of ITP (meaning an increase in platelets) due to infection can last for several weeks, and may be attributable to changes in the "avidity or affinity of the antibody…or the cytotoxic T cells." Tr. at 79, 98. He again referenced the existence of studies to support this theory, but (again) failed to provide specific citations to that literature. *Id*. at 98–99. Dr. Gershwin later admitted, however, that there are no studies describing the timeframe for waxing/waning of ITP due to intercurrent infection, and that the "kinetics" associated with T cell involvement is not currently known. *Id*. at 100. He thus could not say with certainty whether any upper respiratory infection C.L. had been experiencing at this time would have raised C.L.'s platelet levels (although the record does show that C.L. likely had an upper respiratory infection in mid-January of that year). *Id.* at 101. Indeed, he conceded that it is not possible to predict whether an upper respiratory infection will actually produce waxing or waning of platelets in ITP patients. *Id*. at 101. Nothing else he specifically cited, in his report or at trial, suggests that levels of platelets could drop at the onset of ITP and then swing back to a robust and fully normal level months later, only to thereafter drop precipitously again.

Since the ITP diagnosis was first proposed for C.L. in June 2014, C.L.'s platelet levels have remained consistently low, and it is not apparent from the record that the waxing and waning platelet level pattern described by Dr. Gershwin—abnormal, to normal/remission, to abnormal again—continued after C.L. received her diagnosis. Tr. at 114. He did admit, however, that the difference in C.L.'s platelet levels from 340,000 in February 2014 to 23,000 in June that same year was particularly dramatic. *Id*. at 112–13. But he maintained that such a significant drop in platelet levels is consistent with ITP, especially "in the presence of the viral infection" such as the one C.L. experienced in February 2014. *Id.* In the absence of infections, Dr. Gershwin would not expect to see such dramatic variance in platelet levels, even when a patient experiences a waxing and waning symptom pattern. *Id.* at 113.

Finally, Dr. Gershwin opined that the onset of C.L.'s chronic ITP likely occurred within a few weeks of her August 2013 vaccination, a timeframe he deemed medically acceptable. Tr. at 84–85. In so doing, however, he relied heavily on Ms. Loyd's testimony plus the photographs she took of C.L.'s bruising, beginning purportedly in September 2013. *Id.* at 70, 83–84, 102. He agreed, however, that if onset was found to have occurred any time between January and June 2014 (five to ten months after vaccination), a causal relationship with the August vaccinations would not be supported. *Id.* at 115; Second Gershwin Rep. at 1. In his view, the adaptive immune response (critical to production of platelet-targeting antibodies) would be activated for up to six

weeks following vaccination—but no longer. Tr. at 85, 115. Dr. Gershwin also reiterated that ITP can be insidious for long periods, as well as his view that normal platelet counts in an ITP patient can sometimes be attributable to intervening viral infections. *Id.* at 84, 97.

C. Respondent's Experts

1. *John Strouse, M.D., Ph.D.*

Dr. Strouse, a pediatric hematologist, provided four reports and testified at the entitlement hearing on Respondent's behalf. Tr. at 117–60; Dr. Strouse Expert Report, filed as Ex. A on Dec. 5, 2017 (ECF No. 32-1) ("First Strouse Rep."); Second Strouse Report, filed as Ex. I on Apr. 12, 2018 (ECF No. 41-1) ("Second Strouse Rep."); Third Strouse Report, filed as Ex. V on Oct. 8, 2020 (ECF No. 66-1) ("Third Strouse Rep."); Fourth Strouse Report, filed as Ex. Z on Nov. 30, 2020 (ECF No. 81-2) ("Fourth Strouse Rep."). Based upon his review of the medical record and supporting literature, Dr. Strouse opined that C.L.'s chronic ITP was more likely than not unrelated to the vaccines she received in August 2013. First Strouse Rep. at 3; Tr. at 125.

Dr. Strouse received his bachelor's degree from Princeton University before obtaining his medical degree and Ph.D. from Johns Hopkins University School of Medicine and Public Health respectively. Dr. Strouse Curriculum Vitae, filed as Ex. B on Dec. 5, 2017 (ECF No. 32-2). He thereafter completed his residency training in pediatrics at the University of Rochester. *Id.* at 2. He then completed fellowship training in pediatric hematology and oncology at the National Institutes of Health and Johns Hopkins University. *Id.* Dr. Strouse currently serves as a temporary instructor in medicine and pediatrics at the Duke University School of Medicine. *Id.* He is board-certified in pediatric hematology and oncology, and has extensively published on topics within those fields. *Id.* at 1, 2–8; Tr. at 118–20. In addition to his teaching duties, Dr. Strouse spends approximately forty percent of his time in clinical practice, with about half of his patients presenting with sickle cell anemia and the other half presenting with various blood disorders. Tr. at 120–21. Of these, Dr. Strouse diagnoses approximately ten cases of ITP a year. *Id.* at 122.

Dr. Strouse began by describing ITP as a condition in which an individual's blood platelet count falls below 100,000 without any other identifiable cause. Tr. at 123–24. The onset of chronic ITP can be insidious, making it difficult to diagnose, and etiologies are rarely identified. *Id.* at 124, 134–35. Dr. Strouse allowed, however, that immune challenges, including vaccination, can trigger its onset. *Id.* at 153. Patients suffering from ITP may present with bruising, and children can also have fatigue (as Dr. Gershwin maintained), but blood tests are ultimately required to make a formal diagnosis. *Id.* at 124, 153, 155–57.

Based on the foregoing, Dr. Strouse considered C.L.'s medical history and what he felt it revealed. There was no evidence C.L. was suffering from ITP prior to receiving her August 2013 vaccinations. Tr. at 152. But thereafter—between August 2013 and June 2014—the medical record was similarly devoid of any evidence that C.L. was experiencing symptoms of ITP, despite having seen her pediatrician on several occasions during this timeframe. *Id.* at 127–32. Not until June 2, 2014, did the record set forth symptoms Dr. Strouse deemed consistent with ITP. *Id.* at 133 (citing Ex. 2 at 46–47, 52). From that point on, the records showed no instances in which C.L.'s platelets ever returned to a normal range. *Id.* at 142. Thus, although Dr. Strouse agreed that C.L.'s initial presentation was acute, her overall illness was best characterized as chronic because her ITP has persisted for more than twelve months. *Id*. at 133–35.

According to Dr. Strouse, the onset of C.L.'s ITP likely did not occur before May 2014 (just prior to the June 2014 pediatric visit), a timeframe that (even by Dr. Gershwin's admission) would not support a causal association between her diagnosis and her August 2013 vaccinations. Tr. at 125, 139. If C.L.'s ITP had instead begun in September 2013 as was suggested by Dr. Gershwin, Dr. Strouse would have expected to see evidence of bruising and low platelet counts documented in the contemporaneous medical record. *Id.* at 158. Instead, the record does not describe any concerns for bruising until long after, and clearly indicates (given the testing results) that C.L.'s platelet levels were normal in February 2014. *Id.*

In opining as he did, Dr. Strouse took direct aim at the "intercurrent infection" component of Dr. Gershwin's theory as explaining C.L.'s normal platelet count when measured in February 2014. Tr. at 126, 139–40. Dr. Strouse agreed as a general matter that viral infections can stimulate platelet production, although he noted that this will only occur when there is "an incredibly powerful inflammatory stimulus," and thus would not likely be induced by a typical upper respiratory infection. *Id.* at 140–41; *see also* Second Strouse Rep. at 1 (citing M. Vranou et al., *Recurrent Idiopathic Thrombocytopenic Purpura in Childhood*, 51 Pediatric Blood Cancer 261, 263 (2008), filed as Ex. J on Apr. 12, 2018 (ECF No. 41-2) ("Vranou")). Moreover, an exponential increase in platelet levels like that experienced by C.L. (given her 340,000 readings in February 2014, compared to the allegedly far lower levels she would have experienced in September 2013 after her purported onset) "would be quite unusual." Tr. at 141. Indeed, Dr. Strouse noted that he had never seen such a wildly divergent wax/wane pattern in all his years of clinical practice as a hematologist. *Id.* at 126. And he criticized the possibility that C.L.'s February 2014 platelet count represented spontaneous remission, only to be followed by a subsequent relapse in her symptoms manifesting in the spring. *Id.* at 126, 140–41, 144, 159–60.

Dr. Strouse also reviewed, and commented upon, the photographic and anecdotal evidence Dr. Gershwin had relied on to substantiate a September 2013 onset. He found the photographs to lack clarity in the bruising they purportedly evidenced. Tr. at 125–26, 128–29. While he agreed

that the photos showed bruises of some kind, he could not conclude they were the result of any pathology, adding that none of the photos clearly demonstrate petechiae. *Id*. at 136–38. He emphasized that unexplained bruising in young children is fairly common, can be highly variable, and often appear on the head and legs given the activities of young children, and that this could explain the photo evidence. *Id*. at 128–29, 153–54. Otherwise, the apparent lack of antecedent events to explain each bruise did not make C.L.'s case unusual. Tr. at 154–55.

Finally, Dr. Strouse spent some time discussing the underlying contention that the Prevnar vaccine could cause ITP (although his lack of direct immunologic expertise rendered this part of his opinion somewhat less reliable). The Gupta article referenced by Dr. Gershwin, for example, was of interest to Dr. Strouse because it described a single case of ITP following receipt of the Prevnar vaccine. Gupta at 2–4. But Dr. Strouse distinguished Gupta, observing that the subject was undergoing immunosuppressant treatments due to a kidney transplant, and was therefore *more* susceptible to autoimmune diseases like ITP. Tr. at 143. These confounding variables made reliance on Gupta to establish a causal association between Prevnar and ITP more dubious. *Id.* at 143–44.

Dr. Strouse further discussed Wong, which described the waxing and waning nature of ITP. *See generally* Wong; Tr. at 144–45. He highlighted, however, that spontaneous remission was not observed in any of the study participants. Tr. at 144–45*;* Wong at 793. And the waxing and waning patterns described in Wong were not equivalent to the dramatic fluctuations that would necessarily have occurred under Petitioner's theory. Tr. at 144–45; Wong at 793. At best, Dr. Strouse allowed that immune stimulation might in some cases cause platelet levels to increase from 30,000 to 50,000, but it would not result in the ten-fold increase described by Dr. Gershwin when he discussed the February 2014 CBC results. Tr. at 144–45.

In contrast to Petitioner's proffered literature, Dr. Strouse reviewed some epidemiological studies that specifically sought to determine whether an association between the Prevnar vaccine and ITP can be drawn. Tr. at 147–50 (citing S. O'Leary et al., *The Risk of Immune Thrombocytopenic Purpura After Vaccination in Children and Adolescents*, 129 Pediatrics 248, 248–53 (2012), filed as Ex. C on Jan. 26, 2018 (ECF No. 37-1) ("O'Leary"); H.F. Tseng et al., *Postlicensure Surveillance for Pre-specified Adverse Events Following the 13-Valent Pneumococcal Conjugate Vaccine in Children*, 31 Vaccine 2578, 2578–83 (2013), filed as Ex. G on Jan. 26, 2018 (ECF No. 37-5) ("Tseng")). In O'Leary, researchers sought to identify a causal relationship between vaccines and ITP in young children. O'Leary at 249. O'Leary identified 197 cases of ITP out of 1.8 million children in the cohort. *Id.* at 248. Of these, only thirty-eight had received a vaccine within forty-two days of onset, and only six developed chronic ITP. *Id.* at 250. Ultimately, O'Leary concluded that there was no increased risk of ITP following vaccination with Prevnar, though an association was seen following receipt of the MMR vaccine. Tr. at 147–48;

O'Leary at 250. Similarly, Tseng found no greater incidence of ITP following receipt of the Prevnar vaccine, and like O'Leary, post-vaccination incidence rates of ITP did not exceed the expected incidence rate in unvaccinated populations. Tseng at 2581; Tr. at 148–50.

2. *Andrew MacGinnitie, M.D., PhD.*

Dr. MacGinnitie, a pediatric immunologist, offered two expert reports and testimony at the entitlement hearing on Respondent's behalf. Tr. at 160–82; Dr. MacGinnitie Expert Report, filed as Ex. K on Oct. 5, 2020 (ECF No. 62-1) (First MacGinnitie Rep."); Dr. MacGinnitie Supplemental Report, filed as Ex. Y on Nov. 30, 2020 (ECF No. 81-1) ("Second MacGinnitie Rep."). He opined that C.L.'s chronic ITP was unrelated to receipt of the Prevnar vaccine. Tr. at 166.

Dr. MacGinnitie is an attending physician and the Clinical Director for the Division of Immunology at Boston Children's Hospital in Boston, Massachusetts. Dr. MacGinnitie Curriculum Vitae, filed as Ex. L on Oct. 5, 2020 (ECF No. 62-2) ("MacGinnitie CV"); Tr. at 161–62. He is also an Associate Professor of Pediatrics at Harvard Medical School. MacGinnitie CV at 1–2. Dr. MacGinnitie received his undergraduate degree from Yale University, followed by both a medical degree and Ph.D. from the University of Chicago. *Id.* at 1. He thereafter completed his residency, followed by a fellowship in allergy and immunology at Boston Children's. *Id.* He is board certified in pediatrics and allergy and immunology, and has been in practice as an allergist/immunologist since 2004. Tr. at 163; MacGinnitie CV at 10. Ninety-five percent of his patients are children, and he estimated that he spends two-thirds of his time treating patients in a clinical setting. *Id.* at 163–64. Dr. MacGinnitie's research focuses on food allergies, and he serves on the editorial board of the journal Annals of Allergy, Asthma and Clinical Immunology. *Id.* at 163–64. Though he has occasionally evaluated patients suffering from ITP, Dr. MacGinnitie is not a hematologist, and his experience with ITP patients is limited to treating their underlying or concurrent immune deficiencies. *Id.* at 164–65.

Dr. MacGinnitie accepted that the pathogenesis of ITP involves an autoimmune process, even if the exact cause of ITP remains unknown. Tr. at 170. He also allowed that *some* vaccines, such as the MMR vaccine, are reliably associated with ITP, but strenuously contested Dr. Gershwin's contention that *any* vaccine can be similarly causal—including Prevnar. *Id.* at 168, 170.

To support his position, Dr. MacGinnitie highlighted facial distinctions between what is known about the vaccines that are considered likely causal of ITP and Prevnar. Wild measles infections, for example are associated with the development of ITP, lending support to the idea that the MMR *vaccine* might similarly be causal. *Id.* at 168, 179–80; J. Rajantie et al., *Vaccination Associated Thrombocytopenic Purpura in Children*, 25 Vaccine 1838, 1840 (2007), filed as Ex. N

on Oct. 5, 2020 (ECF No. 62-4). But wild *S. pneumoniae* infections are not known to increase the risk of developing ITP. Tr. at 168–69, 181. In addition, differences in vaccine formulation were relevant to causality in Dr. MacGinnitie's view. The MMR vaccine is a live attenuated vaccine containing live fragments of the wild virus, whereas the Prevnar vaccine is a "subunit" vaccine containing pneumococcal bacteria components that cannot replicate. *Id.* at 169. And there is a lack of epidemiological evidence persuasively linking either the Prevnar or Hib vaccine to the development of ITP, in comparison to the MMR vaccine. *Id.* at 169, 179. Dr. MacGinnitie therefore cautioned against applying what is known about ITP following the MMR vaccine to an entirely distinguishable vaccine. *Id.*

Dr. MacGinnitie next moved to a broader evaluation of the immune system's functioning and how vaccines would impact it, sometimes pathologically. As he noted, Petitioner had put forward the general proposition that vaccines stimulate the immune system, but in some instances will cause an aberrant, autoimmune reaction via the mechanism of molecular mimicry. *Id.* at 170, 172. But in order for the molecular mimicry theory to be reliably applied as explaining a disease caused by vaccination, there should be in Dr. MacGinnitie's view evidence of (a) homology between the presenting antigen and a self-structure, and (b) some actual cross-reactivity. *Id.* at 172. Homology alone is not enough to reliably predict cross-reactivity, given the prevalence in nature of amino acid sequence homology in proteins throughout the body. *Id.* at 172–74.

Even with such naturally-occurring homology, however, autoimmune disease remains rare. Tr. at 175. Rather, self-regulating mechanisms in the immune process naturally protect against autoimmunity. Tr. at 176–77. B cells, for example, that have the capacity to recognize self-antigens (and thus manufacture autoantibodies that could participate in a cross reaction) are typically deleted during development, while the thymus helps regulate the maturation of healthy T cells and destruction of those likely to induce autoimmunity. *Id.*; *see also* N. Cooper & J. Bussel, *The Pathogenesis of Immune Thrombocytopaenic Purpura*, Brit. 133 J. Haematology 364, 365 (2006), filed as Ex. R on Oct. 5, 2020 (ECF No. 62-8) ("Cooper"). Conversely, if these regulatory processes are inhibited with immunosuppressive therapies, the risk of autoimmunity is increased. Tr. at 177.

Dr. Gershwin's theory thus (in Dr. MacGinnitie's view) flies in the face of the low likelihood generally of pathologic autoimmunity, especially in the absence of proof that cross-reactivity would occur under circumstances of receipt of Prevnar. Indeed, Dr. Gershwin did not even attempt to identify homologies between any component of the Prevnar vaccine and blood platelets, rendering his molecular mimicry conclusions especially speculative. *Id.* at 173.

Dr. MacGinnitie also criticized Petitioner's reliance on Gupta to establish causation, questioning the evidentiary value of a single case report. Tr. at 177–78. He further noted (consistent

with Dr. Strouse's testimony) that the Gupta subject patient had been undergoing immunosuppressive therapies following kidney transplantation, making it wholly distinguishable from C.L.'s case (since those therapies independently greatly increased the chance of an autoimmune reaction). *Id.* at 178. By contrast, articles like O'Leary—an epidemiological study of 1.8 million children between six and eleven months of age that did not find an increased risk of ITP following vaccination with Prevnar—deserved far more attention on the issue of causation, in Dr. MacGinnitie's view. *Id.* at 178–79; O'Leary at 250.

Besides offering testimony on the causation issues, Dr. MacGinnitie also commented on the medical record, concluding that C.L. did not have ITP as of February 2014 when her CBC revealed a platelet count within normal limits. Tr. at 167. Though he agreed the photographs taken by Ms. Loyd in September 2013 and thereafter showed some evidence of bruising, Dr. MacGinnitie did not observe petechiae, and he opined that this bruising was therefore likely typical for a child her age. *Id.* Instead, and consistent with Dr. Strouse, Dr. MacGinnitie proposed that onset of C.L.'s ITP occurred in May 2014, just prior to the incident where C.L. fell into the baby gate and developed distinctive bruising. *Id.* at 166.

In so concluding, Dr. MacGinnitie disputed Petitioner's argument that C.L.'s ITP course had waxed and waned (sometimes invisibly) over many months post-vaccination. Dr. MacGinnitie instead noted that the medical record established consistently that C.L.'s platelet levels—once below the normal range documented in February 2014—never once rebounded. Tr. at 168. And any fluctuations she experienced were minor, and did not reflect rebounds of a hundred thousand platelets or more. *Id.* This record—of consistently low platelet levels after June 2014—was most consistent with the conclusion that onset occurred not long before that date. The eight-month period between C.L.'s August 2013 vaccination and likely onset in May 2014 was simply too lengthy to associate the vaccine with the first confirmed record evidence of ITP. *Id.* at 170.

III. *Other Evidence*

1. Treating Expert – David Berger, M.D.

Dr. Berger, one of C.L.'s treating physicians, offered a letter in support of Petitioner's claim, but he did not testify at the entitlement hearing. Dr. Berger Letter, filed as Ex. 9 on July 14, 2017 (ECF No. 26-1) ("Berger Letter").

Dr. Berger received his bachelor's degree from Lehigh University before obtaining a medical degree from the Medical College of Pennsylvania. Dr. Berger Curriculum Vitae, filed as Ex. 10 on July 14, 2017 (ECF No. 26-2). He then completed residency training at the University of South Florida College of Medicine Department of Pediatrics. *Id.* at 1. Dr. Berger thereafter

worked as a board-certified pediatrician in Florida until opening his own office, "Wholistic Pediatrics" in Tampa, Florida in 2005. *Id.* Dr. Berger has routinely lectured on topics including biological treatments for autism and "The Biological Plausibility of a Relationship between Vaccines and Autism Spectrum Disorder" at the Defeat Autism Now! ("DAN!") Conference.[15] *Id.* at 2–4.

The filed record establishes that Dr. Berger first treated C.L. in September 2015. Ex. 5 at 1–5. Dr. Berger opines in his letter that the onset of C.L.'s ITP likely occurred in early September 2013. *See generally* Berger Letter. This conclusion was largely based, however, on conversations Dr. Berger had with Ms. Loyd, in addition to the photographs she provided. *Id.* Relying on this conclusion and case reports of ITP following vaccination, Dr. Berger opined that C.L.'s condition was more likely than not the result of the Prevnar vaccine she received in August 2013. *Id.*

2. Photographic Evidence

Prior to the entitlement hearing, Petitioner filed six color photographs of C.L. purporting to establish clinical manifestations of the bruising and petechiae associated with ITP, and she discussed them at trial. Tr. at 11–15; Ex. 6, filed June 22, 2027 (ECF No. 24-1). Ms. Loyd specifically alleged that she had taken these photos and shown them to C.L.'s pediatrician, Dr. Heimback-Graham during her December 2013 visit. That discussion was not documented in the medical record, although Petitioner maintains that Dr. Heimback-Graham dismissed her concerns. Tr. at 41, 44–45.

The first photograph Ms. Loyd discussed purportedly shows a bruise on C.L.'s forehead when she was approximately seven-and-a-half months old. Tr. at 11; Ex. 6 at 1. She was unable to think of any injury that would have caused this bruise, and instead believes that it developed spontaneously. Tr. at 11. The second photo, dated September 13, 2013, is a magnified view of a bruise that Ms. Loyd again believes developed spontaneously. Tr. at 12; Ex. 6 at 2. The next photograph, dated September 18, 2013, shows tiny bruises, which Petitioner later learned were called petechiae. Tr. at 12–13; Ex. 6 at 3. These too seemed to appear without provocation. Tr. at 13–14. A photograph dated October 25, 2013, shows more bruising that appeared when C.L. was approximately eight months old and was trying to walk while holding onto surfaces. Tr. at 14; Ex. 6 at 3. The last photograph, dated November 23, 2013, shows blood under a fingernail purported

[15] DAN! is composed of doctors and medical professionals who believe, among other things, that autism can be caused by vaccines, and who often propose clinically-unsubstantiated treatments. *Murphy v. Sec'y of Health & Hum. Servs.*, No. 05-1060V, 2016 WL 3034047, at *4 n.12 (Fed. Cl. Spec. Mstr. Apr. 25, 2016), *mot. for review den'd*, 128 Fed. Cl. 348 (2016); *Holt v. Sec'y of Health & Hum. Servs.*, No. 05-0136V, 2015 WL 4381588, at *10 ns.41, 43 (Fed. Cl. Spec. Mstr. June 24, 2015; *Dwyer v. Sec'y of Health & Hum. Servs.*, No. 03–1202V, 2010 WL 892250, at *165 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

to be C.L.'s. Tr. at 15; Ex. 6 at 4. Ms. Loyd explained that these bruises also appear spontaneously, but they do not seem painful to C.L. Tr. at 15.

After the entitlement hearing, Petitioner filed three more photographs appearing to show bruising on C.L.'s head and feet. Photographs, filed as Exs. 124–26 on Nov. 6, 2020 (ECF No. 78). The first of these additional photographs was filed with the description, "Thanksgiving 2013 Photo showing bruises on head and hand, " the second with the description, "Sept 2013 Photo of Bruising on both legs," and the third with the description, "Photo of Bruise on Foot Dec 2013." *See* ECF No. 78. These descriptions, however, only appear on the docket entry and do not appear on the photographs themselves.

Importantly, I note that the filed photographs contained in Exhibits 6 and 124–26 have not been formally authenticated, temporally or otherwise. Many have no time stamp or other metadata indicator confirming they were taken at the dates alleged. At most, some of the photos have hand-drawn circles and dates (appearing to have been digitally applied by the Petitioner herself), and this coupled with her affidavit, in which she briefly mentions taking photographs of C.L.'s bruises, is how Petitioner would establish their authenticity. Tr. at 13; Affidavit at 1–2.

IV. *Procedural History*

After the claim's initiation on July 8, 2016, Petitioner filed additional medical records, and on December 2, 2016, Respondent filed his Rule 4(c) Report contesting Petitioner's entitlement to compensation. Respondent's Report, filed Dec. 2, 2016 (ECF No. 17-1). Between July 2016 and December 2019, the parties filed their expert reports and supporting literature. On August 7, 2020, Petitioner filed her pre-hearing Brief (ECF No. 51), and Respondent thereafter filed supplemental expert reports from Drs. Strouse and MacGinnitie. On October 5, 2020, Respondent filed his responsive pre-hearing Brief (ECF No. 63).

A one-day entitlement hearing was held in this matter on October 29, 2020. The parties filed simultaneous post-hearing briefs on January 8, 2021. Petitioner's Post-Hearing Brief, filed on Jan. 8, 2021 (ECF No. 82) ("Pet. Brief"); Respondent's Post-Hearing Brief, filed on Jan. 8, 2021 (ECF No. 83). The matter is now ripe for resolution.

V. *Applicable Law*

A. General Standards of Proof

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—

corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[16] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (2005) : "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation."

[16] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)). Petitioners otherwise always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence, regardless of what evidentiary level of evidence on the "can cause" prong is required. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Legal Standards Governing Factual Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and

testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd sub nom. Rickett v. Sec'y of Health & Hum. Servs*., 468 F. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then 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). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Dep't of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

There are, however, situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("'[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent'") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination

regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed 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. *Lalonde v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health*

& Hum. Servs., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Hum. Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Hum. Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

D. Consideration of Medical Literature

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. Consideration of Comparable Special Master Decisions

In reaching a decision in this case, I have considered other decisions issued by special masters (including my own) involving similar injuries, vaccines, or circumstances. I also reference some of those cases in this Decision, in an effort to establish common themes, as well as demonstrate how prior determinations impact my thinking on the present case.

There is no error in doing so. It is certainly correct that prior decision in different cases do not *control* the outcome herein.[17] *Boatmon v. Sec'y of Health & Hum. Servs.,* 941 F.3d 1351, 1358–59 (Fed. Cir. 2019); *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). Thus, the fact that another special master reasonably determined elsewhere, on the basis of facts not in evidence in this case, that preponderant evidence supported the conclusion that vaccine X caused petitioner's injury Y does not compel me to reach the same conclusion in *this* case. Different actions present different background medical histories, different experts, and different items of medical literature, and therefore can reasonably result in contrary determinations.

However, it is *equally* the case that special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs.,* 76 Fed. Cl. 328, 338–39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the *expertise and experience to know the type of information that is most probative of a claim*") (emphasis added). They would therefore be remiss in ignoring prior cases

[17] By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014). Special masters are also bound within a specific case by determinations made by judges of the Court of Federal Claims after a motion for review is resolved.

presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions. This is especially so given that special masters not only routinely hear from the same experts in comparable cases, but are also repeatedly offered the *same* items of medical literature regarding certain common causation theories. It defies reason and logic to obligate special masters to "reinvent the wheel," so to speak, in each new case before them, paying no heed at all to how their colleagues past and present have addressed similar causation theories or fact patterns. It is for this reason that prior decisions can have high persuasive value—and why special masters often explain how a new determination relates to such past decisions.[18] Even if the Federal Circuit does not *require* special masters to distinguish other relevant cases (*Boatmon,* 941 F.3d at 1358), it is still *wise* to do so.

ANALYSIS

I. *Overview of ITP and its Treatment as Vaccine Program Injury*

C.L.'s diagnosis is not in dispute—the parties agree that she suffers from the chronic form of ITP. Tr. at 28, 110, 114, 135, 142, 146. Some discussion of its nature, and treatment in Vaccine Program cases, is nevertheless warranted.

Although Petitioner has not asserted a Table claim in this case, the Vaccine Table includes ITP as cognizable injury after receipt of certain vaccines, like the MMR vaccine, and this Table definition helps illuminate the nature of the condition.[19] The Table defines ITP as "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 with normal red and white blood cell indices." 42 C.F.R. 100.3(c)(7). ITP occurs in about 100 per million people, with more than half of those cases occurring in previously healthy children. R. Concolini et al., *The Centenary of Immune Thrombocytopenia – Part 1: Revising Nomenclature and Pathogenesis*, 4 Frontiers in Pediatrics 1, 1 (2016), filed as Ex. 20 on Dec. 29, 2017 (ECF No. 35-2). Acute ITP generally resolves within three months, but persistent ITP can last anywhere between three and twelve months. V. Cecinati et al., *Vaccine Administration and the Development of Immune Thrombocytopenic Purpura in*

[18] Consideration of prior determinations is a two-way street that does not only inure to the benefit of one party. Thus, I would likely take into account the numerous decisions finding no association between vaccination and autism when confronted with a new claim asserting autism as an injury, and have informed such claimants early in the life of their case that the claim was not viable for just that reason. But I would *also* deem a non-Table claim asserting GBS after receipt of the flu vaccine as not requiring extensive proof on *Althen* prong one "can cause" matters, for the simple reason that the Program has repeatedly litigated the issue in favor of petitioners.

[19] The Table does not provide for a pneumococcal vaccine/ITP claim, but this fact is immaterial, since Petitioner does not advance a Table claim, and there is otherwise no dispute that C.L. experienced chronic ITP.

Children, 9 Hum. Vaccines & Immunotherapeutics 1, 2 (2013), filed as Ex. 16 on July 14, 2017 (ECF No. 26-8) ("Cecinati"). ITP is deemed to be chronic when it lasts longer than twelve months (as here). *Id.*

Vaccine-caused ITP has been reported in the medical literature, and is generally believed to be the result of an immune response because "antibodies can be detected on platelets in about 79% of cases." Cecinati at 2. While cases involving acute ITP have been litigated with regular success in the Vaccine Program, cases alleging *chronic* ITP following vaccination have seen more variable results. *See, e.g.*, *Flores v. Sec'y of Health & Hum. Servs.*, No. 18-759V, 2021 WL 837069 (Fed. Cl. Spec. Mstr. Feb. 1, 2021) (granting entitlement for a child whose MMR vaccine-induced ITP resolved, but nonetheless required platelet level monitoring for more than six months); *see also Phillips v. Sec'y of Health & Hum. Servs.*, No. 16-906V, 2020 WL 7767511 (Fed. Cl. Spec. Mstr. Nov. 23, 2020) (denying entitlement for a claim of chronic ITP following receipt of the flu and human papillomavirus ("HPV") vaccines); *Gramza v. Sec'y of Health & Hum. Servs.*, No. 15-247V, 2018 WL 1581674 (Fed. Cl. Spec. Mstr. Feb. 5, 2018) (denying compensation for a claim alleging chronic ITP post-HPV vaccination), *mot. for rev. denied*, 139 Fed. Cl. 309 (2018); *Doyle v. Sec'y of Health & Hum. Servs.*, No. 05-605V, 2009 WL 2973106 (Fed. Cl. Spec. Mstr. Aug. 28, 2009) (denying entitlement for a claim alleging chronic ITP following MMR vaccination), *mot. for review den'd,* 92 Fed. Cl. 1 (2010); *but see Cunningham v. Sec'y of Dep't of Health & Hum. Servs.*, No. 01-483V, 2005 WL 6114559 (Fed. Cl. Spec. Mstr. Apr. 20, 2005) (granting entitlement in favor of a petitioner with chronic ITP following receipt of the MMR vaccine).

I have identified no reasoned decisions finding that any version of the pneumococcal vaccine likely caused either acute or chronic ITP.[20]

II. *C.L.'s ITP Onset Most Likely Occurred in May 2014*

While the parties agree that C.L. developed chronic ITP, and that the condition was apparent (in the form of bruising and measured platelet levels) some time after C.L.'s August 2013 vaccinations, they do not agree on the matter of precisely *when* this occurred. Indeed, there is a six-month difference between the two competing proposed dates of onset. Because this fact issue informs Petitioner's overall theory, its resolution is paramount to the disposition of the entire case, and I will therefore address it at the outset.

[20] A handful of cases alleging ITP following receipt of a pneumococcal vaccine, including Prevnar, have been resolved through stipulations and proffers. *See, e.g.*, *Mason v. Sec'y of Health & Hum. Servs.*, No. 14-487V, 2017 WL 3814643 (Fed. Cl. Spec. Mstr. Aug. 4, 2017). But settled cases do not provide a reasonable guideline for decision, and cannot otherwise be relied upon in evaluating causation. *See, e.g.*, *Deshler v. Sec'y of Health & Hum. Servs.*, No. 16-1070V, 2020 WL 4593162, at *19 (Fed. Cl. Spec. Mstr. July 1, 2020).

Petitioner argues that C.L. more likely than not experienced onset no later than September 2013—approximately two weeks after vaccination. Tr. at 84–85; Second Gershwin Rep. at 1. She supported this proposition with her own testimony, the photographs she represents were taken in the Fall of 2013, and Dr. Gershwin's expert opinion regarding the waxing and waning nature of chronic ITP over a lengthy period of time. *Id.*; Ex. 6; Exs. 124–26. According to Dr. Gershwin, C.L. likely developed ITP beginning in September 2013, and its symptoms were observed by Petitioner that fall (although treaters did not take her concerns seriously). C.L.'s ITP was otherwise not acknowledged by medical treaters until June 2014, because her symptoms happened to wane (or go into remission entirely) just when C.L.'s blood count test was performed in February 2014. Tr. at 84–85. Dr. Gershwin forthrightly acknowledged, however, that any finding of onset at a later date—whether the early winter of 2014 or May/June 2014, when C.L.'s low platelet levels were first revealed through blood work—would be fatal to his theory. *Id.* at 115; Second Gershwin Rep. at 1.

Respondent, by contrast, argues that the onset of C.L.'s chronic ITP likely occurred in May 2014, shortly before she received her formal diagnosis, when C.L.'s bruising was first noted in the medical record, leading Petitioner to seek treatment on June 2, 2014. Tr. at 166–70. At this time, Petitioner informed treaters that she had noticed the bruising *two weeks prior* to the pediatric visit—with no mention of the alleged bruising from the prior fall. Ex. 2 at 46. Respondent also cited other parts of the medical record—specifically, the normal platelet count that was documented in February 2014, compared with the low levels consistent with an ITP diagnosis based on a second blood count test performed in June 2014—and the expert opinions of Drs. Strouse and MacGinnitie. Tr. at 127–33, 166–70; Ex. 2 at 40. Both of Respondent's experts also agreed that the photographs produced by Petitioner demonstrate *some* bruising, although it could be attributed to general childhood injuries distinguishable from ITP-associated bruising, and that the photos were otherwise inconclusive at best due to their poor resolution. Tr. at 125–26, 128–29, 136–38, 153–55, 167.

After considering the parties' respective positions and supporting evidence, I find that the onset of C.L.'s chronic ITP more likely than not occurred in May 2014, for several reasons. First, the contemporaneous medical record best supports the conclusion that onset was close-in-time to discovery of the low platelet levels in June 2014. C.L. was regularly seen by her pediatrician between August 2013 and June 2014, but not until early June was a low platelet count revealed from blood testing. Ex. 2 at 46–48; Tr. at 73–74. Although ITP can be insidious, with its initiation predating discovery (especially since the platelet decreases so relevant to the diagnosis are often only inadvertently discovered), it is not likely that C.L. was living with the condition for up to nine months without any outward sign whatsoever of its existence. In addition, the contemporaneous record from this time establish that Petitioner herself reported on June 2, 2014 that C.L. had experienced bruising "over the past two weeks" and "[excessive] bruising started 2-3 weeks

ago"—not that it had been persistent for months but worsened to the point where she felt intervention was required.[21] Ex. 2 at 46; Ex. 4 at 5. It was this bruising that led to the performance of the second platelet count test.

Second, and more importantly, Petitioner's onset theory—of a lengthy, subacute condition that was ignored or missed by treaters, despite Petitioner's voiced concerns—is greatly undercut by other aspects of the medical record. The record contains no evidence of complaints by Petitioner about bruising prior to May/June 2014. But even if I assume that Petitioner did raise such concerns but Dr. Heimback-Graham failed to document them, unrebutted medical record proof establishes that C.L. had *normal* platelet counts (the 340,000 count from the February 2014 CBC test) several months prior to the bruising that resulted in the second blood test and subsequent June 2014 ITP diagnosis. Tr at 40.

For Petitioner's onset theory to be preponderantly valid, she would need to demonstrate that C.L.'s lowered platelet levels began in the early fall of 2013, then rebounded dramatically when tested in the winter—in effect, that she experienced total remission—only to drop precipitously again when tested a second time in June 2014. But based on what is known about how chronic ITP progresses (and corroborated by C.L.'s own experience after June 2014—her platelet levels never appear to have again gone into normal levels, despite some fluctuation at a lower-than-usual level), this kind of course is highly unlikely. Respondent's experts (including Dr. Strouse, the only hematologist who testified in this matter)[22] persuasively explained the deficiencies in this contention. Second Strouse Rep. at 1; First MacGinnitie Rep. at 6. The degree of waxing and waning in platelet levels alleged by Petitioner—or an intervening/spontaneous remission—has not been preponderantly established with sufficiently reliable evidence.

Third, Petitioner's *explanation* for this purported see-saw course was not supported with enough preponderant evidence to rebut Respondent's more persuasive arguments. Petitioner has proposed that intervening infectious processes could cause platelet counts to transiently increase—thus in effect "masking" the underlying disease/condition while the infection was present. Tr. at 77–79, 84–85; Wong at 792; Third Gershwin Rep. at 1. The medical record suggests C.L. had one or two upper respiratory infections between January and March 2014, and thus (Dr. Gershwin

[21] It is not uncommon in the Vaccine Program for claimants to delay treatment of vaccine-related injuries, out of the reasonable belief that the injury may be transient, or the desire to avoid unnecessary medical interventions. Yet, more often than not, when this occurs the claimant *will* report to the treater how long the condition has existed—and, if suspected to be vaccine-caused, will relate this to the vaccine's date. *Cooper v. Sec'y of Health & Hum. Servs.*, No. 17-114V, 2018 WL 8188435, at *5 (Fed. Cl. Spec. Mstr. Aug. 3, 2018). Here, this did not happen.

[22] Dr. Strouse's demonstrated experience in addressing hematologic issues in a pediatric patient population greatly exceeded Dr. Gershwin's more general knowledge of the issues posed in this case, and I therefore reasonably gave Dr. Strouse's determinations on certain matters more weight. *Broekelschen*, 618 F.3d at 1347.

reasoned) C.L.'s platelet levels (when measured in February 2014) might have *seemed* normal, but in fact were only temporarily so.

This contention is not supported with sufficient reliable scientific or medical evidence relevant to the illness in question.[23] This is partially attributable to the fact that Dr. Gershwin's argument conflates ITP with a condition known as thrombocytosis, which is characterized by *abnormally high* platelet levels—in effect, the opposite of ITP. Third Gershwin Rep. at 1 (citing J. Chen & K. Afsari, *Reactive Thrombocytosis Caused by Infection*, 19 Infections Med. 1, 1–4 (2002), filed as Ex. 108 on Aug.17, 2020 (ECF No. 59-8) ("Chen"); S. Zheng et al., *Association between Secondary Thrombocytosis and Viral Respiratory Tract Infections in Children*, Nature: Sci. Rep. (2016), filed as Ex. 109 on Aug. 17, 2020 (ECF No. 59-9) ("Zheng")).[24] Notably, Chen only describes conditions that give rise to thrombocytosis, and makes no mention of ITP. Zheng similarly focuses on the development of thrombocytosis following respiratory tract infections in otherwise healthy children. Neither discusses how respiratory infections influence platelet levels in patients concurrently experiencing ITP.

But even setting the foregoing aside, Petitioner has offered insufficient reliable evidence to conclude, as alleged, that an intercurrent viral infection would likely cause a tenfold platelet increase equivalent to C.L.'s documented February 2014 platelet count of 340,000.[25] *See* Chen; Zheng; Ex. 2 at 40. At best, as Dr. Strouse established, any transient platelet increase attributable to intercurrent infection would not result in the dramatic swing toward normal levels proposed herein. Tr. at 126, 140–41, 144, 159–60. Vranou also severely undercuts Petitioner's arguments regarding the influence intercurrent infections would have on platelet levels. *See* Vranou at 263

[23] I also note that this argument runs contrary to what Program experts have maintained in comparable cases about the relationship between inflammation attributable to an infectious process and ITP. In other cases alleging ITP as the vaccine injury, experts have opined that inflammation attributable to an intercurrent infection would likely *exacerbate* platelet destruction, not ameliorate it. *See, e.g.*, *Ebenstein v. Sec'y of Health & Hum. Servs*., No. 06-573V, 2010 WL 5113185, at *8–9 (Sept. 1, 2010). The *Ebenstein* petitioner alleged that she developed ITP approximately two months after receiving the MMR vaccine. *Ebenstein,* 2010 WL 5113185, at *4. During the intervening period between vaccination and the onset of her condition, she experienced a viral, upper respiratory infection. *Id.* Respondent argued that it was this intervening infection that caused petitioner's ITP, but petitioner's expert opined that "the MMR vaccine is the central cause and that if the virus was involved, *it served only to exacerbate the reaction* initiated by the vaccine." *Id.* at *8–9, *11 (emphasis added). The special master found entitlement for petitioner based in part on this argument. *Id.* at *19–20.

[24] Petitioner did not file the Chen and Zheng articles in their entirety and instead only offered abstracts and excerpts. Without being able to read these articles and full and understand the context surrounding the submitted excerpts, the probative value of these articles is severely diminished.

[25] Again, Petitioner's theory is that C.L.'s ITP began months *before* the February 2014 blood test that revealed normal platelet levels. So she is alleging that C.L.'s platelet counts, if they had been measured before that date, would have been *consistent* with an ITP diagnosis (below 100,000), rebounded to above 300,000 when tested, then fallen again to the levels revealed in the June 2014 test.

("fluctuation of platelet counts is known to occur in children with the chronic form of the disease, usually following viral infections; moreover, to our experience derived from 239 [chronic ITP] patients…platelet overproduction *does not overcome the platelets destruction, to reach normalization*") (emphasis added). And Respondent's experts established that platelet level fluctuations occur, but only in narrow ranges—allowing for differences of 10-20,000, but not the much larger increase that would have been necessary to account for C.L.'s normal platelet levels in February 2014. Tr. at 140–41.

Two other issues also undermine Petitioner's contentions about the likely course of chronic ITP. First, as Drs. Strouse and MacGinnitie observed, C.L.'s platelet levels never returned to a normal range after receiving her official diagnosis in June 2014. Tr. at 144–45, 168. This low platelet level course is not at all consistent with the up and downs Petitioner argues C.L. was experiencing prior to this time, and instead evinces the kinds of limited-range platelet level variances that would be characteristic of a case of chronic ITP that only began around the May-June time period, not long before. Second, Petitioner's theory amounts to the argument that C.L. experienced a spontaneous remission in the winter of 2014—something that Petitioner's filed literature notes is highly uncommon. Wong at 792, Lateef at e237.[26] The evidence offered in this case does not preponderantly support the conclusion that such a shift would likely occur, only to be followed by a subsequent consistently-low platelet count.

Beyond the above, Petitioner's onset allegations relied heavily on her own testimony, fortified with the photos offered herein. While I listened carefully to the testimony, and have reviewed the photos as well (despite their authenticity limitations),[27] ultimately this evidence was not enough to shift the balance of proof in Petitioner's favor. The photographs do provide *some* evidence the C.L. had some isolated bruise marks on her face, hands, and legs in the Fall of 2013. But the photos are not sufficiently detailed or sharp to assess the extent of bruising, or to evaluate its clinical significance, and they therefore do not preponderantly establish onset. Respondent's

[26] It is not enough to argue in response that "all" vaccine injuries are uncommon (and thus evidence contrary to what would be expected for disease course is not harmful to a petitioner's showing). Petitioners have the burden to offer *preponderant* evidence in support of their claim—they cannot simply point to any post-vaccine injury and deem it causal, shielding themselves with the "rarity of injury" argument whenever disparities or insufficiencies in their proof are pointed out.

[27] It has not been established beyond Petitioner's testimony or sworn statements that the photos were in fact taken at the times/dates alleged. More persuasive proof to authenticate them temporally would be required in most proceedings. *Cooper*, 2018 WL 8188435, at *1–2 (noting that petitioner was required to submit additional evidence to authenticate photographic evidence); *Kersavage v. U.S.*, 36 Fed. Cl. 441, 444–45 (1996) (finding that a provided affidavit was insufficient to authenticate offered photographs, and noting that even if the photographs were admissible, they would be afforded very little weight). While the absence of evidentiary rules in the Program means I could consider this evidence despite my concerns, and have done so, I need not give it the same weight as photos that were properly authenticated as to their date. *Kersavage*, 36 Fed. Cl. 444–45.

experts also did not deem the images as demonstrating the petechiae or "significant" bruising that would be characteristic of ITP, in their medical experience. Tr. at 128–29, 167. I concur in that assessment after reviewing them myself.

In addition, Petitioner's contentions about her attempts to bring these issues to the attention of pediatric treaters find no corroboration in the medical record, as no records before June 2014 memorialize concerns about bruising. At best, Petitioner appears to have asked Dr. Heimback-Graham to perform the CBC test on C.L. in February 2014—although as noted above the record itself gives no explanation for why the test was actually performed. But even assuming that Petitioner *did* at that time express concerns about unexplained bruising, such complaints yielded testing that established C.L. was *not* then suffering from ITP. The additional three-plus months that passed thereafter without further evidence of bruising until far closer in time to the actual diagnosis is more consistent with the conclusion that C.L.'s chronic ITP started when the record suggests it was discovered by treaters.

III. *Petitioner Has Not Established the Althen Prongs*[28]

A. *Althen* Prong Three

My onset finding herein is largely fatal to the entirety of the claim in this case. Based on reliable testimony offered by Dr. Gershwin, Petitioner has established that ITP onset occurring between two and six weeks following vaccination (ignoring for the moment whether the Prevnar vaccine can be deemed to be causal) would be medically acceptable. Tr. at 85–86. It is also consistent with the timeframes deemed to satisfy the third *Althen* prong in other relevant cases. *Parmer v. Sec'y of Health & Hum. Servs.*, No. 16-880V, 2021 WL 1524512, at *20–24 (Fed. Cl. Spec. Mstr. Mar. 25, 2021) (ITP within a few weeks after flu vaccine) *see also* MacGinnitie Rep. at 6 (conceding ITP caused by MMR vaccine would likely develop within thirty days). But Dr. Gershwin also conceded that an onset of *five to ten months post-vaccination* would not be medically acceptable for purposes of proving vaccine causation. Tr. at 115; Second Gershwin Rep. at 1 ("[i]f indeed the onset was not until five months post-vaccination, then I would agree with [Dr. Strouse's] assessment" that C.L.'s vaccinations were not associated with her ITP). As a result, my determination that C.L.'s chronic ITP began no sooner than May 2014—eight to nine months post-vaccination—means the third *Althen* prong cannot be preponderantly met. Insufficient evidence stands for the proposition that ITP *in any form* could take that long post-vaccination to manifest.

[28] I address the *Althen* prongs in order of their significance herein rather than consistent with their usual sequence.

B. *Althen* Prong Two

Petitioner has similarly failed to satisfy her burden under *Althen* prong two, which requires preponderant proof of a logical sequence of cause and effect connecting the vaccine at issue to the alleged injury. *Althen*, 418 F.3d at 1278.

As noted above, the medical record evidence, even when coupled with Petitioner's testimony and the photos, is insufficient to suggest that C.L. had begun to experience what would later be diagnosed as chronic ITP any time within four to five months post-vaccination (i.e., before February 2014). There is also little proof suggesting any kind of autoimmune process was underway in this timeframe, and the first blood test that could have revealed a subacute or insidious ITP process, from February 2014, was resoundingly unsupportive of the diagnosis. And the record does not demonstrate C.L.'s bruising, as documented by Petitioner in the photos, was the beginning of a long, subclinical process. Beyond the fact that the vaccine was received temporally prior to actual onset, there is hardly any persuasive or reliable evidence in this record that would suggest C.L.'s chronic ITP was in fact likely caused by the August 2013 second dose of Prevnar.

Treater support is another evidentiary pillar that petitioners often marshal to establish the "did cause" *Althen* prong, but here it is absent or lacking in reliability. Dr. Heimback-Graham (C.L.'s primary pediatrician from August 2013 until her diagnosis in June 2014) certainly never opined the Prevnar vaccine was associated in any way with C.L.'s chronic ITP—and in Petitioner's recollection actually pushed back against concerns about the condition or vaccine safety. Tr. at 17–19, 45–46, 50. Moreover, even after the diagnosis, most of C.L.'s treating physicians continued to encourage vaccination. Tr. at 18–19; Ex. 2 at 22, 35, 38; Ex. 4 at 5, 41. At most, some treaters might have observed an association between ITP and other vaccines, like the MMR (which C.L. had not received). Tr. at 25–26; Ex. 4 at 5.

While several treaters noted post-diagnosis that C.L. was not receiving vaccinations (due to her IVIG therapies or more general concerns about ITP), the primary treater to explicitly espouse a causal relationship between C.L.'s ITP and her August 2013 vaccinations appears to have been Dr. Berger. Ex. 2 at 55; Ex. 115 at 41; Ex. 116 at 5–7, 9. But Dr. Berger did not evaluate C.L. until September 1, 2015—two years after C.L. received the August 2013 vaccinations—and his record notations seem to draw as much upon Petitioner's history recitation of onset as his own findings. Ex. 5 at 1–5; Ex. 116 at 5–7, 9. Neither the records from Dr. Berger's treatment or his opinion explain what might have supported an association between C.L.'s ITP and the Prevnar vaccine, and he lacks demonstrated expertise in treating or researching ITP, especially when compared to the more reliable backgrounds and expertise in hematology and immunology possessed by Respondent's two experts.

Petitioner's *Althen* two showing otherwise runs into the same problem that characterized her onset/timeframe argument under *Althen* prong three. For both, Petitioner unpersuasively attempts to explain away the nine-month period from vaccination to discovery of the low platelet counts. Petitioner maintains, in effect, that the Prevnar vaccine triggered a chronic autoimmune process that was largely subacute, occasionally manifesting with bruising but remaining hidden from treaters until the platelet drop was self-evident after testing. Pet. Brief at 9–11. But this narrative is not corroborated by the record. Thus, if Petitioner were correct, then whenever C.L. went to the pediatrician, she must have been in a subacute/waning phase—sometimes assisted by an intercurrent infection. Tr. at 84–85; *see also* Ex. 2 at 40. But not all her pediatric visits were prompted by concerns of illness or infection. And the one-time C.L. was tested prior to her actual/likely onset, her platelet levels were normal—a finding that Petitioner's expert, Dr. Gershwin, did not convincingly explain away as a function of infection. The record in this case is simply unsupportive of Petitioner's theory.

The argument that a vaccine-caused autoimmune condition was "subclinical" or "asymptomatic," hiding it from discovery for long periods of time, has certainly been aired in other cases alleging vaccine-induced ITP. *See, e.g., Phillips*, 2020 WL 7767511, at *28–29. In *Phillips*, the petitioner alleged that he developed chronic ITP as a result of the flu and/or HPV vaccines, but his condition remained "asymptomatic" for approximately three months. *Id.* at *3–4. Though the *Phillips* petitioner did offer some evidence to support the argument that some ITP patients will experience an insidious onset, the special master found that "[w]hile it is possible that patient could present to the hospital with no symptoms and subsequently receive an ITP diagnosis, this possibility does not constitute evidence that this happened in Petitioner's case." *Id.* at *29. Here, as there, the record does not allow me to conclude that C.L. experienced a lengthy subclinical course.

C. *Althen Prong One*

Although it is not central to my disposition of this case, I also find that Petitioner has not preponderantly established that the Prevnar vaccine *can* cause ITP.

Admittedly, the scientific literature offered in this matter clearly supports Petitioner's contention that certain wild infections are associated with an increased risk of developing an autoimmune disease like ITP. Cooper at 365, 369–70. There is also substantial evidence to support the proposition that some vaccines (in particular, the MMR vaccine) can play a causal role in the development of ITP. O'Leary at 250–51; Cecinati at 1–6. And the mechanism of molecular mimicry is not only a reliable scientific concept, but provides a likely explanation for how ITP may progress and/or be instigated by an infection or vaccination.

Thus, it could be *plausibly* contended that *other* vaccines, like Prevnar, could cause ITP as well. Of course, it bears repeating: plausibility is *not* the evidentiary standard applicable to a petitioner's "can cause" showing. *See Boatmon*, 941 F.3d at 1359; *see also LaLonde*, 746 F.3d at 1339 ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)). As a result, causally associating Prevnar with ITP requires more than analogizing this case to what has been demonstrated to be preponderantly likely for different vaccines.

Petitioner's causal theory starts to fall apart when the specifics of the theory—as applied to the pneumococcal vaccine as well as the facts of this case—are looked at closely. First, the overwhelming majority of reported ITP cases following MMR vaccination are *acute*, resolving within six months of onset. *See, e.g.*, Cecinati at 4 (noting that "[m]ore than 90% of children are completely cured within six months of diagnosis, and less than 10% develop chronic disease"). Evidence to support a causal association between *any* vaccine and the development of chronic ITP, as opposed to the acute form, is far less apparent—and acute and chronic ITP have not been shown to be interchangeable, such that this relative paucity of evidence is rendered unimportant.

Second, none of the literature filed in this matter, including epidemiological studies, found an increased risk of developing *any* form of ITP following vaccination with Prevnar. *See* O'Leary at 250–51; Wise at 1708; M. Yong et al., *Epidemiology of Paediatric Immune Thrombocytopenia in the General Practice Research Database*, 149 Brit. J. Haematology 855, 855–64 (2010), filed as Ex. W on Oct. 8, 2020 (ECF No. 66-2) ("Yong"). O'Leary, for example is a large, epidemiological study involving 1.8 million children and 15 million vaccine doses. O'Leary at 250. A total of 197 ITP cases were identified, and of these, only 17 cases were reported in children between six weeks and eleven months of age. *Id.* at 251. Further still, only one child in this age range developed chronic ITP. *Id.* Overall, the study concluded that "[n]one of the routine childhood vaccines [including PCV] given in the first year of life was significantly associated with an increased risk of ITP." *Id.* at 250, 252–53.

The findings in Yong are similarly detrimental to Petitioner's claim. The purpose of Yong was to compare incidence rates and characteristics of ITP between pediatric and adult patients based on information contained in the General Practice Research Database. Yong at 855. The study also examined the role infections and immunizations play in the development of ITP in children. *Id.* at 855–56. To do this, data points were grouped in accordance with the United Kingdom vaccine schedule recommendations, which proposes that children under two-years old receive PCV (among other vaccinations). *Id.* at 856. Out of 257 identified cases of pediatric ITP, 43 were in children younger than two. *Id.* at 857. Of these, eleven were found to have received a vaccination within six weeks of onset. *Id.* at 858, 860. Although PCV was recommended for children under two-years old, the study found that within this age group, none had received PCV within six weeks

of developing ITP. *Id.* By contrast, seven children in this age group had received the MMR vaccine. *Id.*

The epidemiologic evidence on this subject is particularly persuasive. Although it is unquestionably the case that Vaccine Program litigants are not required to offer epidemiological evidence to prevail, special masters may take note of its existence and consider it when determining if a claimant has met his burden of proof on the first *Althen* prong. *See Palattao v. Sec'y of Health & Hum. Servs.*, No. 13-591V, 2019 WL 989380, at *37 (Fed. Cl. Spec. Mstr. Feb. 4, 2019) (citing *D'Toile v. Sec'y of Health & Hum. Servs.*, 726 F App'x 809, 811–12 (Fed. Cir. 2018)). Notably, O'Leary was filed by *both* parties, making it difficult for Petitioner to argue herein (as many petitioners do when attempting to rebut damaging epidemiologic proof) that my consideration of this particular article amounts to "requiring" Petitioner to have found positive epidemiologic evidence to prevail.

Petitioner's causation theory also relied heavily on case reports—a category of evidence inherently given less weight in the Program, especially when contrasted with on-point and reliable epidemiologic proof. *See Pearson v. Sec'y of Health & Hum. Servs.*, No. 17-489V, 2019 WL 1150044, at *11 (Fed. Cl. Spec. Mstr. Feb. 7, 2019) (concluding that case reports receive only limited evidentiary weight and cannot cure *Althen* prong one deficiencies); *see also Harris v. Sec'y of Health & Hum. Servs.*, No. 10-322V, 2014 WL 3159377, at *18 (Fed. Cl. Spec. Mstr. June 10, 2014) (noting that "case reports are generally not a valuable form of evidence")). What is more, some of the studies cited by Petitioner, like Gupta, presented inapposite facts that prevented giving them the weight urged.

Petitioner's reliance on the Wise study was similarly unhelpful. Wise is a post-licensure study that relied on VAERS data. But as prior Program cases have repeatedly observed, VAERS reports alone are not particularly useful in determining whether a causal connection exists between a vaccine and injury. *See, e.g.*, *Flores v. Sec'y of Health & Hum. Servs.*, No. 10-489V, 2013 WL 5587390, at *13 (Fed. Cl. Spec. Mstr. Sept. 12, 2013). Indeed, Wise itself warns that, for the reasons stated above, "interpretation of VAERS reports requires caution because many reported events may not be due to the vaccine." Wise at 1708. Given these limitations, the overall weight I afford to VAERS-derived findings, such as those reported in Wise, is minimal. Moreover, Wise's actual findings are not all that supportive of Petitioner's theory. Out of more than 4,000 VAERS reports, only 14 cases, or 0.35 percent, were determined to involve ITP and Prevnar.[29] Tr. at 68; Wise at 1702. Of these, thirteen involved multiple vaccines in addition to Prevnar. Wise at 1707. Wise's authors were especially cautious in describing their findings relating to ITP, given that

[29] Wise specifically noted that there were sixty-eight reports of "possible thrombocytopenia," but only fourteen provided documentation confirming the diagnosis. Wise at 1707.

most of the reports followed administration of multiple vaccines at the same time, and many patients had also reported infections close in time to the onset of their ITP. *Id.* at 1708 (noting "[t]he 12 reports of thrombocytopenia with profoundly depressed platelet counts illustrate uncertainties in the interpretation of passive surveillance data.").

Other evidence purportedly supporting Petitioner's theory proved no more persuasive. For example, Dr. Gershwin gave weight to the PDR exhibit, arguing that it reflected the Prevnar manufacturer's understanding of the post-vaccination risk of ITP. Tr. at 66. This, however, is an overstatement of what the document actually says. An examination of the PDR does list ITP as a moderate potential adverse reaction, but adds that the incidence rate is unknown. PDR at 6. This is as consistent with the conclusion that ITP has only been *temporally* associated with Prevnar. Dr. Gershwin was also correct in observing that the PDR cautions providers about the potential for ITP relapse in previously stabilized patients following receipt of a pneumococcal vaccine. *Id.* at 5. But even this assertion was contradicted by other evidence offered by Petitioner—specifically Wong, which noted that chronic ITP patients who are also treated with a splenectomy receive pneumococcal vaccinations prophylactically. Wong at 793.

The final insufficiency with Petitioner's *Althen* one showing was the theory's proposed mechanism. Dr. Gershwin embraced molecular mimicry to explain how the antigens in the Prevnar vaccine would initiate an autoimmune, cross-reactive attack on the platelets, resulting in their destruction. But though molecular mimicry is a generally accepted scientific concept, and is frequently invoked in Program cases, the mere mention of it does not constitute satisfaction of the preponderant evidentiary standard. *Forrest v. Sec'y of Health & Hum. Servs.*, No. 14-1046V, 2019 WL 925495, at *3 (Fed. Cl. Spec. Mstr. Jan. 18, 2019) (citing *Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 135 (2011), *aff'd without opinion*, 463 F. App'x 932 (Fed. Cir. 2012)). Rather, it must be shown that the mechanism likely does link the vaccine in question to the relevant injury. *See Yalacki v. Sec'y of Health & Hum. Servs.*, No. 14-278V, 2019 WL 1061429, at *34 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), *aff'd*, 146 Fed. Cl. 80 (2019).[30]

No such showing was made in this matter. Petitioner did not preponderantly establish that *any* component of the Prevnar vaccine has sufficient homology to induce cross-reactivity with blood platelets, thereby resulting in ITP. Indeed, Dr. Gershwin did not even try to establish amino acid sequence homology, something many other petitioners base the majority of their "can cause" showing upon. Tr. at 183; *McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL

[30] Of course, Program petitioners need not even propose *any* mechanism to prevail. *Knudsen*, 35 F.3d at 549. However, my discussion of mechanism herein is not the product of a unilateral urge (and hence reflects me "requiring" evidence that Petitioner did not attempt to muster). Rather, *Dr. Gershwin himself proposed it*—and I am (fairly and legitimately) evaluating his success in so doing.

3640610, at *24–27 (Fed. Cl. Spec. Mstr. May 22, 2015) (expert who identified sequential homology between vaccine components and self-structures satisfied petitioner's *Althen* prong one burden).[31]

If no reliable proof was offered as to homology, then what else could explain how an autoimmune process was initiated herein? Dr. Gershwin suggested (somewhat in passing) that the Prevnar vaccine's diphtheria conjugate, included to increase the vaccine's immunogenicity, was culpable, since other vaccines containing the same component have been more reliably established to be causally associated with ITP. *See, e.g.*, Tr. at 66–67 (Dr. Gershwin opining that Prevnar contains "a diphtheria protein," and both diphtheria and the DPT vaccine are associated with the development of ITP); First Gershwin Rep. at 9. As additional support for this contention, Petitioner submitted the vaccine's package insert, which contains prescribing information and formulation details, confirming the conjugate's presence in the vaccine. Package Insert, filed as Ex. 94 on Aug. 17, 2020 (ECF No. 58-4).

But this argument not only gives too much credit to the role the conjugate plays (without substantiation from other reliable scientific or medical evidence),[32] but also misconstrues the exact nature of the conjugate. As the filed package insert establishes, the diphtheria protein at issue is CRM_{197}—a *non-toxic variant* of diphtheria toxin derived from lab-cultured bacteria. Ex. 94 at 24. It has not been reliably established in this case, however, that the pathogenicity of non-toxic CRM_{197} can be conflated with what is known about naturally occurring diphtheria toxin, which is what produces illness in those infected by the wild *C. diphtheria* bacterium, or even the diphtheria toxoid (a chemically-modified form of the original toxin). Other Program petitioners have unsuccessfully relied on evidence relating to the pathogenicity of diphtheria *toxin* to explain how a pneumococcal vaccine conjugated with *non-toxic* CRM_{197} can result in autoimmunity. *See, e.g.*, *Deshler* at *11, *20 (pneumococcal vaccine not shown to have caused Guillain-Barré syndrome ("GBS")). Petitioner's showing on this point herein was no more reliable or evidentiarily-substantiated.

Finally, Petitioner has not persuasively explained how chronic ITP attributable to a vaccine could remain effectively subclinical for almost two thirds of a year. How would receipt of Prevnar trigger a repeating and persistent autoimmune process, recurring for years and years in the form of abnormally low platelet levels—yet not manifesting conclusively until nine months post-

[31] Merely establishing some degree of homology is not necessarily even enough to constitute preponderant evidence that a vaccine can cause a specific injury. *See Pek v. Sec'y of Health & Hum. Servs.*, No. 16-736V, 2020 WL 1062959, at *16 (Fed. Cl. Spec. Mstr. Jan. 31, 2020) (citing *Blackburn*, 2015 WL 425935, at *7 n.14)).

[32] The epidemiological evidence offered in this matter did not observe a causal association between other diphtheria-containing vaccines, such as Tdap and the development of ITP in young children, other than what would be suggested from case reports. O'Leary at 251–53; Cecinati at 3.

vaccination? What biologic processes were set up by vaccination that would not be subject to arrest later? Neither Dr. Gershwin's testimony nor the literature filed in this case offered a reliable answer to this question sufficient to meet the preponderant standard.

It is not enough to simply note that ITP is an autoimmune condition subject to triggering by environmental factors—for autoimmunity does not inexorably imply chronicity. There are many autoimmune-mediated diseases or illnesses that are monophasic in nature (like GBS), subsiding either after the initial cause for cross-reactivity stops or the immune system rebalances. Such injuries have been credibly associated with certain vaccines. But there are also chronic autoimmune disease processes, such a multiple sclerosis, which relapse and remit but which have been less commonly attributed to vaccination, even if "flares" can be caused by transient factors that themselves might be vaccine-instigated, like a fever. *See*, *e.g.*, *Samuels v. Sec'y of Health & Hum. Servs*., No. 17-071V, 2020 WL 2954953 at *20–21 (Fed. Cl. Spec. Mstr. May 1, 2020). Petitioner's showing assumes that trigger is destiny—a contention barely different, in the absence of reliable scientific or medical evidence, for the routinely-rejected contention that temporal association between a vaccine and injury is enough to prove causation. *Grant*, 956 F.2d at 1144 ("temporal association is not sufficient…to establish causation in fact.").

CONCLUSION

Ms. Loyd was sincere in her expressions of concern and devotion for C.L.'s well-being. There is no doubt that this claim was brought with a good-faith belief that the Prevnar vaccine caused C.L. to develop chronic ITP, and I have great sympathy more generally for her desire to ascertain a possible cause for C.L.'s medical distress. But I am required to apply the law of the Vaccine Program correctly, rather than based upon my personal sympathies. Such an application to this case does not lead me to conclude that preponderant evidence supports Petitioner's cause of action. I therefore **DENY** entitlement in this case.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court **SHALL ENTER JUDGMENT** in accordance with the terms of this decision.[33]

Any questions regarding this order may be directed to my law clerk, Elizabeth Yoder, at (202) 357-6340.

IT IS SO ORDERED.

s/Brian H. Corcoran

[33] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.

Brian H. Corcoran
Chief Special Master