In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: December 16, 2025

EUGENE ANTHONY BROWN,	*	
Petitioner,	*	No. 20-426V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Idiopathic Thrombocytopenia; Twinrix; Influenza; Tdap; IPV.
Respondent.	*	

Nathaniel C. Enos, Conway Homer, P.C., Boston, MA, for petitioner.
Sarah B. Rifkin, U.S. Dept. of Justice, Washington, DC, for respondent.

DECISION[1]

On April 14, 2020, Eugene Anthony Brown ("petitioner") filed a petition for compensation in the National Vaccine Injury Compensation Program.[2] Petition (ECF No. 1). Petitioner alleges that the Hepatitis A and Hepatitis B ("Twinrix"), influenza ("Flu"), inactivated polio ("IPV"), meningococcal ("MCV4P"), and tetanus-diphtheria-acellular-pertussis ("Tdap") vaccines he received on May 18, 2017, caused him to suffer from chronic idiopathic thrombocytopenic purpura ("ITP") and sequalae. Amended Petition at ¶ 5 (ECF No. 19). Based on a review of the evidence submitted in the record, the undersigned finds that petitioner has failed to establish that he is entitled to compensation. Therefore, entitlement is **DENIED** and the case shall be **DISMISSED.** [3]

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[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

[3] Pursuant to Section 13(a)(1), in order to reach my decision, I have considered the entire record, including all of the medical records, expert records, and literature submitted by the parties. This opinion discusses the elements of the record I found most relevant to the outcome.

I. Procedural History

Petitioner initiated his claim on April 14, 2020, alleging that the MMR and varicella vaccinations he received on May 17, 2017, caused him to suffer from ITP. Petition at Preamble. Petitioner filed an Amended Petition on September 28, 2020 changing the causal vaccines to the Twinrix, Flu, IPV, MCV4P, and Tdap vaccines, which he received on May 18, 2017 based on his medical records. Amended Petition at ¶ 5. Petitioner filed an expert report from Dr. Edwin N. Forman on February 14, 2022. Petitioner ("Pet'r") Exhibit ("Ex.") 18 (ECF No. 31). Respondent filed responsive expert reports from Dr. Michele P. Lambert and Dr. Ross M. Kedl on August 15, 2022. Respondent ("Resp't") Ex. A (ECF No. 37); Resp't Ex. C (ECF No. 38-1). The undersigned subsequently held a Rule 5 status conference, after which Petitioner filed a supplemental expert report from Dr. Forman. Pet'r Ex. 54 (ECF No. 46). Respondent later filed a responsive supplemental report from Dr. Lambert. Resp't Ex. E (ECF No. 56). The parties opted to resolve the case on the record in lieu of having an entitlement hearing.

Petitioner filed a motion for ruling on the record on August 5, 2024, and respondent filed his response on September 4, 2024. Pet'r Mot. for Ruling on the Record ("Pet'r Br.") (ECF No. 62); Resp't Resp. to Pet'r Mot. for Ruling on the Record ("Resp't Br.") (ECF No. 63). Petitioner filed his reply on September 19, 2024. Pet'r Reply (ECF No. 64).

The matter is now ripe for adjudication.

II. Legal Standard for Adjudication

To receive compensation through the Program, petitioner must prove either (1) that [he] suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); *Capizzano v. Sec'y of Health & Hum. Servs.,* 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that he suffered a Table Injury, he must prove that a vaccine he received caused his injury. To do so, he must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury ("*Althen* Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for his injury ("*Althen* Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and his injury ("*Althen* Prong Three"). § 13(a)(1); *Althen*, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Recently, in *Kottenstette,* the Federal Circuit reiterated that proof of causation does not "require identification and proof of specific biological mechanisms[.]" *Kottenstette v. Sec'y of Health & Hum. Servs.,* -- Fed.Appx.—(Fed. Cir. June 15, 2021) (citing *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 549 (Fed. Cir. 1994). Causation "can be found in vaccine cases….without detailed medical and scientific exposition of the biological mechanisms." *Knudsen,* 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical

literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1325 (Fed. Cir. 2010).

Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. *See Moberly*, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); *Althen*, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

In Vaccine Act cases, expert testimony may be evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo*, 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). In Vaccine Program cases, the *Daubert* analysis has been used in the weighing of the scientific evidence actually proffered and heard rather than as a tool for the pre-trial exclusion of expert testimony. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (Fed. Cl. 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"), *aff'd*, 420 F. App'x 923 (Fed. Cir. 2011). The flexible use of the *Daubert* factors to determine the persuasiveness and/or reliability of expert testimony in Vaccine Program cases has routinely been upheld. *See, e.g., Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 742–45 (2009). 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").

Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280 (holding that Congress created a system in which "close calls regarding causation are resolved in favor of injured claimants"); *Knudsen*, 35 F.3d at 551 ("If the evidence (on alternative cause) is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded.").

III. Summary of Evidence Submitted

a. Medical Records

i. Petitioner's Pre-Vaccination Medical History

Petitioner was born on May 28, 1998 and was nineteen years old when he received the vaccines at issue. Pet'r Ex. 1 at 1; Pet'r Ex. 3 at 25. In the three years prior to vaccination, he did not seek medical care beyond treatment for sports-related concerns and periodic visits to his local CVS Minute Clinic and his primary care provider ("PCP"), Jim Hussey, D.O. See generally Pet'r Ex. 2 at 19-35; Pet'r Ex. 14 at 3-13; Pet'r Ex. 6 at 3. On September 21, 2015, at age seventeen, petitioner saw Dr. Hussey for a respiratory illness, sinusitis and pneumonia. Pet'r Ex. 2 at 28. He underwent lab testing as part of his care, and a complete blood count ("CBC") revealed a low platelet count of 92 K/uL.[5] Ex. 2 at 115. Although petitioner had originally sought care for respiratory symptoms, Dr. Hussey became concerned about the low platelet count incidentally discovered through the lab work. *See* Pet'r Ex. 7 at 50, 61-62. Dr. Hussey called petitioner at home and advised him to visit the emergency department ("ED") as soon as possible. *Id*. at 50. *See also Id*. at 61-62 (fax cover sheets sent to the Lake Pointe ED, including handwritten notes directing that petitioner be seen "in ED STAT!") (emphasis original). Petitioner went to the ED that day, and a repeat CBC showed a platelet count of 121 K/uL. *Id*. at 135. Petitioner was treated for his respiratory symptoms and discharged. *Id*. at 57-60.

Three days later, on September 25, 2015, petitioner returned to his PCP for a follow-up exam. Pet'r Ex. 2 at 24. Petitioner's headache had "much improved" and his platelet level had risen to 196 K/ul, a normal level. *Id.* at 112. There are no records of additional platelet counts recorded at any time in his life prior to September 2015. There were also no other blood draws between September 25, 2015 and May 18, 2017, when he received the Hepatitis A and Hepatitis B ("Twinrix"), influenza ("flu"), inactivated polio ("IPV"), meningococcal ("MCV4P"), and tetanus-diphtheria-acellular-pertussis ("Tdap") vaccines.

ii. Post-Vaccination Medical History

At 18-years old, following his freshmen year of college, petitioner joined the Army National Guard. Pet'r Ex. 3 at 25. On May 18, 2017, petitioner received the Hepatitis A and Hepatitis B ("Twinrix"), influenza ("Flu"), inactivated polio ("IPV"), meningococcal ("MCV4P"), and tetanus-diphtheria-acellular-pertussis ("Tdap") vaccines. Pet'r Ex. 3 at 19,25.

Three days later, on May 20, 2017, petitioner was sent to the emergency department ("ED") at Baptist Hospital for "possible psychosis." Pet'r Ex. 11 at 9; Pet'r Ex. 16 at 3. As part of the diagnostic work-up, a CBC was ordered. *Id.* at 221. Petitioner's platelets were measured as "low" at 94 K/ul. *Id.* at 221. Petitioner's platelets were measured again on May 22, 2017 at the VA Hospital, and were 77 K/ul. Pet'r Ex. 4 at 194. Petitioner was transferred to Richland Springs Hospital for evaluation regarding his CBC. Pet'r Ex. 4 at 238. While awaiting a transfer to a psychiatric department, the attending physician wrote, "Plan was to send [patient] to Three Rivers as patient is military, but CBC showed thrombocytopenia (94). Awaiting result of repeat CBC. *Unexplained thrombocytopenia in the face of other normal lab results is unlikely to indicate any change in medical work-up or treatment." Id.* (emphasis added).

Petitioner was hospitalized at Richland Springs until May 31, 2017. *See* Pet'r Ex. 4 at 239-42; Pet'r Ex. 5 at 42. During his time at Richland Spring Hospital, repeat CBCs showed his platelet counts as follows:

Date	Level
5/22/2017	100
5/23/2017	108
5/25/2017	109
5/27/2017	108
5/31/2017	100

Pet'r Ex. 4 at 613-15. Petitioner was discharged from Richland Springs to Eisenhower Army Medical Center on May 31, 2017. The discharge summary on May 31, 2017 explained, "CBC was monitored during his hospitalization. His…CBC on 5/25/2017 which revealed platelets of 109…A re-check of platelets on 05/27/2017 revealed platelets levels of 108." Pet'r Ex. 4 at 240. Petitioner was not provided any treatment for his low platelets. Petitioner was transferred to an in-patient psychiatric care at an Army Medical Center, where he remained for another two weeks. *See generally* Pet'r Ex. 5. Upon admission, it was noted that his platelets were "108-stable." *Id.* at 70. During this hospitalization, his platelet levels were as follows:

Date	Level
6/1/2017	94
6/3/2017	81
6/4/2017	77
6/12/2017	89

Pet'r Ex. 5 at 14, 17, & 20. Again, petitioner was not treated for his low platelet levels.

After his discharge, petitioner was separated from the Army and returned thome to Texas. He had a follow-up appointment with Dr. Hussey on June 21, 2017. Pet'r Ex. 2 at 15-18. Under "Physical Exam" Dr. Hussey wrote that petitioner had a "history of thrombocytopenia," and petitioner's physical examination was normal. *Id.* at 17. Dr. Hussey diagnosed petitioner with "acquired thrombocytopenia," and also referred petitioner to neurologist, Dr. Akhavi. The CBC from June 21, 2017 revealed petitioner had a platelet level of 102, which was marked as "below low normal." *Id.* at 111.

On July 13, 2017, petitioner went to the emergency department of Methodist Charlton Medical Center, for "lack of sleep" which was "less than 8 hours in the past week," and "sleep deprivation psychosis." Pet'r Ex. 9 at 12. His CBC on July 13, 2017 demonstrated a platelet count of 126 K/ul. *Id.* at 8. Petitioner was again admitted to inpatient psychiatric care until July 21, 2017. Pet'r Ex. 75-78. Upon discharge, it was noted that "low platelets identified but no improvement with improved sleep wake cycle," but no additional treatment was provided for his noted low platelets.

On July 27, 2017, petitioner was evaluated by hematologist, Dr. Korie Flippo. Pet'r Ex. 10 at 80. Under the "History of Present Illness" it provides that petitioner is a "19 year-old gentleman, who is noted to be thrombocytopenic over [these] last several months. *His father is also thrombocytopenia*….three days after he received multiple vaccinations and he has been on leave since that time. He denies any bruising or bleeding. They diagnosed him with a sleep

deprivation psychosis." *Id.* (emphasis added). Family history was recorded as "father has blood clots and has thrombocytopenia." *Id.* Petitioner's platelets were recorded as "86,000." *Id.* at 81. Dr. Flippo wrote, "No evidence of DIC." Dr. Flippo continued to monitor petitioner's platelet levels. *See generally* Pet'r Ex. 10.

Petitioner's lab work did not reveal anti-platelet antibodies and his bone marrow biopsy was normal. Pet'r Ex. 10 at 45. Dr. Flippo did not recommend any specific treatment for petitioner's low platelets, aside from monitoring and follow-up. *See e.g.* Pet'r Ex. 10 at 45 ("Assessment and Plan: Thrombocytopenia—we would continue to monitor and recommend follow up on his platelets.").

At an appointment with Dr. Flippo on January 5, 2018, petitioner was referred to UT Southwestern for a second opinion regarding his low platelets. Pet'r Ex. 10 at 34. Petitioner reported increased sleeping. *Id.* At this appointment petitioner's platelets were 86,000. *Id.* at 35.

On July 27, 2018, a year later, petitioner had an appointment with Dr. Yu Min Paul Shen at UT Southwestern. Pet'r Ex. 10 at 119. Petitioner went to the appointment with his father and reported that three days after he received a panel of vaccinations, his platelet levels were discovered as "low." *Id.* Petitioner reported that in the past 5-6 months his platelet levels were just above 100,000, but he had no bleeding symptoms such as gum bleeding, nose bleeding, or blood in his urine. *Id.* Petitioner reported "occasional nose bleeds associated with sinus congestion" and he works out regularly and never has a problem with bleeding. *Id.* Dr. Shen's impression was that petitioner had "persistent but mild thrombocytopenia," and he even noted that petitioner had a platelet level of 92,000 in September 2015. *Id.* at 122. Dr. Shen also wrote that petitioner's more likely explanation of his low platelet count was "chronic immune thrombocytopenia," which is a "diagnosis of exclusion after an extensive search for alternative causes of thrombocytopenia." *Id.* at 123. He continued, stating, "even though the antiplatelet antibody test was noted to be negative and Dr. Flippo's note, it does not rule out the possibility of chronic immune thrombocytopenia." *Id.* Dr. Shen stated, "It is highly conceivable that the vaccinations had induced autoimmune antibody to his platelets and this has improved over time. *The good thing about this is that even if he has ITP, there is no need for intervention given that his platelet count has never been less than 50,000.* Evidence-based recommendations from the American Society of Hematology suggest that we do not treat ITP unless the platelet count is less than 30,000 consistently." *Id.* (emphasis added). Petitioner did not have any additional appointments with Dr. Shen.

Petitioner returned to his regular hematologist, Dr. Flippo three days later and reported he was "feeling well" and "doing much better." Pet'r Ex. 10 at 16. He continued to see Dr. Flippo for follow-up care and monitoring through 2020. During such appointments, his platelet levels ranged from 114 K/ul to 89 K/ul. *See* Pet'r Ex. 10 at 7; Pet'r Ex. 78 at 7. At petitioner's last appointment on November 16, 2020, Dr. Flippo diagnosed petitioner with thrombocytopenia, stating, "This was most likely ITP, gave him warning signs of increased bruising or bleeding. He is currently stable." *Id.* at 5.

b. Expert Opinions

i. Petitioner's Expert: Dr. Edwin Forman, Hematologist

Petitioner submitted two reports from pediatric hematologist, Dr. Edwin Forman, who opined that the vaccines petitioner received on May 18, 2017 was the causative factor for petitioner developing immune thrombocytopenia purpura ("ITP"). Pet'r Exs. 18 at 4; Pet'r Ex. 54 at 5.

Dr. Forman explained that the diagnosis of ITP is made on clinical grounds and "the exclusion of other conditions that can cause thrombocytopenia." Pet'r Ex. 18 at 4. Dr. Forman explained that approximately 2-3 days after petitioner received the six vaccinations, petitioner "developed thrombocytopenia," but that the platelets were "likely too high" for petitioner to develop clinical symptoms like bleeding, ecchymosis, or petechiae. *Id.*

Dr. Forman stated that "familial or inherited thrombocytopenia, the platelet remains low," and that if petitioner had inherited thrombocytopenia, he would not have platelet counts of 150,000 or above at times. *Id.* Instead, he characterized petitioner's diagnosis as "chronic ITP," stating that petitioner's platelets remained less than 150,000 for over a year.

In his second report, Dr. Forman rebuts respondent's experts' opinions that petitioner had familial thrombocytopenia. Pet'r Ex. 54 at 3-4. He states that petitioner's platelet count of 197,000, which was seen in labs from September 2015 (pre-vaccination) "is rarely present" in familial thrombocytopenia and that "there is no history or laboratory data available for petitioner's father," and therefore, he cannot conclude that petitioner's thrombocytopenia was inherited. *Id.* at 3. Additionally, he noted that petitioner's pre-vaccination transient platelet drop was associated with a viral infection, which can cause a temporary drop in platelet count. *Id.*; Pet'r Ex. 18 at 5. Dr. Forman's opinion was that petitioner had post-vaccination ITP.

Dr. Forman opined that the vaccines petitioner received on May 18, 2017, caused him to develop ITP through molecular mimicry. Pet'r Ex. 18 at 5-6. He stated that the exact mechanism of ITP is not well understood, the medical literature characterizes ITP as an autoimmune disease resulting from platelet antibody mediated destruction and impaired megakaryocyte and platelet production. *Id.* at 6. Consolini et al. explains that autoantibodies were discovered to platelets that led to their destruction, but also that later it was discovered that abnormal T-helper cell defects could direct autoreactive B cells to produce autoantibodies. Pet'r Ex. 26 at 3.[4] Additionally, Chapter 133 of Hematology also endorses a role for cytotoxic T cells having an effect on platelets in patients that have active ITP, but no detectable platelet autoantibodies. Pet'r Ex. 35 at 5.[5] The Cines et al. article explains that platelet antibodies are only discovered in 60% of patients and that "it is not known whether some patients with ITP have a central B-cell tolerance defect or whether loss of peripheral tolerance mediates acute or

[4] Consolini, R. et al., *The Centenary of Immune Thrombocytopenia-Part 1: Revising Nomenclature and Pathogenesis*, 4 Frontiers in Pediatr. Doi: 10.3389/fped.2016.0012 (2016). [Pet'r Ex. 26].

[5] Hoffman R. et al., Hematology: Basic Principles and Practice, 6th Ed. Elsevier Saunders (2013). [Pet'r Ex. 35].

chronic ITP." Pet'r Ex. 25 at 9.[6]

Dr. Forman also references several case reports that describe ITP occurring after vaccination. Pet'r Ex. 18 at 5. Arya et al. described two cases of children receiving the diphtheria-pertussis-tetanus ("DPT") vaccines and developing ITP afterwards. Pet'r Ex. 21 at 2.[7] Arya first described an 18-month-old who received a booster DPT vaccination and then "over 72 hours" developed ecchymosis and bruising spots on his abdomen and extremities, and his platelet count was 9,600. *Id.* at 1. The second patient described in the same article was a four-year old who developed purpuric spots 8 days after receiving his first DPT vaccine. *Id.* at 2. The four-year old's platelet count was 50,000. Both children received steroids for an extended period and still had ecchymosis and purpuric spots afterwards. *Id.*

Neau et al. described seven cases of ITP after the administration of the recombinant hepatitis B vaccine. Pet'r Ex. 45.[8] Neau stated that prior to the vaccination all seven patients had normal platelet counts and that there was an average of 7 weeks before the thrombocytopenia was discovered. *Id.* at 1. Nuevo et al. also wrote about a case report of a child developing ITP after receipt of the hepatitis B vaccine. Pet'r Ex. 47 at 1.[9] The author explained that the child developed a petechial rash over her thorax, abdomen, upper and lower extremities and her platelet count was discovered to be 11,000. *Id.* Nuevo also included a chart of reported cases of ITP after hepatitis B vaccination and noted that the interval between vaccination and onset of ITP was between 1 day to 3 months. *Id.* at 2. Importantly though, the one-day onset of ITP was after the second dose of the hepatitis B vaccine. *Id.* at 3.

Finally, the O'Leary article, which examined pediatric ITP cases across different Kaiser medical centers and found a "significant association of ITP with MMR" which are routinely administered to children between ages 12 to 19 months of age. Pet'r Ex. 48 at 4.[10] Additionally, the same article found a significantly elevated risk of ITP after the hepatitis A vaccine for ages 7 to 17 and for varicella vaccine and Tdap vaccine for ages 11 to 17. *Id.* at 1.

Dr. Forman opined that the finding of ITP two days post-vaccination was an acceptable medical timeframe for the vaccines petitioner received to result in ITP. Pet'r Ex. 18 at 6; Pet'r Ex. 54 at 3. He referred to the case report described in Hamiel et al., where a child repeatedly

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[6] Cines, D. et al., *The ITP Syndrome: Pathogenic and Clinical Diversity,* 113 (26) Blood 6511-6521 (2009). [Pet'r Ex. 25].

[7] Arya L. et al., *Thrombocytopenic Purpura following DPT Vaccination,* 10 Pediatr. Hematol. Oncol. 381-383 (1992). [Pet'r Ex. 21].

[8] Neau, D. et al., *Immune Thrombocytopenic Purpura After Recombinant Hepatitis B Vaccine: Retrospective Study of Seven Cases,* 30 Scand. J. Infect. Dis. (1998). [Pet'r Ex. 45].

[9] Nuevo, H. et al., *Thrombocytopenic Purpura After Hepatitis B Vaccine: A Case Report and Review of the Literature,* 23 Pediatr. Infect. Dis. J. 183-184 (2004). [Pet'r Ex. 47].

[10] O'Leary, S. et al., *The Risk of Immune Thrombocytopenia Purpura after Vaccination in Children and Adolescents,* 129 Pediatrics 248-255 (2012). [Pet'r Ex. 48].

developed ITP after receiving influenza vaccines. Pet'r Ex. 32 at 1.[11] The authors noted that the child developed symptoms of thrombocytopenia one week after his first dose of the flu vaccine, then within 6 days after the second and third flu vaccines. *Id.* Hamiel also discussed other articles on ITP following vaccination and stated that, "some individual reports of ITP occurring in adults within 4 to 17 days after influenza vaccination have been published." *Id.* at 3. Dr. Forman also stated that the 7-to-10-day range of onset post-vaccination cited by respondent's expert was "more of a mean than a range," and that the O'Leary and Baxter articles support a closer in time temporal association. Pet'r Ex. 54 at 6. Dr. Forman stated that petitioner received a high number of vaccines on May 17, 2017, and argued that it was possible that petitioner had either been exposed or vaccinated to one or more of the viruses he was immunized against, which would cause a faster immune response. *Id.*

ii. Respondent's Expert: Dr. Michele P. Lambert[12]

Dr. Lambert provided two expert reports on this matter, both of which she opined that petitioner's thrombocytopenia was a long-standing, asymptomatic, inherited condition, and that the vaccines petitioner received were not the cause of his thrombocytopenia. *See* Resp't Ex. A at 3; Resp't Ex. E at 3.

Dr. Lambert first explained the difference between immune thrombocytopenia ("ITP") and inherited macrothrombocytopenia. Resp't Ex. A at 3-4. She explained that ITP "is characterized by a platelet count of" less than 100,000 "in the absence of other hematologic abnormalities and without any evidence of other underlying etiologies." *Id.* Inherited macrothrombocytopenias, on the other hand "are a group of inherited platelet disorders that are generally associated with autosomal dominant inheritance of variants in platelet related gene that most often impact the platelet cytoskeletal machinery." *Id.* at 3-4. Dr. Lambert notes that "these platelet disorders are rarely associated with a bleeding phenotype, are often mistaken for chronic ITP, and are associated with a high mean platelet volume, moderate to mild thrombocytopenia, and elevated immature platelet fraction." *Id.* at 4. Dr. Lambert acknowledged that the hematologic work of petitioner's father was "incomplete" but she argued that petitioner's low but stable platelet ranges was consistent with a familial macrothrombocytopenia. Resp't Ex. A at 4.

Dr. Lambert referenced Arnold et al., which explained that ITP's clinical presentation can

[11] Hamiel, U. et al., *Recurrent Immune Thrombocytopenia After Influenza Vaccination: A Case Report,* 138 Pediatrics 2-5 (2018). [Pet'r Ex. 32].

[12] Dr. Lambert is a board-certified pediatrician and pediatric hematologist/oncologist. She is an Associate Professor of Pediatrics at the University of Pennsylvania and is an attending physician at the Children's Hospital of Philadelphia where she is the clinical director of the Special Coagulation Laboratory, a co-director of the multidisciplinary Immune Dysregulation Frontier Clinic, and the director of the Pediatric Platelet Disorder Program. She is a member of the American Society of Hematology, the American Society of Pediatric Hematology/Oncology, the International Society of Thrombosis and Haemostasis and the Hemostasis and Thrombosis Research Society. Resp't Ex. A at 1. Dr. Lambert earned her bachelor's degree from Rensselaer Polytechnic Institute and her medical degree from UMDNJ – New Jersey Medical School. Resp't Ex. B. She completed her residency in pediatrics at St. Christopher's Hospital for Children and completed her fellowship in Hematology/Oncology at the Children's Hospital of Philadelphia. *Id.*

range of "asymptomatic thrombocytopenia to nuisance bruising to life-threatening intracranial hemorrhage." Resp't Ex. A, Tab 8 at 1.[13] Arnold also explains that the "diagnosis of primary ITP, a platelet count of <100 X 10/L in the absence of an identifiable cause, is nonspecific," and that in their study, they had identified a subset of patients that met the standard criteria, but never requirement treatment and their symptoms were mild. *Id.* at 4-5. Arnold stated that one in seven patients suspected of ITP of having primary ITP was misdiagnosed at some point during their disease course. *Id.* at 1.

Further, Dr. Lambert argued that patients with definite ITP have "extremely low platelet counts below 20x10/L at some point in their disease course." Resp't Ex. E at 2. Citing Li et al, Dr. Lambert wrote, "…in addition, 42.7% of patients with suspected ITP17 exhibited severe thrombocytopenia. Comparatively, only 10.5% of patients with non-immune thrombocytopenia exhibited severely low platelet counts." *Id.*; *see also* Resp't Ex. A, Tab 6.[14] Dr. Lambert noted that petitioner's platelet count was fairly uniform, and at times rose above 100K, which is more consistent with a long-standing asymptomatic congenital thrombocytopenia. Resp't Ex. E at 2.

iii. Respondent's Expert-Dr. Ross Kedl

Respondent also submitted an expert report from Dr. Ross Kedl, an immunologist. Resp't Ex. C. Dr. Kedl opined that the vaccines petitioner received on May 18, 2017 did not cause him to develop ITP and that Dr. Forman's opinion is based on identifying the nearest preceding event—the vaccinations—as the cause. *Id.* at 2. Dr. Kedl agrees with Dr. Lambert that petitioner did not have immune-mediated thrombocytopenia, but instead "idiopathic" thrombocytopenia. *Id.* at 4.

With respect to Dr. Forman's opinion regarding the mechanism for which the vaccines could cause ITP, Dr. Kedl argues that Dr. Forman does not provide any homology between any of the vaccines the petitioner received and platelet antigens. Resp't Ex. C at 5. Most relevant to this case and to the dispositive issue in this matter, Dr. Kedl states that the onset of 2 days post-vaccination is "insufficient" for the theory of molecular mimicry. *Id.* He states that a 7–10-day onset of symptoms of thrombocytopenia is "generally accepted as necessary for the activation and expansion of an adaptive immune response to any vaccination or infectious challenge." *Id.*

IV. Analysis and Conclusion

The parties agree that petitioner suffers from thrombocytopenia. *See* Resp't Br. at 10; Pet'r Br. at 3. Instead, they mostly disagree about the underlying cause of petitioner's condition, with Dr. Forman arguing that petitioner suffers from chronic immune thrombocytopenia, and Dr. Lambert opining petitioner has a congenital form of thrombocytopenia. *See* Pet'r Ex. 18 at 6; Resp't Ex. A at 4; Resp't Ex. E at 2. Respondent agrees that petitioner's thrombocytopenia

[13] Arnold, D. et al., *Misdiagnosis of Primary Immune Thrombocytopenia and Frequency of Bleeding: Lessons from the McMaster ITP Registry,* 1(25) Blood Advances 2414-2420 (2017). [Resp't Ex. A, Tab 8].

[14] Li, N. et al., *Platelet Variability Index: A Measure of Platelet Count Fluctuations in Patients with Immune Thrombocytopenia,* 5(20) Blood Advances 4256-4264 (2021). [Resp't Ex. A, Tab 6].

is "chronic" as it is long-standing, but it is not acute. Ultimately, this conflict goes to the role of the vaccines petitioner received on May 18, 2017, in the development of his condition. Further, this case turns on a much simpler issue: *when* petitioner's ITP began in relation to his vaccinations.

As discussed below, petitioner has failed to provide preponderant evidence to satisfy *Althen* prongs two and three.

a. *Althen* prong one

Dr. Forman argued that the most likely mechanism for which the vaccines petitioner received could cause ITP was molecular mimicry. Pet'r Ex. 18 at 6; Pet'r Ex. 54 at 4 ("Molecular mimicry is repeatedly cited as a mechanism for causing ITP after vaccination." He also notes that in several of the case reports, the vaccines the patients received "were causal rather than coincidental." Pet'r Ex. 54 at 4; *see e.g.* Pet'r Ex. 32 at 4 ("The cause of ITP remains unknown in most cases, but it can be triggered by a viral infection or other immune triggers, such as vaccinations, most likely by the mechanism of molecular mimicry."). The medical articles and numerous case report articles does support molecular mimicry as a possible causal mechanism of post-vaccination ITP. *See* Pet'r Exs. 43 at 2; Pet'r Ex. 25 at 8; Pet'r Ex. 29 at 2. Further, the undersigned, as well as other special masters, have accepted the theory of molecular mimicry as a causal mechanism for ITP following vaccination. *See Mitchell v. Sec'y of Health & Hum. Servs.*, No. 19-1534V, 2023 WL 4483134 (Fed. Cl. Spec. Mstr. Jan. 11, 2023) (accepting the flu vaccine can cause ITP through the mechanism of molecular mimicry); *Walls v. Sec'y of Health & Hum. Servs.*, No. 16-557V, 2020 WL 13801342, at *15-16 (Fed. Cl. Spec. Mstr. June 23, 2020) (accepting molecular mimicry as the mechanism for the DtaP, Hib, Hep B & PCV vaccines to cause ITP); *Phillips v. Sec'y of Heath & Hum. Servs.,* No. 16-906V, 2020 WL 7767511, at *25 (Fed. Cl. Spec. Mstr. Nov. 23, 2020) (accepting molecular mimicry between the HPV vaccine and ITP, denying on other grounds); *Johnson v. Sec'y of Health & Hum. Servs.,* No. 14-113V, 2017 WL 772534 (Fed. Cl. Spec. Mstr. Jan. 6, 2017) (accepting molecular mimicry as a causal mechanism between ITP and the HPV vaccine); *Ebenstein v. Sec'y of Health & Hum. Servs.*, No. 06-573V, 2010 WL 5113185, at *2 (accepting molecular mimicry links the MMR vaccine and ITP).

Petitioner received multiple vaccines on May 18, 2017, some of which were implicated in the case reports cited by Dr. Forman as a causal link to ITP and epidemiological evidence is not necessary for petitioner to establish *Althen* prong one. Thus, the undersigned will accept Dr. Forman's theory of molecular mimicry as the mechanism to explain how the flu, hepatitis A and B vaccine, IPV, meningococcal, and Tdap can cause ITP.

However, the fatal issue to petitioner's claim lies with the onset of his thrombocytopenia and then subsequent clinical course.

b. *Althen* prong three

Petitioner has failed to demonstrate the onset of his chronic thrombocytopenia began within an appropriate timeframe given the proposed mechanism of molecular mimicry.

Petitioner received the IPV, Tdap, Twinrix, meningococcal, and flu vaccinations on May 18, 2017. Two days later, on May 20, 2017, he was hospitalized for a mental health illness and his low platelet level was found during this admission. *See* Pet'r Ex. 11 at 221. Petitioner did not report any other symptoms possibly related to thrombocytopenia, such as petechiae or bruising.

Dr. Forman opined that a 2-3 day timeframe between vaccinations and thrombocytopenia is generally accepted to infer vaccine causation. Important to the third *Althen* prong is that "the explanation for what is a medically acceptable time frame must also coincide with the theory of t vaccine causation of the injury alleged (under *Althen* prong one). *De Bazan,* 539 F.3d at 1352. A temporal relationship between a vaccine and an injury standing alone does not constitute preponderant evidence of vaccine causation. *See e.g. Veryzer,* 100 Fed. Cl. at 356 (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury"), *aff'd* 475 F. App'x 765 (Fed. Cir. 2012). Accepting petitioner's theory of molecular mimicry between the vaccines and ITP, the onset of petitioner's symptoms needs to fall within a relevant timeframe consistent with that theory. This is where the onset of 2-3 days in petitioner's case fails.

Importantly, most of the medical literature filed in this case, including articles by petitioner, invoke a later onset of ITP post-vaccination than two days. The Hamiel case report Dr. Forman cited explained that the onset of ITP symptoms after the child patient received the flu vaccine on three separate occasions began 6-7 days post-vaccination. Pet'r Ex. 32 at 2. The Neau article describes cases of ITP occurring after the recombinant hepatitis B vaccine occurring between 2 weeks to three months after vaccination. Pet'r Ex. 45 at 2. The Nagasaki article, which describes three elderly patients developing ITP symptoms after receiving the flu vaccine had first symptoms occurring within four weeks of the vaccination. Pet'r Ex. 43 at 3.[15] Similarly, the Casoli case report described a patient developing ITP symptoms 15 days after receiving the flu vaccine. Pet'r Ex. 23 at 1. The Vlacha article, which describes a case of a pediatric patient developing recurrent thrombocytopenia after repeated MMR vaccines indicated that onset of his symptoms occurred 19- and 23-days post-vaccination. Pet'r Ex. 73 at 2.[16]

Moreover, the cases in the Vaccine Program in which molecular mimicry has been invoked as the causal mechanism for ITP, the onset of the symptoms of those petitioners is later than 2-3 days. For example, in *Walls,* the onset of petitioner's ITP's symptoms was found to be nine days post-vaccination. *Walls,* 2020 WL 13801342, at *21. The petitioner in *Mitchell* developed symptoms of ITP 35-days after the flu vaccine, which the Special Master found to be consistent with mechanism of molecular mimicry. *Mitchell,* 2023 WL 4483134, at *27.

While some of the case reports do note a more rapid onset of symptoms following repeat vaccinations, suggesting a challenge-rechallenge circumstance, there is not sufficient evidence to

[15] Nagasaki, J. et al., *Post-influenza Vaccination Idiopathic Thrombocytopenic Purpura in Three Elderly Patients,* Case Rep Hematol. 2016:7913092 (2016). [Pet'r Ex. 43].

[16] Vlacha, V. et al., *Recurrent Thrombocytopenia After Repeated Measles-Mumps-Rubella Vaccination,* 97(5) Pedatr. 738-39 (1996). [Pet'r Ex. 73].

demonstrate that petitioner had previously received any of the vaccines he had received on May 18, 2017 or that he had developed any specific immune response to viruses against which the vaccines are meant to protect. In fact, prior to his vaccination, it was noted that petitioner was "negative" for antibodies to the hepatitis A and B virus. *See* Pet'r Ex. 3 at 20 ("Hepatitis A Virus Ab-Negative (Not Immune); Hepatitis B Virus Surface Ab-Negative (Susceptible)"). No medical records were filed to indicate that petitioner had previously received any of the vaccines in question. Thus, the evidence does not support a challenge-rechallenge or recall response which could explain an earlier onset than would be expected based on molecular mimicry in the adaptive immune response. The literature supports a longer period of onset as in Vlacha, Nuevo, and Kelton articles.

Accordingly, petitioner has failed to demonstrate by preponderant evidence that the onset of his chronic thrombocytopenia two days post-vaccination is a medically acceptable timeframe consistent with the theory of molecular mimicry.

c. *Althen* prong two

As petitioner has failed to demonstrate that the onset of his idiopathic thrombocytopenia two days post-vaccination was a medically appropriate timeframe under *Althen* prong three, he cannot demonstrate a logical sequence of cause and effect as required by *Althen* prong two.

Under *Althen* prong two, petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Capizzano*, 440 F.3d at 1324 (quoting *Althen*, 418 F.3d at 1278). While *Althen* prong one requires a petitioner to show that the vaccine *can* cause the underlying condition, under prong two he or she must show that the vaccine *did* cause the condition in his or her specific case. *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1356 (Fed. Cir. 2006).

While it is true that petitioner's low platelet level was found two days after his vaccination, it does not establish that the vaccines he had received were the actual cause for the illness. Additionally, petitioner's clinical course and treatment—or lack thereof—was inconsistent with immune mediated thrombocytopenia after vaccination as described in the medical literature. Indeed, given his lack of symptoms, his relatively mild and stable platelet counts, and the noted thrombocytopenia in his father, it appears more likely that an underlying mild thrombocytopenia was incidentally discovered after the vaccinations but was not caused by them.

For example, the Arya article described two cases of pediatric patients who developed nosebleeds and purpuric spots approximately three and eight days after receiving booster doses of DPT vaccines. Pet'r Ex. 21 at 1. Further, the platelet levels in the pediatric patients were found to be between 30,000 and 50,000 and they were treated with steroids for multiple weeks. *Id.* The Kelton article described a patient who developed purpura and hemoptysis two weeks after the flu vaccine, and his platelets were 20,000. Pet'r Ex. 64 at 1.[17] This patient was treated with steroids until his platelet level normalized. When the same patient received the

[17] Kelton, J., *Vaccination-Associated Relapse of Immune Thrombocytopenia*, 245 JAMA 369-371 (1981). [Pet'r Ex. 64].

pneumococcal vaccine one year later, he developed purpura and nose bleeds two weeks after vaccination and his platelet level was 32,000. *Id.* The Vlacha case report describes a pediatric patient that developed petechiae and bruising 23 days after receiving the third dose of the MMR vaccine. Pet'r Ex. 73. The patient's platelet level was 10,000 and he was treated with steroids for multiple weeks. *Id.* And while the Nagasaki article did report on an elderly patient developing thrombocytopenia without any other associated symptoms, the onset of the thrombocytopenia was four weeks post-vaccination and her platelet level was 39,000, requiring treatment. Pet'r Ex. 43 at 1.

In petitioner's case, he did not have any associated symptoms of immune thrombocytopenia, such as bruising, nosebleeds, or bleeding gums prior to the onset of his low platelet levels, as described in the case reports above. Further, the platelet levels of the patients in the case reports were far lower than petitioner's on initial blood draws and they all required some type of treatment. As Dr. Lambert noted in her reports, petitioner's stable and relatively high platelet count makes much more likely that petitioner's thrombocytopenia was inherited and not immune mediated. Resp't Ex. A at 4; Resp't Ex. E at 2. Given the stark contrast between petitioner's presentation and the cases describing immune thrombocytopenia purpura, and the lack of treatment, there is not sufficient evidence to support a logical sequence of cause and effect between the vaccines petitioner received and his idiopathic thrombocytopenia.

Accordingly, petitioner is unable to demonstrate by preponderant evidence *Althen* prong two.

V. Conclusion

After a careful review of the record, petitioner has failed to provide preponderant evidence that the vaccines he received on May 17, 2017, caused him to develop idiopathic chronic thrombocytopenia. Accordingly, petitioner's claim is hereby **DISMISSED.**

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master