In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: December 16, 2025

JOEL LEMIEUX,	*	
	*	
Petitioner,	*	No. 19-1121V
	*	
v.	*	Special Master Gowen
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Immune Thrombocytopenia; Influenza.
Respondent.	*	

Milton C. Ragsdale, IV, Ragsdale LLC, Birmingham, AL, for petitioner.
Ryan D. Pyles, U.S. Dept. of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On August 1, 2019, Joel Lemieux ("petitioner") filed his claim in the National Vaccine Injury Compensation Program.[2] Petition (ECF No. 1). Petitioner alleges that as a result of receiving the influenza vaccine on October 11, 2016 he developed immune thrombocytopenia pupura ("ITP"). *Id.* After an entitlement hearing on May 16, 2024, and a review of the evidence, the undersigned finds that petitioner has established by preponderant evidence that he is entitled to compensation.

I. Procedural History

Petitioner filed his claim on August 1, 2019 and filed accompanying medical records on September 12, 2019. Petitioner's Exhibits ("Pet'r Exs.") 4-15 (ECF Nos. 6-7). Petitioner filed an

[1] Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this decision contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. **This means the decision will be available to anyone with access to the Internet.** Before the decision is posted on the court's website, each party has 14 days to file a motion requesting 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). "An objecting party must provide the court with a proposed redacted version of the decision." *Id.* **If neither party files a motion for redaction within 14 days, the decision will be posted on the court's website without any changes.** *Id.*

[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.

expert report from Eric Gershwin, M.D.[3] and medical literature on March 22, 2021. Pet. Exs. 16-25 (ECF No. 20). Respondent filed his Rule 4(c) report on July 6, 2021, recommending against compensation. Respondent ("Resp.") Report ("Rep't.") (ECF No. 22). Respondent also filed an expert report from Andrew J. MacGinnitie, M.D.[4] and from Lisa Kreuziger, M.D.[5] Resp. Exs. A & C. Petitioner filed a supplemental expert report from Dr. Eric Gershwin on September 21, 2021. Pet. Ex. 30 (ECF No. 26).

The undersigned held a status conference on October 5, 2021. During the status conference, I explained that petitioner's diagnosis of ITP was not in question by the medical records or the experts from both parties. Rule 5 Order (ECF No. 27). I recommended that the parties seek to resolve this matter informally given the number of flu-ITP cases that have been resolved in favor of petitioner in the Vaccine Program. *Id.* at 2. Respondent also sought an opportunity to respond to Dr. Gershwin's supplemental expert report. *Id.*

The parties engaged in unsuccessful settlement negotiations until February 6, 2024 and wanted to proceed with an entitlement hearing on May 16-17 2024. Joint Status Report (ECF No. 74). Both parties submitted pre-hearing briefs, exhibit lists and updated medical literature that their experts were going to rely upon during the hearing.

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[3] Dr. Eric Gershwin, MD, MACR, MACP, currently serves at the University of California at Davis School of Medicine in the Division of Rheumatology, Allergy and Clinical Immunology. Pet'r Ex. 17 at 1. He received his medical degree from Standard University in 1971. He is Board Certified in Internal Medicine with a subspeciality in Rheumatology and Allergy and Clinical Immunology. *Id.* at 2. He is licensed to practice medicine in California. *Id.* For two years, he was a clinical associate in immunology at the National Institutes of Health. *Id.* Dr. Gershwin became an assistant professor of medicine at the University of California School of Medicine in Davis, California and in 1977 became a Director of the Allergy-Clinical Immunology Program at the University of California of Medicine. *Id.*; Tr. 50. He is the Editor-in-Chief of the Clinical Reviews in Allergy Journal and serves as co-editor for other medical journals from 1983 through present day. *Id.* at 4-5. Additionally, Dr. Gershwin has been the primary author or co-author on numerous medical articles related to the field of immunology and autoimmune diseases, including immune thrombocytopenia purpua. *Id.* at 9-139; Tr. 53-55. Based on Dr. Gershwin's educational and professional experience in the field of immunology, he was accepted as an expert in the field of immunology. Tr. 56.

[4] Dr. Andrew MacGinnitie is an attending physician and Clinical Chief for the Division of Immunology at Boston's Children's Hospital. Resp't Ex. A at 1; Resp't Ex. B. Dr. MacGinnitie received his medical degree from the University of Chicago, Pritzker School of Medicine and was a resident in Pediatrics at Boston Combined Residency Program. Resp't Ex. B at 1. Dr. MacGinnitie is board certified in both Allergy/Immunology and Pediatrics. Resp't Ex. A at 1. Dr. MacGinnitie was an attending physician at Children's Hospital of Pittsburgh of UPMC from 2004 to 2011. Resp't Ex. B at 2. He has treated patients with immune thrombocytopenia purpura ("ITP") in his clinical practice. Resp't Ex. A at 1. Dr. MacGinnitie has authored or co-authored over 25 medical articles related to the field of immunology and allergy. Resp't Ex. A at 12-15. Dr. MacGinnitie was accepted as an expert in the field of immunology and allergy. Tr. 132.

[5] Dr. Lisa Baumann Kreuziger is an Associate Professor of Medicine in the Division of Hematology and Oncology at the Medical College of Wisconsin in Milwaukee, Wisconsin. Resp't Ex. C at 1. She received her medical degree from the University of Wisconsin in 2006 and completed her residency at the Mayo Clinic in Rochester, Minnesota. *Id.* She is board certified in hematology and medical oncology and is licensed to practice medicine in Wisconsin and Minnesota. *Id.* at 2-3. She serves as the Associate Medical Director for the BloodCenter in Wisconsin and is the Medical Director at Versiti in Milwaukee, Wisconsin, as well as, an Associate Professor at the Medical College of Wisconsin. Resp't Ex. D at 2. She has treated patients with ITP. Tr. 171. Dr. Kreuziger has co-authored numerous medical articles in the field of hematology. *Id.* at 7-9. Dr. Kreuziger was accepted as an expert in the field of hematology. Tr. 173.

An entitlement hearing was held on May 16, 2014. Petitioner and Dr. Eric Gershwin testified during the entitlement hearing along with Drs. MacGinnitie and Kreuziger. After the hearing the parties jointly decided not to file post-hearing briefs. Accordingly, this matter is now ripe for adjudication.

II. Legal Standard for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Rooks v. Sec'y of Health & Hum. Servs.,* 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). 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 or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010).

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 her injury ("*Althen* Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and her 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 the Evidence

a. Medical History as Reflected by the Medical Records and Petitioner's Testimony

Prior to petitioner receiving his flu vaccination on October 11, 2016, petitioner had a history of lumbar disc disease, gastroesophageal reflux disease, hypertension, and asthma. Pet'r Ex. 4 at 8-9; *see also* Tr. 8 (petitioner testified to having chronic back pain due to a workplace

injury). On October 11, 2016, petitioner received his flu vaccine from his primary care physician, Dr. Matthew Kulick. *Id.* at 6.

Petitioner testified that he observed a small lump on his arm at the injection site of the vaccine. Tr. 13. However, by that evening, the lump on his arm had resolved. Tr. 13. He reported feeling ill, as if he was "coming down with a cold" for the next two or three days, but went back to normal. *Id.* With respect to his first symptom of ITP, he testified that around the 12th or 13th of November, he observed having red marks on his chest and neck. Tr. 15. The red-marks followed a three day period of itchiness, that petitioner initially attributed to new sheets. Tr. 14-15. Petitioner testified that he called Dr. Kulick's office to make an appointment regarding his red marks, and the next available appointment was two weeks away. Tr. 17.

On November 30, 2016, petitioner went to Dr. Kulick and reported that he was noticing bruising for 2-3 weeks and red marks were appearing on his arms, chest, leg, and feet. Pet'r Ex. 4 at 5. Dr. Kulick observed petechiae on petitioner's body and ordered a CBC. *Id.* The CBC found that petitioner's platelet levels were "4 thou/mcL" (4,000) with the normal range listed as "140-440 thou/mcL." *Id.* at 49. Dr. Kulik directed petitioner to go to the emergency room due to his low platelet levels.

On December 1, 2016, petitioner went to the emergency department of McLaren Oakland Hospital. Pet'r Ex. 5 at 67. Under "History of Present Illness" petitioner reported having petechiae on all of his extremities and denied any bleeding, fevers, chills, or other complaints. *Id.* His platelet count at the hospital was "3 LL" and he was diagnosed with "acute severe thrombocytopenia, suspect ITP," and petitioner received a platelet transfusion immediately and was admitted for one night. *Id.* Petitioner was discharged the following day, on December 2, 2016, with a diagnosis of thrombocytopenia and the discharge summary explains that petitioner was "seen by his PCP for new onset petechiae that has been ongoing for the past three weeks." *Id.* at 73. After petitioner received an IVIG infusion, his platelet count improved to 3,800 and he was given dexamethasone for four days. *Id.* Petitioner was to follow-up with hematologist, Dr. Knoll after discharge. *Id.* at 74. His discharge diagnosis was, "acute severe thrombocytopenia, suspect ITP." *Id.*

After his hospitalization, petitioner had a follow-up with his PCP on December 7, 2016 and reported having red blisters, tingling around his lips, and itchiness all over his body. Pet'r Ex. 4 at 4. Petitioner reported that he felt like his body was on fire, but his temperature was low. *Id.* Dr. Kulick also wrote, "Thinks he had an allergic reaction after flu injection while taking hydrochlorothiazide, wants to discuss." *Id.* Dr. Kulick referred petitioner to hematology. *Id.*

Petitioner had an appointment with hematologist, Dr. Feroze Momin for his ITP on December 9, 2016. Pet'r Ex. 6 at 4. Petitioner reported developing a petechial rash after the flu vaccine and his platelets went down to 2,000. *Id.* Dr. Momin noted that petitioner had been given IVIG while hospitalized and given 40 mg Decadron to take. *Id.* At this appointment petitioner's peticheal rashes were recorded as "resolved." *Id.* Dr. Momin diagnosed petitioner with "ITP by history, treated with IVIG and high dose Dexamethasone," and directed petitioner to begin a steroid taper and return Friday. *Id.* at 5. When petitioner's blood was drawn on December 13, 2016, his platelets were recorded at 143 and "low." *Id.* a 7. At a follow-up

appointment on December 19, 2016, petitioner's platelet count was 154 and petitioner reported being "less anxious" after his steroid taper. *Id.* at 11. Dr. Momin diagnosed petitioner with "ITP by history temporally associated with flu shot administration," but Dr. Momin also wrote that the cause of petitioner's ITP was "unknown" and that "ITP in adults is usually relapsing: If remission fails after tapering steroids splenectomy/Rituximab may be considered." *Id.* at 10. Given petitioner's anxiety and depression, which was worsened by the steroids, Dr. Momin recommended petitioner be re-evaluated by his psychiatrist to adjust medications as necessary. *Id.*

Petitioner underwent a bone marrow biopsy on December 23, 2016, which findings were "compatible with the clinical history of idiopathic thrombocytopenia purpura ("ITP")." Pet'r Ex. 6 at 11. There was no evidence of leukemia, lymphoma or significant dysplasia. *Id.*

Petitioner went to the Royal Oak Hospital emergency department on December 23, 2016, for tingling sensations and bilateral leg pain about three weeks after being diagnosed with ITP. Pet'r Ex. 9 at 7. It was noted that petitioner "appeared severely anxious." *Id.* at 11. Based on his physical examination, the attending physician Dr. Steven did not believe that petitioner had Guillain-Barre syndrome or significant neuropathy, and that petitioner did not require IVIG at the time given his platelet count had improved. *Id.* Petitioner was discharged.

Petitioner returned to Dr. Momin on January 3, 2017 to discuss his bone marrow biopsy and continued management of ITP. Pet'r Ex. 6 at 17. Dr. Momin noted that petitioner's bone marrow biopsy showed "megakaryocytes adequate in marrow, suggesting peripheral destruction (ITP) as the most likely cause," and that the 40 mg of Decadron caused petitioner severe anxiety, but that petitioner was on 4 mg of Decadron as necessary and his platelets were around 25,000. *Id.* at 17. Dr. Momin discussed other treatment options with petitioner and settled on Rituxan infusions. *Id.*

Petitioner received four Rituxan infusions on January 20, January 27, February 3, and February 10, 2017 with little change in his platelet levels. Pet'r Ex. 7 at 9, 32, 62, & 90. On February 17, 2017, petitioner returned to Dr. Momin, and petitioner's platelet count was 12,000. Pet'r Ex. 6 at 24. Dr. Momin noted that petitioner's ITP was refractory to Rituximab and he was prescribed Eltrombopag/N plate. *Id.*

At a follow-up appointment with Dr. Momin on April 28, 2017, petitioner's platelet level was 18,000 and he reported "feeling better" with no new symptoms. Pet'r Ex. 6 at 33. Petitioner's diagnosis remained ITP refractory to Rituximab and steroids and petitioner was to continue Eltrombopag. *Id.* at 32.

Despite the Eltrombopag, petitioner's platelet count dropped to 5,000 by July 26, 2017. *See* Pet'r Ex. 6 at 34. On July 28, 2017, petitioner had an appointment with Dr. Momin who noted that petitioner had mild bruising and his platelet count remained low. *Id.* at 50. Dr. Momin revised petitioner's diagnosis to "recurrent ITP refractory to Eltrombopag" and referred petitioner to Royal Oak Hospital for IVIG treatment. *Id.*

Petitioner did not present to Royal Oak Hospital until August 22, 2017. Pet'r Ex. 11 at 4. When he arrived, petitioner's platelet level was 10,000 and he had been experiencing headaches with photophobia. *Id.* His petechial rash had slowly returned and he was experiencing some mild joint pain. *Id.* Petitioner was initially treated with IVIG and steroids, but on the second day of IVIG, petitioner developed a fever of 102, and the IVIG was discontinued. *Id.* at 4-5. Petitioner's platelets recovered to 165,000 and he was discharged on August 26, 2017. *Id.* at 5.

Petitioner had a follow-up appointment with Dr. Momin on November 3, 2017, where Dr. Momin noted petitioner's reaction to the IVIG and that it had been "difficult to reach [petitioner]." Pet'r Ex. 6 at 63. Dr. Momin wrote that petitioner was "currently receiving N-plate [infusions] at the Royal Oak Infusion Center" and if petitioner had no response, than petitioner would have to consider a splenectomy. *Id.* Dr. Momin also wrote, "[Petitioner] still believes his ITP resulted from the flu shot he received." *Id.*

Petitioner received Nplate injection on November 29 and December 6, 2017. *See* Pet'r Ex. 11 at 82-83. Despite these infusions, petitioner's platelets were 3,000 and he went to the emergency department of Royal Oak Hospital on December 13, 2017. Pet'r Ex. 11 at 56, 62. Petitioner did not report any accompanying symptoms of his low platelets, only a petechial rash was observed. *Id.* at 56. Upon admission, his platelets were 7,000 and petitioner was admitted for IVIG infusion. *Id.* at 63. While he was hospitalized, petitioner had a consult with Dr. Deshmukh Ganesh for a splenectomy. *Id.* at 66. Dr. Ganesh wrote that the "interval between IVIG infusions seems to be decreasing," but petitioner was going to seek a second opinion at the University of Michigan to see if there are any other options other than a splenectomy. *Id.* Dr. Ganesh also wrote that petitioner was "apprehensive about post-splenectomy vaccinations, as [petitioner] has had many bad reactions to vaccines in the past." *Id.* Petitioner and Dr. Ganesh had a "long conversation…discussing [the] splenectomy and post-splenectomy vaccinations, etc.," and the note indicates that petitioner would follow-up with Dr. Ganesh after his appointment with the hematologist at University of Michigan. *Id.* at 69. Petitioner received two infusions of IVIG while hospitalized and he was discharged on December 15, 2017.

On January 11, 2018, petitioner had an appointment with hematologist, Dr. Asif Alavi. Pet'r Ex. 12 at 32. The "History of Present Illness" at this appointment recounted petitioner's medical history, including multiple different treatments of IVIG, Nplate, and dexamethasone, and various platelet levels. *Id.* This section of the record also states, "[Patient] relates his history as having a flu shot in October 2016. The next day, he developed a large knot at the site of his injection and the next day, he developed large lumps on his right leg that became purulent." *Id.* Petitioner testified that this history is inconsistent with what occurred. Tr. 34. Petitioner stated that he did not have any large lumps on his legs until around November 29th or 30th [of 2016] and that he did have an injection site bump, but it went away. *Id.*

Dr. Alavi described petitioner's condition as "refractory immune thrombocytopenia" and that at his current appointment petitioner had bruises present. *Id.* Under the "Immunization" section of the record, it states, "Flu vaccine is felt to have triggered his immune response leading to his immune thrombocytopenia. He had a tetanus booster at age 13 when he passed out and required emergency room treatment." *Id.* at 32. Petitioner reported headaches when his platelets were low. *Id.* Petitioner's physical exam was positive for large bruises covering his trunk and arms, and a mild papular rash covered his back and trunk. *Id.* at 33. Petitioner's

platelets were 9,000 at this appointment. *Id.* Dr. Alavi's impression of petitioner was, "Immune thrombocytopenia refractory to steroids, rituximab, Promacta, and Nplate. He responds to IVIG 0.4 gm/kg for five days, but has severe serum sickness when he receives the medication." *Id.* at 34. Dr. Alavi wrote that petitioner "refused splenectomy" and instead recommended a "dual approach therapy" and petitioner would restart Eltrombopag 50 mg daily and also trial Danazol 200 mg twice daily. *Id.* If petitioner's platelets fall below a response to the combined regime, Dr. Alavi was recommending IVIG for one dose to increase platelet levels. *Id.* at 34-35.

On January 18, 2018, petitioner sought a third opinion with hematologist, Dr. Charles Schiffer at the Karmanos Cancer Center at Wayne State University. Pet'r Ex. 13 at 8. The "History of Present Illness" from this appointment also recounts petitioner's history regarding his treatment and platelet levels since November 2016. *Id.* at 8-9. Petitioner associated the onset of his ITP to the flu vaccine in October 2016 at this appointment as well. *Id.* at 8. At this appointment, petitioner reported developing weakness, joint pain and a fever, then 2 to 3 days later developed petechiae with bruising. *Id.* Petitioner testified that this record was also incorrect with respect to the development of petechiae and bruising. Tr. 37. He stated that he did "feel a little under the weather" after the flu vaccine, but did not have petechiae and bruising 2-3 days post-vaccination. *Id.*

At the appointment, Dr. Schiffer noted that petitioner had an appointment with Dr. Schiffer on January 11, 2018 who recommended a trial of Promacta and Danazol. *Id.* at 9. Dr. Schiffer diagnosed petitioner with "Immune thrombocytopenia" and agreed with the treatment plan provided by Dr. Alavi, but Dr. Schiffer also informed petitioner not to "exclude splenectomy as an option" as it has been "shown to be effective especially in patients who respond to steroids or IVIG." *Id.* at 10. Dr. Schiffer also recommended that petitioner discontinue use of acetaminophen due to "acetaminophen-related ITP" even though it was rare. *Id.*

On February 13, 2018, petitioner received one infusion of IVIG, and he returned to Dr. Alavi on February 22, 2018 for a follow-up. *See* Pet'r Ex. 12 at 52-53. Petitioner reported experiencing a flu-like syndrome for five days after the IVIG infusion. *Id.* at 52. Petitioner was taking 50 mg of Promacta and Danazol 200mg three times a day. *Id.* But petitioner's platelet levels were 4,000 and Dr. Alavi recommended another infusion of IVIG and to give petitioner medication to reduce serum sickness symptoms. *Id.* at 53. Further, Dr. Alavi wanted to increase petitioner's Promacta dosage, but was waiting on insurance authorization. *Id.*

Petitioner began monthly IVIG infusions in 2018 when his platelet count dropped below 10,000. *See* Pet'r Exs. 12at 100; Pet'r Ex. 15 at 9; Pet'r Ex. 27 at 104-05. At an appointment on June 21, 2018, Dr. Alavi noted that in early June petitioner's platelet count was significantly low and petitioner had to receive an IVIG infusion, which again resulted in serum sickness in the petitioner. Pet'r Ex. 12 at 100. At the appointment Dr. Alavi increased petitioner's Promacta dosage to 100 mg daily in hopes that petitioner could discontinue IVIG. *Id.* at 101. Dr. Alavi also endorsed petitioner's disability status, stating that petitioner is "a candidate for disability for multiple reasons. He develops severe thrombocytopenia with a significant bleeding risk that would be present with almost any line of work." *Id.* at 102. Seven days later, on June 28, 2018, Dr. Alavi wrote an addendum to the June 21st appointment, noting that petitioner's platelets were

again significantly low and that petitioner "is not responding as well to IVIG as his last infusion was less than 2 weeks prior," and that petitioner current dosage and regime of Danazol and Promacta for 3 months "can be considered to have failed this therapeutic approach." *Id.* at 100. Dr. Alavi sought approval for Fostamtinib, given petitioner's ITP was refractory to all other agents. *Id.*

At a follow-up appointment on July 26, 2018, Dr. Alavi noted that petitioner's insurance company did not approve Fostamatinib and the office was trying to appeal the insurance decision. Pet'r Ex. 27 at 74. Petitioner was started on Cyclosporine along with the Promacta, tapering the Danazol, but he continued to receive IVIG infusions if his platelets dropped below 10,000. *Id.* By August 9, 2018, petitioner's platelets were 56,000 and he was to continue with Cyclosporine and Promacta. *Id.* Unfortunately, this combination of drugs did not work and petitioner's platelets dropped again. *Id.* at 168. At an appointment on April 25, 2019, Dr. Alavi recounted petitioner's interval history, writing:

> [Petitioner] was then started on Fostamatinib 100 mg twice daily on his last visit on 3/13/2019, received IVIG on March 13, 2019. Follow-up platelet was 77, however, his response dwindled as counts dropped to 6 on March 27, 2019, 3 on April 11, 2019, and 2 on April 23, 2019, where he was ready to start on Elthrombopag[6] on April 23, 2019.

Id. at 168. Dr. Alavi wrote that petitioner would be re-started on Danazol 200 mg three times a day and he would stop Fostamatinib. *Id.* at 169. Petitioner was also referred to the emergency department for another IVIG infusion because his platelets were below 10,000. Petitioner continued to have appointments with Dr. Alavi monthly in 2019 and into 2020.

By the January 2, 2020 appointment, petitioner was receiving IVIG infusions every 2-3 weeks and did respond well, but had serum sickness after the infusions that resulted in fatigue and left petition bedbound for several days afterwards. Pet'r Ex. 27 at 7. Dr. Avali also ordered a trial of Vincristine. *Id.* at 8. Through 2020, petitioner continued to receive IVIG infusions, took Danazol and Eltrombopag. *See* Pet'r Ex. 27 at 9,23, 306. In May 2020, petitioner began to receive weekly injections of Nplate, which continued into 2021. *Id.* at 283; *see also* Pet'r Ex. 41 at 459.

At some point after 2020, Dr. Alavi wrote a letter stating that petitioner was being treated for immune thrombocytopenia and that petitioner's "condition started after he received an influenza vaccine. For this reason, we are recommending against him receiving any further vaccinations, including the SARS-COV-2 vaccine." Pet'r Ex. 37.

Petitioner's treatment plan remained relatively stable in 2022, when he received weekly N-plate injections, but experienced fatigue and hopelessness. *See* Pet'r Ex. 42 at 349-50. On November 2, 2023, petitioner had an appointment with hematologist, Dr. Mohammed Masri at McLaren Oakland Medical Clinic, referred to by Dr. Alavi. Pet'r Ex. 51 at 243. Petitioner's platelet count was 33,000 and he reported one nosebleed and fatigue. *Id.* Dr. Masri wrote that petitioner had "chronic refractory ITP" and that he was "doing well on Nplate and switched to Doptelet at the end of May 2023." *Id.* at 246. Dr. Masri also wrote, "Reaction to previous flu

[6] Elthrombopag is better known by its brand name Promacta

vaccine causing ITP and reaction to other vaccines such as tetanus patient has not been vaccinated for Covid." *Id.*

At petitioner's April 9, 2024 follow-up with Dr. Masri, it was noted that petitioner's treatment plan of Doptelet was maintaining petitioner's platelet level, but it was dipping into the 20,000 range. Pet'r Ex. 54 at 4688. Dr. Masri and petitioner discussed switching back to N-plate, but petitioner did not want to come in for the weekly injection, so he was going to continue Doptelet. *Id.* at 4691. This was the last appointment petitioner had prior to the entitlement hearing on May 16, 2024.

b. Summary of Expert Opinions

1. Petitioner's Expert: Dr. M. Eric Gershwin

Dr. Eric Gershwin provided an opinion in support of vaccine causation for petitioner. Petitioner submitted two expert reports from Dr. Gershwin and Dr. Gershwin testified at the entitlement hearing on May 16, 2024. *See* Pet'r Exs. 16, 30.

Dr. Gershwin opined that the flu vaccine petitioner received on October 11, 2016 was the cause of petitioner developing immune thrombocytopenia purpua. Pet'r Ex. 16 at 3-4. Dr. Gershwin stated that there was no evidence in the medical records for an underlying autoimmune condition or infection that would have caused petitioner to develop ITP or for petitioner to be more susceptible to loss of tolerance and development of ITP. *Id.* at 3.

Dr. Gershwin explained that ITP (Immune Thrombocytopenia Purpura) is an autoimmune condition, platelets are attacked by both antibodies and likely T-cells that cause the destruction of the platelets. Tr. 59. He testified that the incidence of adult ITP is rare, "somewhere between 1.5 and maybe 6.5 cases out of 100,000." Tr. 60. During the hearing, Dr. Gershwin referred to the Swinkles et al. article, filed by respondent, and stated that the article demonstrates that "there is no single epitope that is consistent with patients in ITP." Tr. 61; Resp't Ex. C, Tab 1.[7] Swinkles explains that "autoantibodies and cytotoxic CD8+T cells (Tc) mediate the anti-platelet response leading to thrombocytopenia." *Id.* Dr. Gershwin testified that the Swinkles article demonstrates that some patients with ITP have antiplatelet antibodies, but other patients do not have identified antiplatelet antibodies. Tr. 61. Swinkles also provides, "Besides autoreactive B cells, CD8+T cells have also been implicated in ITP pathogenesis….Increased levels of CD8+T cells were found in patients without autoantibodies, suggesting that CD8+T cell-mediated autoimmunity can be elicited separately from autoantibody-mediated autoimmunity." Resp't Ex. C, Tab 1 at 5.

Dr. Gershwin opined that the flu vaccine could cause immune thrombocytopenia through molecular mimicry between a component of the vaccine and a platelet antigen. Pet'r Ex. 16 at 6. He described molecular mimicry generally, as occurring "when similarities between foreign and self-peptides favor an activation of autoreactive T or B cells by a foreign-derived antigen in a

[7] Swinkles, M. et al., *Emerging Concepts in Immune Thrombocytopenia,* 9 Front. Immunol, https://doi.org/10.3389/fimmu.2018.00880 (2018). [Resp't Ex. C, Tab 1].

susceptible individual." *Id.* at 7. However, he also explained that in addition to molecular mimicry, autoimmune responses occur through other mechanisms, including a breach in tolerance, non-specific bystander activation, or persistent antigenic stimuli. *Id.* Dr. Gershwin testified that the two classic examples of molecular mimicry that are accepted is Guillain-Barre syndrome and certain viral illnesses, including Zika, Campylobacter, mycoplasma, H1N1 influenza vaccine, and rheumatic heart disease and beta hemolytic strep. Tr. 75-77.

To support his theory for how the flu vaccine could induce ITP through molecular mimicry, Dr. Gershwin referenced an article by Perricone et al. which examined ITP cases after vaccinations, and also discussed the mechanisms in which ITP could occur post-vaccination. Tr. 79; Pet'r Ex. 23.[8] The article states that "Vaccine may induce ITP by several mechanisms…The most likely is through virally induced molecular mimicry." *Id.* at 2. The article continues:

> The molecular mimicry is considered the classic pathogenetic mechanism responsible for ITP development after vaccinations. The epitope, integrated within the vaccine antigen, shares a similar structure with a self-peptide, driving toward self-reactivity. The consequent polyclonal activation and the proliferation of B cells cause the autoantibodies production….The autoantibodies produced through this mechanism generally IgG, interact with several platelet surface GP.
>
> Autoantibodies against GPIb-IIa and/or GPIb-IX were identified as the most likely ligands for antiplatelet antibodies in ITP. Moreover, GPIa-IIa and GPIV were also identified by antigen capture techniques. These antibodies represent the hallmark of the disease.

Id. at 2. However, the authors also note autoantibodies do not explain all ITP cases, especially in those that are anti-platelet antibody negative cases. The same article states:

> In the anti-platelet-antibody-negative cases, a complementary mechanism based on T cell immune-mediated mechanism has been suggested. In particular, a dysregulation of T cell subsets was described, with a prevalence of Th1 profile and increased production of pro-inflammatory cytokines, such as IFN-γ and TNF, and chemokines.

Id. at 3. Dr. Gershwin also testified that the Swinkles article filed by respondent recognizes the mechanism of molecular mimicry to induce ITP. Tr. 66; *see also* Resp't Ex. C, Tab 1 at 3 ("One suggested mechanism by which infections lead to autoimmunity is through molecular mimicry. In this case, viral proteins resemble platelet receptors to evade the immune system. In cases of an immune response against these viral proteins, cross reactivity may occur against platelet receptors, which subsequently lead to autoantibodies specific for both the viral protein and platelet receptors. This could explain the initiation of ITP in some cases.").

Dr. Gershwin acknowledged the limitations of his theory of molecular mimicry, mainly that there are technology limits to dissect the vast human T-cell and B-cell repertoire in the immune system and lack of enough statistical power in epidemiological studies to specifically

[8] Perricone, C. et al., *Immune Thrombocytopenic Purpura ("ITP") Associated with Vaccinations: A review of Reported Cases*, 60 Immnol. Res. 226-235 (2014). [Pet'r Ex. 23].

state with certainty that molecular mimicry is the cause of autoimmune conditions. Pet'r Ex. 16 at 6-7; Pet'r Ex. 30 at 3-4; *see also* Tr. 82. Dr. Gershwin testified that creating an epidemiological study to determine an association between the flu vaccine and ITP is not "theoretically possible based on the current methodology and the database," because there are differences in the flu vaccine formula each year, how rare ITP is in the population, and the genetic differences between people. Tr. 83.

With respect to ITP more specifically, Dr. Gershwin testified that it is very difficult to identify what the molecular mimic is in ITP, in part because of genetic differences in epitopes, especially differences in the receptors on platelets. Tr. 62. Again, referencing the Swinkle article, he noted that the authors stated that FcγR receptors are "important in ITP pathogenesis" and the variability in these receptors on the platelets among patients with ITP also effects which therapies are effective. Resp't Ex. C, Tab 1 at 7-8. Swinkle provides, "Epitopes targeted by platelet autoantibodies seem to differ between patients, coinciding with different responses to therapy and different bleeding phenotypes." *Id.* at 8. Dr. Gershwin argued that because of genetic differences in patients, and the variability of epitopes, it is extremely difficult to identify specific target epitopes. Tr. 90-91.

Dr. Gershwin also testified that molecular mimicry between the MMR vaccine and ITP has been accepted as the causal mechanism, even though there is no study that examines the MMR proteins to platelet proteins. Tr. 98, 232. In response to Dr. Kreuziger's testimony that molecular mimicry is an accepted mechanism for HIV or hepatitis C infections causing ITP, he testified that "there is no paper that shows a sequence of the HIV virus and a sequence of the platelet glycoprotein that shows they match up," and explained that there are three accepted mechanisms for how HIV can induce thrombocytopenia. Tr. 231. He agreed with Dr. Kreuziger that some viruses, such as the wild influenza virus or HIV can induce thrombocytopenia, but that is only one mechanism whereas molecular mimicry is consistently endorsed throughout multiple articles filed by both petitioner and respondent. Tr. 233-34.

Dr. Gershwin stated that the Garbe et al. article demonstrates that the flu vaccine can cause ITP. Tr. 73. The Garbe article sought to evaluate drug-induced thrombocytopenia and found three cases of ITP related to the influenza vaccination. Pet'r Ex. 20 at 10.[9] The authors rated the causality between the flu vaccine and ITP as "probable" and in the case-control analysis "influenza vaccination was associated with a statistically significant 4-fold risk." *Id.*; Tr. 73.

In addition to the many articles endorsing molecular mimicry as a theory for inducing ITP, Dr. Gershwin stated that there was nothing else, such as a virus, or medication in petitioner's medical history that could have caused his ITP. Tr. 87-89. He observed that a year prior to the vaccination, petitioner's bloodwork was in the normal range. Tr. 88. Dr. Gershwin also stated that petitioner did not have any clinical features of ITP prior to the vaccination and there was an "absence of underlying secondary causes of ITP, like connective tissue disease," or an encounter with a wild virus. Tr. 89. Further, Dr. Gershwin argued that petitioner's treating hematologist, Dr. Alavi, "believed that the vaccination was the cause of ITP." Tr. 99. During

[9] Garbe, E. et al., *Drug-induced Immune Thrombocytopenia: Results from the Berlin Case-Control Surveillance Study*, 68 Eur. J. Pharmacol. 821-832 (2012). [Pet'r Ex. 20].

the hearing, Dr. Gershwin referred to the note from petitioner's appointment with Dr. Alavi on January 11, 2018, where it states, "Immunization: Flu vaccine is felt to have triggered his immune response leading to his immune thrombocytopenia." Tr. 103; *see also* Pet'r Ex. 12 at 32.

Dr. Gershwin stated that two case report articles, Hamiel and Almohammadi, support his opinion that the flu vaccine can cause ITP. Tr. 93. Hamiel describes a child who developed ITP after the flu vaccine and had recurrences of thrombocytopenia after receiving subsequent flu vaccines. Pet'r Ex. 52 at 1.[10] The article notes the MMR vaccine is the only vaccine widely considered to have "demonstrated a cause-and-effect relationship," to ITP, but that "individual case reports have described a possible association of ITP with other vaccines, such as varicella, tetanus-diphtheria-acellular pertussis, poliomyelitis, pneumococcal, hepatitis A and hepatitis B, rabies, and HPV." *Id.* at 4. Additionally, Hamiel also notes that there are "some individual reports of ITP occurring in adults within 4 to 17 days after influenza vaccination." *Id.*

Almohammadi et al. describes a case report of a 68-year-old gentleman who received the flu vaccine and the pneumococcal conjugate and two days later developed bleeding oral ulcers and a gross hematuria. Pet'r Ex. 53 at 1.[11] The patient's platelet level was 0 when he was admitted and given IVIG, dexamethasone and oral prednisone for three days. *Id.* at 3. Almohammadi wrote, "ITP is linked with different kinds of vaccinations….A number of case-control studies and case reports regarding post-influenza vaccination ITP have been published. Vaccine-associated ITP may be caused by molecular mimicry, which demands the activation of autoreactive B or T cells by peptides in the vaccines that display structural parallel to antigens found on platelets." *Id.* Dr. Gerhswin testified that this article is important because it not only shows a temporal association between flu vaccine and ITP, but it also demonstrates a rechallenge to the immune system and the onset of the patient's ITP symptoms began closer in time to each flu vaccine. Tr. 229-30.

Dr. Gershwin also opined that the timing between when petitioner received the influenza vaccine and the onset of his symptoms of thrombocytopenia was also consistent with a vaccine injury. Pet'r Ex. 16 at 3. Dr. Gershwin stated that the review of petitioner's records showed that the onset of his symptoms of ITP was between three- and four-weeks post-vaccination. Pet'r Ex. 16 at 2; Tr. 122. In response to respondent's experts' opinions that petitioner's ITP likely began prior to the vaccination, because one medical record written more than a year later put onset "2 to 3" days after the vaccination is unreliable and that there was no supporting evidence in petitioner's records to indicate that he had been experiencing symptoms of ITP prior to the vaccination. Pet'r Ex. 30 at 2. Further, Dr. Gershwin opined that the onset of symptoms of ITP four weeks after vaccination is consistent with the theory of molecular mimicry. Tr. 151. He testified, "it takes up to six weeks to make the antibody to the influenza vaccine that cross-reacts and produces ITP." Tr. 105.

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[10] Hamiel, U. et al., *Recurrent Immune Thrombocytopenia After Influenza Vaccination: A Case Report,* 138 Pediatrics, e20160124 (2016). [Pet'r Ex. 52].

[11] Almohammadi, A. et al., *Epistaxis and Gross Haematuria with Severe Thrombocytopenia Association with Influenza Vaccine,* 12 BMJ Case Rep. doi:10.1136/bcr-2019-229423 (2019). [Pet'r Ex. 53].

2. Respondent's Expert: Dr. Andrew MacGinnitie

Dr. MacGinnitie, an immunologist, wrote one expert report for respondent and testified at the May 16, 2024 entitlement hearing. Resp't Ex. A (ECF No. 23). Dr. MacGinnitie agreed that petitioner had ITP but opined that the flu vaccine was not the cause of petitioner's ITP. While Dr. MacGinnitie does not offer an alterative cause for petitioner developing ITP, he argues that the petitioner's symptoms of ITP began 2-3 days after the flu vaccine and this timeframe for onset is "too rapid to be explained by an adaptive immune response," to the flu vaccine, and that Dr. Gershwin's theory for how the flu vaccine could cause ITP through molecular mimicry is unsupported by epidemiological studies. Resp't Ex. A at 5-8; Tr. 133 ("I think more likely than not it was unrelated to vaccination—[petitioner's] ITP was unrelated to vaccination.").

Dr. MacGinnitie acknowledged that there is an association between the MMR vaccine and ITP that was demonstrated in epidemiological studies. Tr. 134, 142; Resp't Ex. A at 3-4. He testified that if there was an association between the flu vaccine and ITP, it would have likely been observed in some studies. Tr. 135. In his report, Dr. MacGinnitie referenced the Grimaldi-Bensouda et al. article, which assessed the risk of ITP after vaccines, and wrote that the study found "no increased risk of developing ITP with influenza vaccination in the 2 months prior to disease onset." Resp't Ex. A at 4; *see also* Resp't Ex. A, Tab 1.[12] The study found 198 cases of ITP and identified 9 cases of patients who had received the influenza vaccine within two months of onset. Resp't Ex. A, Tab 1 at 5. Dr. MacGinnitie explained that even though these 9 cases of ITP were found after the patient received the flu vaccine in the two months prior to onset, "most cases that are seen after vaccination occur by chance," and that this article demonstrates that there is not "a significantly increased risk" of ITP after flu vaccination. Tr. 137.

He also referred to the Lafaurie et al. article to support his opinion that the flu vaccine is not associated with ITP. Tr. 137. Lafaurie et al. sought to examine the risk associated between ITP and the flu vaccine in adults after the Grimaldi and Garbe studies produced differing results. Resp't Ex. F.[13] The Lafaurie study indicated that they found similar results as the Grimaldi study, which demonstrated no increased risk between the influenza vaccine and ITP within a six-week period following vaccination compared to the incidence of ITP overall. *Id.* at 1. Dr. MacGinnitie stated that the Lafaurie article is a large study that found no increased risk of ITP post-flu vaccination and that this study is more reliable than the Garbe study. Tr. 138; *see also* Resp't Ex. A at 4.

When asked to examine the Garbe study, Dr. MacGinnitie conceded that the article did conclude that based on "standardized causality assessment," and "case-controlled analysis" the influenza vaccine was associated with a statistically significant four-fold risk [of ITP]." Tr. 162. However, he again argued that the Garbe study's sample was small and the larger, later LaFaurie study did not demonstrate an increased risk of ITP post-flu vaccination. *Id.*

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[12] Grimaldi-Bensouda, L. et al., *A Case-Control Study to Assess the Risk of Immune Thrombocytopenia Associated with Vaccines,* 120 Blood 4938-4944 (2012). [Resp't Ex. A, Tab 1].

[13] Lafaurie, M. et al., *Risk of Immune Thrombocytopenia Induced by Influenza Vaccine: A Nationwide Population-Based Study in France,* 134 Blood

Dr. MacGinnitie disagreed with Dr. Gershwin's theory of molecular mimicry as the causal mechanism for how the flu vaccine can cause ITP. Tr. 144, 163; Resp't Ex. A at 4-5. He argued that Dr. Gershwin had not identified a similarity between the influenza vaccine components and platelet epitopes and asserted that Dr. Gershwin's statements explaining why identifying such homology is difficult is an admission that molecular mimicry in this context is unreliable. Resp't Ex. A at 5; Tr. 144-45. Dr. MacGinnitie testified that "there hasn't been definitive evidence that most case of ITP are secondary to molecular mimicry," but that "it's a reasonable hypothesis." Tr. 145. However, he asserted that Dr. Gershwin's theory of molecular mimicry between the flu vaccine and ITP does not meet the four criteria set forth in the article "Molecular Mimicry and Autoimmunity," which Dr. Gershwin authored, and therefore, the hypothesis can be rejected. Resp't Ex. A at 5-6; Tr. 145. Dr. MacGinnitie stated that there are known autoantibodies against platelets and in approximately 60% of people with ITP are anti-platelet autoantibody positive. Tr. 146. He recognized, however, that the medical field has not studied other identifiable targets on platelets because it does not make much of a difference for treatment. Tr. 146-47. Dr. MacGinnitie noted that petitioner's anti-platelet antibodies were tested, and the results were negative, but he also agreed with Dr. Greshwin "that this is sometimes the case in ITP and does not prove anti-platelet antibodies are not present." Resp't Ex. A at 5.

When Dr. MacGinnitie was asked what biologic mechanisms are involved in the development of ITP, he testified that in "most cases of ITP, there is no cause identified," and that while many ITP patients have antibodies against platelets, the mechanism by which those antibodies are generated is "less clear." Tr. 163-64. However, Dr. MacGinnitie conceded that molecular mimicry is "generally accepted as a plausible theory regarding the development of certain autoimmune diseases," but that Dr. Gershwin's failure to show specific homology between the flu vaccine and platelets makes molecular mimicry implausible in this case. Tr. 164-65.

Dr. MacGinnitie disagreed with Dr. Gershwin's interpretation of petitioner's medical records that the treating physician, Dr. Alavi endorsed flu vaccine causation. Tr. 153. Dr. MacGinnitie testified that the excerpt from the January 11, 2018 appointment was based on the petitioner's perspective, not the actual opinion of the treating physician. Tr. 152-53; *see also* Pet'r Ex. 12 at 32. Dr. MacGinnitie also testified that the letter from Dr. Alavi exempting petitioner from future vaccinations, including the COVID-19 vaccine does not infer causation either. Tr. 153; *see* Pet'r Ex. 37.

With respect to the onset of symptoms of ITP through molecular mimicry, Dr. MacGinnitie agreed that "the timing of roughly four weeks would be compatible." Tr. 151.

3. Respondent's Expert-Dr. Lisa Kreuziger, hematologist

Dr. Lisa Kreuziger, a hematologist, also supplied an opinion for respondent in this matter through an expert report and testifying at the entitlement hearing. *See* Resp't Ex. C. Dr. Kreuziger also did not dispute petitioner's diagnosis of acute ITP that began in 2016. Resp't Ex. C at 6.

She described ITP as an autoimmune disease that occurs "due to production of autoantibodies against common platelet antigens and autoreactive cytotoxic T cells," and thrombocytopenia is "secondary to increased clearance of platelets and impairment of production of platelets." Resp't Ex. C at 5. ITP is a rare disease that affects approximately 3.3-3.9 per 100,000 adults per year. *Id.* Dr. Kreuziger wrote that "[t]he exact cause of ITP is not definitely known." *Id.*

Dr. Kreuziger opined that the flu shot was not the cause of petitioner's ITP and that it was coincidental that he developed ITP after the October 11, 2016 flu shot. Tr. 175; *see* Resp't Ex. C at 8. To support her opinion, Dr. Kreuziger also referred to the Grimaldi-Bensouda article, as well as an article by Rajantie et al., which examined the risk of developing ITP in children after vaccination. Resp't Ex. C at 6; Resp't Ex. C, Tab 6.[14] The Rajantie article reviewed 506 cases of ITP in Nordic countries and identified 35 pediatric cases of ITP of which all had a vaccination within one month prior to diagnosis. Resp't Ex. C, Tab 6 at 2. Of the 35 identified patients, 24 patients had received the MMR vaccine one month prior to diagnosis and 11 cases of ITP had received other vaccines including DPT, polio, and hepatitis A or B. *Id.* at 2. Dr. Kreuziger noted that none of the vaccines the children received prior to the onset of ITP was the flu vaccine. Resp't Ex. C at 6. She testified that the Grimaldi-Bensouda and Lafaurie articles do not support an association between the flu vaccine and ITP. Tr. 175-80. With respect to the Lafaurie article, Dr. Kreuziger stated that they found 238 patients with ITP that had the flu vaccine out of 4,267 and that in the controls they found 519 ITP cases out of 8,337 without vaccination, meaning there was "no association between the influenza vaccine and ITP." Tr. 179; *see also* Resp't Ex. F.

Dr. Kreuziger also disagreed that molecular mimicry between the flu vaccine and platelets can result in ITP. Resp't Ex. C at 6. She argued that no medical literature has identified "a similar molecular structure between the influenza virus and platelet antigens," and Dr. Gershwin did not attempt to even provide molecular structural similarities. *Id.* at 7. Dr. Kreuziger testified that "there is known association of molecular mimicry with certain infections…with HIV and hepatitis C, and mimicry with platelet antigens." Tr. 215. Without specifically endorsing molecular mimicry as the mechanism to explain how the MMR vaccine can cause ITP, Dr. Kreuziger testified that "there is an epidemiologic association between the MMR vaccination and ITP," but she did not research the exact mechanism in which the MMR vaccine can cause ITP. Tr. 218-19.

With respect to the onset of petitioner's ITP, Dr. Kreuziger stated that it was difficult to determine the onset of petitioner's ITP because of varying medical histories in the medical records. Resp't Ex. C at 8. She noted that petitioner initially reported bruising and petechiae for 2-3 weeks at his November 28, 2016 appointment, which would put onset in mid-November, but later petitioner reported symptoms consistent with ITP approximately 2-3 days after vaccination. Resp't Ex. C at 8 (citing Pet'r Ex. 4 at 5); *see also* Pet'r Ex. 12 at 32 ("He relates his history as having a flu shot in October of 2016. The same day, he developed a large knot at the site of his injection and the next day, he developed large lumps on his right leg that became purulent."); Pet'r Ex. 13 at 9 ("He states that his history dates back to October 2016 in which he received a

[14] Rajantie, J. et al., *Vaccination Associated Thrombocytopenia Purpura in Children,* 25 Vaccine 1838-40 (2007). [Resp't Ex. C, Tab 6].

flu shot. On the same day, he states had a reaction that progressed to weakness, joint pain, and fevers, then 2 to 3 days later he developed petechiae with bruising."). She wrote that the "development of autoantibodies takes 10-14 days with peak antibody levels occurring 4-6 weeks after exposure," and that development of symptoms 2-3 days is not consistent with the development of an antibody after an exposure. *Id.* at 8.

IV. Analysis

a. *Althen* prong one

Under *Althen* prong one, petitioner 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. Such theory must only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d 548-49. Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *See 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). However, a "petitioner must provide a 'reputable medical or scientific explanation' for [her] theory." *Boatmon v. Sec'y of Health and Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Moberly*, 592 F.3d at 1322). While the theory need not be medically or scientifically certain, "it must still be 'sound and reliable'" *Id.* (quoting *Knudsen*, 35 F.3d at 548-49). 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*, 35 F.3d at 548-49. Causation "can be found in vaccine cases…without detailed medical and scientific exposition of the biological mechanisms." *Knudsen*, 35 F.3d at 548-49.

Petitioner, through his expert, Dr. Gershwin, proposed a theory of molecular mimicry as the mechanism for how the flu vaccine can cause ITP. Pet'r Ex. 16 at 6; Tr. 98. Both of respondent's experts, Dr. MacGinnitie and Dr. Kreuziger, argued that Dr. Gershwin's theory is unreliable as he did not demonstrate any specific homology between components of the flu vaccine and platelets. For the reasons discussed below, the undersigned finds that petitioner has provided preponderant evidence that the flu vaccine can cause ITP, satisfying *Althen* prone one.

The experts agree, along with the medical articles filed, that ITP is an autoimmune condition and that in some cases of ITP, molecular mimicry is the likely causal mechanism. *See* Pet'r Ex. 16; Resp't Exs. A & C. Swinkles provides, "[o]ne of the suggested mechanisms by which infectious lead to autoimmunity is the occurrence of molecular mimicry." Resp't Ex. C, Tab 1 at 3. The Grimaldi-Bensouda article suggests that molecular mimicry is the mechanism for the development of autoimmune diseases post-vaccination, stating, "This could be because of molecular mimicry, in which antigens of the host are recognized as being similar to antigens of the immunization, thus provoking autoantibodies." Resp't Ex. A, Tab 1 at 1. The Perricone article also endorses molecular mimicry as a mechanism for inducing ITP, stating, "molecular mimicry is considered the classic pathogenic mechanism responsible for ITP developed after vaccinations. The epitope, integrated within the vaccine antigen, shares a similar structure with a self-peptide, driving forward self-reactivity." Pet'r Ex. 23 at 3.

Additionally, both Drs. MacGinnitie and Kreuziger agree that molecular mimicry is an accepted mechanism for inducing certain autoimmune conditions, and at least Dr. Kreuziger accepts it as a theory for the MMR vaccine to induce ITP, even without specific homology demonstrated. *See* Resp't Ex. A at 5; Tr. 144 (Dr. MacGinnitie agreeing that molecular mimicry is a mechanism for inducing autoimmune diseases"); Resp't Ex. C at 7 (Dr. Kreuziger stating, "although molecular mimicry has support in the medical literature as a mechanism leading to certain autoimmune diseases, there is not a proven mechanism by which influenza vaccine can lead to thrombocytopenia."); Tr. 214 (Dr. Kreuziger testifying "there is a known association of molecular mimicry with certain infections like…HIV and hepatitis C, and mimicry with platelet antigens.").

Despite the acceptance in general of molecular mimicry, both of respondent's experts argued that extending molecular mimicry as a mechanism between the flu vaccine and ITP is speculative due to the lack of epidemiological studies demonstrating an association between the flu vaccine and ITP and the failure of Dr. Gershwin to identify specific homology between the flu vaccine components and platelet antigens. *See* Resp't Ex. A at 5; Resp't Ex. C at 7; Tr. 167. These arguments are unpersuasive.

Dr. Gershwin credibly explained the difficulty with identifying homology between the components of the flu vaccine and platelet epitopes. The Swinkles article explained, "Epitopes targeted by platelet autoantibodies seem to differ between patients, coinciding with different responses to therapy and different phenotypes." Resp't Ex. C, Tab 1 at 8. Further, the article also explains that 60% of ITP patients have autoantibodies that are detected against two specific platelet glycoproteins, but that "not all patients have platelet-reactive B cells, suggesting that B cell independent autoimmune mechanisms exist." *Id.* at 5. Additionally, Swinkles explains that patients with ITP can have "multiple autoantibodies [to platelets], some undetected by the current methods." *Id.* at 8. Additionally, Dr. Kreuziger appeared to accept molecular mimicry as the potential causal mechanism, mostly based on epidemiological evidence demonstrating an increased risk between the MMR vaccine and ITP in children, but without identifying specific homology between MMR vaccine components and platelet epitopes. *See* Tr. 217. Importantly, requiring petitioner to produce an exact homology between the flu vaccine and platelet epitopes would impermissibly raise petitioner's burden. *See Knudsen,* 35 F.3d at 549 ("[T]o require identification and proof of specific biologic mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.").

The medical articles filed also demonstrate an association between the flu vaccine and ITP. Garbe et al. found "a statistically significant [four]-fold risk" of developing ITP, after identifying three cases of ITP following the flu vaccine and rating the causality as "probable." Pet'r Ex. 20 at 10. The Grimaldi-Bensouda article found 9 cases of ITP within two months of patients receiving the flu vaccine. Resp't Ex. A, Tab 1 at 5. The authors found "no evidence that vaccination in general was associated with an observable increase of the incidence of ITP." *Id.* at 4. While Grimaldi-Bensouda's conclusion was that there was not an *increased* risk of ITP after the flu vaccine, the article still demonstrated cases of ITP developing 8 weeks post-flu vaccination. The Perricone article also summarized the available studies and case reports of ITP following the flu vaccine, highlighting an association between the flu vaccine and ITP. *See* Pet'r Ex. 23 at 5. Even though the respondent's experts emphasized that Grimaldi-Bensouda or even

the Lafaurie article do not find an *increased risk* of ITP following the flu vaccine, they do not eliminate the potential that rare events of ITP may be caused by the flu vaccine.

Additionally, Dr. Gershwin cited the Hamiel and Almohammadi case reports as support for his theory that the flu vaccine can cause ITP, because they are evidence of the challenge/rechallenge phenomenon where the patients develop the same symptoms after exposure to the same antigens. Tr. 92-94. The Hamiel case report describes a child developing ITP three times after receiving the flu vaccine. Pet'r Ex. 52 at 2-3. The authors of this case report wrote, "The cause of ITP remains unknown in most cases, but it can be triggered by a viral infection or other immune triggers, such as vaccination, most likely by the mechanism of molecular mimicry." *Id.* at 3. Hamiel et al. concluded the case report stating, "We report the case of a child with 3 occurrences of ITP, each preceded by an influenza vaccination 6 to 7 days before the onset of symptoms. This report is therefore the first to show with a high degree of confidence an association between the trivalent influenza vaccine and the development of ITP." *Id.* Almohammadi also described the case of an adult who developed nose bleeds after receipt of the flu vaccine on three separate occasions, and upon the last receipt of the flu vaccine, also developed severe thrombocytopenia. Pet'r Ex. 53. Almohammadi wrote, "It is highly likely that the severe thrombocytopenia in our patient was due to the influenza vaccination due to the temporal association of the vaccination with the thrombocytopenia and ruling out other diagnosis." *Id.* at 2. Additionally, the authors opined that, "Vaccine-associated ITP may be caused by molecular mimicry, which demands the activation of autoreactive B or T cells by peptides in the vaccine that display structural parallel to antigens found on platelets." *Id.* Even though Hamiel and Almohammadi are case reports and are not direct proof of causation, they serve as persuasive circumstantial evidence to support Dr. Gershwin's theory. *See Contreras v. Sec'y of Health & Hum. Servs.,* 107 Fed. Cl. 280 (Fed. Cl. 2012); *see also Capizzano,* 440 F.3d at 1325-26.

Finally, molecular mimicry has been an accepted mechanism for how the flu vaccine can cause ITP in other cases in the Vaccine Program. *See Mitchell v. Sec'y of Health & Hum. Servs.,* No. 19-1534V, 2023 WL 4483134 (Fed. Cl. Spec. Mstr. Jan. 11, 2023); *Parmer v. Sec'y of Health & Hum. Servs.*, No. 16-880V, 2021 WL 1524512, at * 20-21 (Fed. Cl. Spec. Mstr. Mar. 25, 2021).

In summary, petitioner has offered a sound and reliable medical theory by preponderant evidence to show how the flu vaccine can cause ITP through the mechanism of molecular mimicry. Thus, the undersigned finds petitioner has met his burden under *Althen* prong one.

b. *Althen* prong three

Althen prong three requires petitioners to establish a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen,* 418 F.3d at 1281. That term has been defined as a "medically acceptable temporal relationship." *Id.* Petitioners must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan,* 539 F.3d at 1352. The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause

the injury alleged (under *Althen* prong one). *Id.*; *see also Pafford*, 451 F.3d at 1358. 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 a causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury.").

At times, consideration of *Althen* prong three may be necessary before considering a logical sequence of cause and effect for *Althen* prong two. Additionally, there was some question of the onset of petitioner's ITP discussed by respondent's experts. Therefore, consideration of *Althen* prong three is necessitated before moving to *Althen* prong two.

Petitioner received the flu vaccine on October 11, 2016 and his first medical appointment when he reported symptoms that are consistent with ITP was on November 28, 2016 with his pain management physician's office. *See* Pet'r Ex. 8 at 11. At this appointment with Nurse Practitioner Marlene Hamama, it was noted that petitioner was "having bruising reaction secondary to hydrochlorthiazide," and that petitioner was going to see his primary care physician. *Id.* at 12. Two days later, on November 30, 2016, petitioner was seen by Dr. Kulik, where petitioner reported having bruising and red marks on his arms, chest, legs, and feet for approximately 2-3 weeks. Pet'r Ex. 4 at 5. Further, petitioner testified that around November 12th or 13th, he noticed he had developed pin-prick red marks "going up and down my legs." Tr. 15-16. Petitioner testified that he became worried that the pin-prick red marks were not going away so he made the next available appointment with his PCP for November 30, 2016. Tr. 17. During the appointment on November 30, 2016, petitioner had blood drawn for testing. Pet'r Ex. 4 at 5. Petitioner testified that later the same day, Dr. Kulik called him instructing him to go to the hospital immediately because of his low platelets. Tr. 21. Upon admission to the McLaren Oakland Hospital, it was noted that petitioner had "new onset petechiae that has been ongoing for the past 3 weeks." Pet'r Ex. 5 at 66. Petitioner was diagnosed with "acute severe thrombocytopenia, suspect ITP," and platelet transfusions were initiated on December 1, 2016. Pet'r Ex. 5 at 70.

Dr. Gershwin opined that onset of ITP can occur within six weeks following the flu vaccine. Pet'r Ex. 16 at 9; Tr. 106. Dr. Gershwin stated that in this case, petitioner's onset of ITP was approximately three weeks post-vaccination, which would fall into the medically appropriate timeframe consistent with the theory of molecular mimicry. Tr. 106-08. Dr. MacGinnitie also agreed that the onset of ITP of four weeks would be an acceptable timeframe consistent with the theory of molecular mimicry, although he disagreed that the flu vaccine can cause ITP through molecular mimicry. Tr. 151. Dr. Kreuziger noted that with some medical records, petitioner told providers that the onset of his ITP symptoms began two to three days post-vaccination, which would be inconsistent with Dr. Gershwin's theory of molecular mimicry. Resp't Ex. C at 8; *see also* Pet'r Ex. 12 at 32; Pet'r Ex. 13 at 8.

Importantly, petitioner testified that the notation in his record from his appointment with Dr. Schiffer that notes the onset of petitioner's petechiae and bruising beginning 2-3 days after his flu vaccination was incorrect. Tr. 37. The record states:

> On the same day, he states he had an injection with reaction that progressed to weakness, joint pain, and fevers and then 2 to 3 days later he developed petechiae with bruising.

Pet'r Ex. 13 at 8. Petitioner testified that he was feeling "a little under the weather," after the flu shot, but he maintained that his ITP symptoms began around November 12th or 13th. Tr. 20. Given that petitioner's records from November 2016 and December 2016 were made closer in time to the onset of petitioner's ITP symptoms, these records are more reliable as to the date of onset than the record from Dr. Schiffer, nearly two years later.

The timeframe of developing ITP six-weeks post-vaccination, as proposed by Dr. Gershwin, is consistent with the medical literature filed in this case. Yamamoto et al. endorsed an onset of ITP after the flu vaccine between 4-35 days. Pet'r Ex. 26 at 5. Perricone noted multiple case reports of ITP developing after the flu vaccine with timeframes between 4- and 26-days post-vaccination. Pet'r Ex. 23 at 5. Nagasaki et al., which described three case reports of older patients developing ITP after the flu vaccine, found the onset of ITP occurring at two, four, and five weeks after the flu vaccination. Pet'r Ex. 58 at 1-2.[15]

As petitioner developed symptoms of his ITP three weeks post-vaccination, which is consistently reported in the medical records, respondent's experts did not contradict that Dr. Gershwin's proposed timeframe of onset given the theory of molecular mimicry, and Dr. Gershwin's proposed timeframe was supported by the medical literature, petitioner has preponderantly established *Althen* prong three.

c. *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). "Petitioner must show that the vaccine was the 'but for' cause of the harm…or in other words, that the vaccine was the 'reason for the injury.' " *Pafford*, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. *Andreu*, 569 F3d at 1367; *Capizzano*, 440 F.3d at 1326 ("[M]edical 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 trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. *Cucuras*, 993 F. 2d at 1528. While the medical records and opinions of treating physicians must be considered, they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the "diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court.").

Petitioner has demonstrated by preponderant evidence a logical sequence of cause and effect establishing that the flu vaccine he received on October 11, 2016 caused him to develop

[15] Nagasaki, J. et al., *Postinfluenza Vaccination Idiopathic Thrombocytopenic Purpura in Three Elderly Patients*, Case Rep. Hematol. 2016: 7913092, doi: 10.1155/2016/7913092 (2016). [Pet'r Ex. 58].

chronic ITP. There are three reasons why I concluded that petitioner has met his burden under *Althen* two. First, petitioner has proffered a sound and reliable mechanism of vaccine causation. Second, the onset of petitioner's ITP was approximately three weeks after his flu vaccination, an appropriate time frame in which molecular mimicry triggered by the vaccine could cause ITP. Third, there was no alternative cause found in the medical records that could have induced his ITP.

Petitioner received his flu vaccine on October 11, 2016 and approximately three weeks later developed bruising and petechiae, signs of thrombocytopenia. Pet'r Ex. 4 at 3-4. His bloodwork showed his platelet was 4,000 on November 30, 2016. Pet'r Ex. 4 at 50. The onset of his ITP symptoms appearing three weeks post-vaccination is similar to the case reports described in the medical literature and other cases in the Vaccine Program. *See* Pet'r Ex. 58 (a patient was found to have onset of thrombocytopenia four-week post-flu vaccine). In *Mitchell*, the petitioner developed bruising on the front and back of her thighs approximately five weeks after she had received the flu vaccine. *Mitchell*, 2023 WL 4483134, at *27.

While petitioner's treating physicians do not necessarily state with specificity that his ITP was caused by the flu vaccine, Dr. Alavi noted that petitioner's ITP began after the flu vaccine and exempted petitioner from future vaccines. *See* Pet'r Ex. 37.

When a petitioner has established that vaccination can cause a given condition and has demonstrated that the timing prong has also been met, it allows the petitioner to establish that the vaccination was the but-for-cause of his condition. The Federal Circuit has provided guidance with respect to this issue. "Evidence demonstrating petitioner's injury occurred within a medically acceptable timeframe bolsters a link between the injury alleged and the vaccination at issue under the "but-for" prong of the causation analysis." *Capizzano*, 440 F. 3d at 1326 (finding medical opinions that explain how a vaccine can cause the injury alleged coupled with evidence demonstrating a close temporal relationship "are quite probative" in proving actual causation.") *Pafford*, 451 F.3d at 1358; *see also Contreras*, 107 Fed. Cl. at 295 (finding that there is a "logical overlap between three *Althen* prongs, and that evidence that goes to one prong may also be probative for another prong"). Consistent with the above, petitioner has established *Althen* prong two.

V. Conclusion

For the reasons discussed above, the undersigned finds that petitioner has established by preponderant evidence that his flu vaccine caused his ITP. Therefore, petitioner is entitled to compensation. A separate damages order will be issued.

IT IS SO ORDERED.

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