In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: December 10, 2021

APRIL FERGUSON, *parent of J.F., a minor*,	*	PUBLISHED
Petitioner,	*	No. 17-1737V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling on Entitlement; Tetanus-Diphtheria-Acellular Pertussis ("Tdap") Vaccine; Meningococcal Conjugate Vaccine; Influenza ("Flu") Vaccine; Immune Thrombocytopenia Purpura ("ITP").
Respondent.	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On November 6, 2017, April Ferguson ("petitioner"), parent of J.F., a minor, filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleges that J.F.

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the 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, the undersigned agrees that the identified material fits within this definition, the undersigned 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). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

suffered immune thrombocytopenia purpura ("ITP")[3] as the result of a tetanus-diphtheria-acellular pertussis ("Tdap"),[4] meningococcal conjugate, and influenza ("flu")[5] vaccinations administered on October 23, 2014. Petition at 1-2 (ECF No. 1); Petitioner's Exhibit ("Pet. Ex.") 2 at 1; Pet. Motion for Ruling on the Record ("Pet. Mot."), filed June 14, 2021, at 1, 3, 11 (ECF No. 63). Respondent argued against compensation, stating that "this case is not appropriate for compensation under the terms of the Act." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 13).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner has provided preponderant evidence that the Tdap vaccine caused J.F.'s ITP, satisfying petitioner's burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, petitioner is entitled to compensation.

I. ISSUES TO BE DECIDED

Diagnosis is not at issue. See Pet. Ex. 8 at 2-3; Resp. Ex. A at 2. The parties' experts agree that the proper diagnosis is ITP. Pet. Ex. 8 at 2-3; Resp. Ex. A at 2. More specifically, J.F. has been diagnosed with "primary chronic autoimmune thrombocytopenia." Resp. Ex. A at 2.

Petitioner does not allege a Table injury, and thus, petitioner must prove causation-in-fact by preponderant evidence. Petitioner alleges that "J.F. was a healthy child who developed ITP

[3] Throughout the medical records, J.F.'s treating physicians refer to J.F.'s condition as idiopathic thrombocytopenia purpura and immune thrombocytopenia purpura. The undersigned will refer to both as ITP throughout this Ruling.

[4] Although the petition alleges J.F. received a diphtheria-tetanus-acellular-pertussis ("DTaP") vaccination, J.F.'s medical records indicate J.F. received a Tdap vaccination. Petitioner's Exhibit ("Pet. Ex.") 2 at 1.

[5] The petition does not include J.F.'s flu vaccination on October 23, 2014; however, petitioner's Motion for a Ruling on the Record and petitioner's expert's reports reference J.F.'s flu vaccination. Pet. Ex. 8 at 3; Pet. Ex. 11 at 1-2; Pet. Motion for Ruling on the Record ("Pet. Mot."), filed June 14, 2021, at 1, 11 (ECF No. 63). Respondent's expert also discusses the significance of J.F.'s flu vaccination, and cites to medical literature regarding the flu vaccine. Respondent's ("Resp.") Ex. A at 2-3. Further, respondent's Response to petitioner's Motion discusses the flu vaccine. Resp. Response to Pet. Mot. ("Resp. Response"), filed July 19, 2021, at 13 (ECF No. 66). Therefore, the undersigned's analysis includes J.F.'s flu vaccination.

within weeks of receiving Tdap, Meningococcal[,] and [flu] vaccines."[6] Pet. Mot. at 11. "Both the flu vaccine and Tdap have been associated with the development of ITP. It is more likely than not that J.F. developed ITP as a result of his vaccinations. He is entitled to compensation under the Vaccine Act." Id.

Respondent disagrees that petitioner has proven the Althen criteria by preponderant evidence. See Resp. Response to Pet. Mot. ("Resp. Response"), filed July 19, 2021, at 10-15 (ECF No. 66). Respondent argues that petitioner has (1) "fail[ed] to present a reliable medical theory causally connecting [J.F.'s] vaccinations and chronic ITP," (2) "fail[ed] to show a logical sequence of cause and effect between [J.F.'s] vaccinations and his chronic ITP," and (3) failed to show a temporal relationship between the J.F.'s vaccinations and chronic ITP. Id.

II. BACKGROUND

A. Procedural History

Petitioner filed her petition on behalf of her minor child, J.F., on November 6, 2017, which was followed by medical records in February 2018. Petition; Pet. Exs. 1-2. On June 4, 2018, respondent filed his Rule 4(c) Report, in which he recommended against compensation. Resp. Rept. at 2.

In October 2018, petitioner filed witness affidavits from petitioner, Jolie MacDougal, Vanessa Ferguson, and Tony Winterburn, as well as additional medical records. Pet. Exs. 3-7. Petitioner filed an expert report from Dr. Edwin N. Forman on November 29, 2018. Pet. Ex. 8. Thereafter, the parties began to engage in settlement negotiations. Non-PDF Scheduling Order dated Feb. 25, 2019.

This case was reassigned to the undersigned on October 3, 2019. Notice of Reassignment dated Oct. 3, 2019 (ECF No. 30). On June 30, 2020, the undersigned held a status conference. Order dated June 30, 2020 (ECF No. 43). The parties were still engaging in settlement negotiations. Id. at 1. Both parties requested an expert report from respondent. Id. Respondent filed an expert report from Dr. John J. Strouse on November 2, 2020. Resp. Ex. A.

The undersigned held a Rule 5 conference on January 7, 2021. Order dated Jan. 8, 2021 (ECF No. 54). The undersigned preliminarily found J.F.'s onset was three weeks after his vaccinations, which is consistent with vaccine-associated ITP. Id. at 2. The undersigned requested an additional expert report with medical literature from petitioner's expert, specifying

[6] Petitioner alleged that J.F. suffered ITP as a result of the Tdap, meningococcal conjugate, and flu vaccines. Petition at 1-2; Pet. Mot. at 1, 1 n.1. However, in her Motion for a Ruling on the Record, petitioner does not specifically assert that the meningococcal vaccine administered to J.F. has been associated with ITP, although the word "vaccinations" is used throughout the Motion. Pet. Mot. at 7-9, 11. Petitioner's expert, Dr. Edwin N. Forman, references two articles related to meningococcal vaccines and opines that "more likely than not [] the vaccines, singly or in combination, were the cause of J.F.'s ITP." Pet. Ex. 8 at 3; see also Pet. Ex. 11 at 2. Thus, the undersigned's analysis includes all of the vaccinations that J.F. received.

the purported medical theory. Id. Additionally, the parties agreed to submit the case for adjudication of entitlement through a ruling on the record. Id. at 3.

Petitioner filed a supplemental expert report from Dr. Forman on February 22, 2021. Pet. Ex. 11. On June 14, 2021, petitioner filed a motion for a ruling on the record, and respondent filed his response to petitioner's motion on July 19, 2021. Pet. Mot.; Resp. Response.

This matter is now ripe for adjudication.

B. Medical Terminology

"Immune thrombocytopenia purpura (ITP) is an autoimmune disorder in which autoantibodies inhibit platelet production and impair the circulating ones, leading to thrombocytopenia and, consequently, mucocutaneous and even major bleeding." Pet. Ex. 20 at 1.[7] Thrombocytopenia is defined as a platelet count of less than 100 x 10^9/L. Pet. Ex. 22 at 1.[8] Vaccine-related thrombocytopenia is thought to be an immune condition "because antibodies can be detected on platelets in about 79% of cases." Id.

"The typical manifestation of acute ITP is the abrupt onset of bruising and bleeding in an otherwise healthy child." Pet. Ex. 15 at 1.[9] "Petechiae[10] and ecchymoses[11] are evident in most patients. Epistaxis[12] and oral mucosal bleeding are seen in fewer than a third of patients." Id. "Less often, the gastrointestinal and genitourinary tracts are affected. Serious bleeding

[7] Paula David & Yehuda Shoenfeld, Editorial, ITP Following Vaccination, 99 Int'l J. Infectious Diseases 243 (2020).

[8] Valerio Cecinati et al., Vaccine Administration and the Development of Immune Thrombocytopenic Purpura in Children, 9 Hum. Vaccines & Immunotherapeutics 1158 (2013).

[9] David B. Wilson, Acquired Platelet Defects, in 1 Nathan and Oski's Hematology and Oncology of Infancy and Childhood 1076, 1080 (Stuart H. Orkin et al. eds., 8th ed. 2015). Petitioner filed only one page from this chapter.

[10] Petechia is "a pinpoint, nonraised, perfectly round, purplish red spot caused by intradermal or submucous hemorrhage." Petechia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=38200 (last visited Aug. 23, 2021).

[11] Ecchymosis is "a small hemorrhagic spot, larger than a petechia, in the skin or mucous membrane forming a nonelevated, rounded or irregular, blue or purplish patch." Ecchymosis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15403 (last visited Aug. 23, 2021).

[12] Epistaxis is a nosebleed or "hemorrhage from the nose." Epistaxis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=16952 (last visited Aug. 23, 2021).

occurs in [approximately] 3% of children with ITP. The most feared manifestation, intracranial hemorrhage, may develop in [approximately] 0.5%." Pet. Ex. 12 at 1.[13]

Most cases of ITP in children "resolve within 3 months;" however, "[s]ome children will have the persistent form of ITP, defined by failure to achieve spontaneous remission or to maintain remission without treatment, lasting between 3 and 12 months." Pet. Ex. 12 at 1. "Approximately 20% of children and the majority of adults develop chronic ITP, defined by ITP lasting [more than or equal to] 12 months." Id.

ITP is usually idiopathic, but has been reported after infections and vaccinations. Pet. Ex. 20 at 1. "In [approximately] 60% of cases, there is a history of an earlier infection within the past month, but a specific pathogenic trigger is only rarely discovered." Pet. Ex. 12 at 1. Some children "have an identifiable virus, such as Epstein-Barr virus, varicella zoster virus, [flu] virus, or HIV." Pet. Ex. 14 at 2.[14]

There is a "small increased risk" of ITP following the measles-mumps-rubella ("MMR") vaccination. Pet. Ex. 12 at 1. ITP has also been reported after other vaccines, including hepatitis B, diphtheria-tetanus-pertussis ("DTP"), and hepatitis A. Pet. Ex. 14 at 2; see also Pet. Ex. 27 at 3;[15] Pet. Ex. 29 at 2.[16]

C. Factual History

1. Medical History

Prior to the vaccinations at issue, J.F., born on March 3, 2004, had a medical history that included a heart murmur diagnosed at birth, asthma, pharyngitis, strep throat, impetigo, concussion, and constipation. Pet. Ex. 1 at 2, 4, 9-10, 12-13, 16, 19, 37. On October 23, 2014, J.F. received Tdap, meningococcal conjugage, and flu vaccinations. Id. at 20; Pet. Ex. 2 at 1. Physical examination by Mary Pascolini, Certified Nurse Practitioner ("CNP"), was normal. Id. at 22. No bruising or other signs of a low platelet count were reported or noted during the physical examination at this visit. Id.

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[13] Uri Hamiel et al., Recurrent Immune Thrombocytopenia After Influenza Vaccination: A Case Report, 138 Pediatrics e1 (2016).

[14] Sean T. O'Leary, The Risk of Immune Thrombocytopenic Purpura After Vaccination in Children and Adolescents, 129 Pediatrics 248 (2012). This article was also cited by respondent's expert. See Resp. Ex. A, Tab 4.

[15] James B. Bussel, Disorders of Platelets, in Manual of Pediatric Hematology and Oncology 321, 343-353 (Philip Lanzkowsky ed., 5th ed. 2005).

[16] J. Paul Scott & Veronica H. Flood, Platelet and Blood Vessel Disorders, in 2 Nelson Textbook of Pediatrics 2609, 2612-14 (Robert M. Kliegman et al. eds., 21st ed. 2019).

J.F. presented to the Akron Children's Hospital ("ACH") Emergency Department ("ED") on January 13, 2015 for emesis (vomiting), diarrhea, and abdominal pain. Pet. Ex. 1 at 23. Petitioner reported J.F. had four episodes of emesis that morning and one episode of diarrhea. Id. at 24. Dr. Huwaida Mansour conducted a physical examination that revealed nasal congestion but no redness of the throat and no swelling of the lymph nodes. Id. No bruising was noted. Id. at 24-25. Dr. Mansour diagnosed J.F. with emesis, diarrhea, and gastroenteritis. Id. at 25. J.F. was prescribed Zofran[17] and fluids, and discharged home. Id.

On January 29, 2015, J.F. saw Dr. Louis Brine at ACH for a rash. Pet. Ex. 1 at 25. Petitioner reported J.F.'s rash has been present on the right side of his scalp for one week. Id. at 26. The onset was acute and the course was unchanging. Id. The rash was described as crusty, red, and bumpy. Id. J.F. did not have a fever, cough, ear pain, headache, vomiting, or diarrhea. Id. Petitioner also stated she was concerned with J.F.'s bruising, and reported that he was currently wrestling in school. Id. Dr. Brine's physical examination revealed a raised, red, scabbed lesion on the right side of J.F.'s scalp without discharge. Id. He diagnosed J.F. with impetigo and bruising. Id. at 25-26. J.F. was prescribed mupirocin calcium and clindamycin for impetigo, and a complete blood count ("CBC") with differential was ordered due to his bruising. Id. CBC results revealed a low platelet level of 10 (low panic; range 200-450).[18] Id. at 141.

Later that day, J.F. returned to ACH for bilateral bruising to his legs and thrombocytopenia. Pet. Ex. 1 at 26-27. Admission to ACH was recommended after J.F.'s blood work revealed a platelet count of 10 (low panic). Id. at 27, 29. J.F.'s parents reported an episode of epistaxis on January 25 that resolved in less than 10 minutes. Id. at 27. J.F. had regular, daily, non-bloody bowel movements. Id. Julia R. Golden, CNP, performed a physical examination that revealed petechiae to the tongue and "several healing impetigo lesions noted [on] right forehead, right upper cheek and scalp, not open, no drainage noted. Bruise to forehead. Scattered bruising [on] bilateral legs with multiple bruises ~ 2cm in diameter." Id. at 28. Ms. Golden's impression was "post viral thrombocytopenia with a likely diagnosis of acute [ITP]." Id. at 29. J.F. was admitted, and intravenous immune globulin ("IVIG")[19] was ordered. Id.

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[17] Zofran is "used for prevention of nausea and vomiting." Zofran, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=54067 (last visited Aug. 23, 2021); Ondansetron, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=35063 (last visited Aug. 23, 2021).

[18] J.F.'s platelet counts in his medical records range from 5 to 710 x 10^9/L (liter of blood). According to J.F.'s medical records, a normal count ranges from 200 to 450 x 10^9/L. Pet. Ex. 1 at 141. Respondent and the parties' experts refer to J.F.'s platelet levels using a different measurement unit than is used in J.F.'s medical records. For simplicity, throughout this Ruling, the measurement unit for platelet counts used in J.F.'s medical records will be referenced.

[19] IVIG is "used in the treatment of primary immunodeficiency disorders and [ITP]." Immune Globulin Intravenous (Human), Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=78975 (last visited Aug. 23, 2021).

On January 31, 2015, J.F. was seen by hematologist, Dr. Daniel F. Pettee. Pet. Ex. 1 at 30. Dr. Pettee noted J.F.'s "[p]arents also admit[ted] to petechiae on cheeks over the weekend that resolved." Id. J.F.'s platelet count after his first dose of IVIG was 6 (low panic). Id. at 30, 144. J.F. received his second dose of IVIG overnight. Id. at 30. Overnight, J.F. had a headache, nausea, and emesis. Id. at 30, 34. He also "developed rigors that resolved with Demerol and slowing infusion rate." Id. at 30.

Dr. Pettee's physical examination revealed "several healing impetigo lesions noted [on] right forehead and scalp, crusted, no active drainage. Scattered bruising to bilateral legs with multiple bruises ~ 2cm in diameter, but fading. No petechiae." Pet. Ex. 1 at 31. He had no oral bleeding. Id. at 34. J.F.'s platelet count increased to 22 (low panic). Id. at 34, 144. Dr. Pettee's impression was ITP. Id. at 34. In his discharge note, Dr. Pettee stated that J.F. "was ill approximately 1.5-2 weeks ago with fever, nausea/vomiting[,] and diarrhea." Id. at 35. J.F. was ordered to follow up in one week for blood work and one month for examination. Id. at 34. He was prescribed Zofran, and ordered to refrain from wrestling, contact sports, and gym class. Id. at 33-34. He was discharged home. Id.

Blood work from February 5, 2015 showed a platelet count of 19 (low panic). Pet. Ex. 1 at 145. On February 9, 2015, J.F.'s platelets were 16 (low panic). Id.

J.F. returned to ACH on February 11, 2015 for new bruising and platelet count of 11 (low panic). Pet. Ex. 1 at 36-37, 145. Petitioner reported J.F. "developed four new bruises when he woke up this morning on his right leg, right thigh, right arm, and on the bridge of his nose (from a breathe right strip)" and "a few petechiae in his right axilla a few days ago as well which have not progressed." Id. at 37. Petitioner and J.F. denied "hematochezia,[20] hematemesis,[21] bleeding from the gums, or hematuria,[22]" but noted J.F. had "epistaxis from his left nare 4 days ago that lasted a few minutes." Id. Petitioner reported that J.F. had an upper respiratory infection over the past few days. Id. J.F. had not had a fever, but "complain[ed] of clear-yellow rhinorrhea and nasal congestion which is improving. He denie[d] cough, headaches, throat pain, chest pain, abdominal pain, change in bowel habits, diarrhea, constipation, muscle pain or joint pain or swelling." Id. He also reported no fatigue and a normal appetite, and "denie[d] any rough housing and . . . wrestling." Id.

Hematologist Dr. John F. Fargo noted a CBC done that day revealed a platelet count of 11 (low panic). Pet. Ex. 1 at 37, 145. Physical examination revealed no petechiae in throat and

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[20] Hematochezia is the "presence of blood in the feces." Hematochezia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=21736 (last visited Aug. 23, 2021).

[21] Hematemesis is the "vomiting of blood." Hematemesis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=21717 (last visited Aug. 23, 2021).

[22] Hematuria is "blood (erythrocytes) in the urine." Hematuria, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=21814 (last visited Aug. 23, 2021).

"bilateral cervical lymphadenopathy." Id. at 38. Dr. Fargo's skin examination showed "[s]cattered bruising [] on right pre-tibial area, right upper outer thigh, extensor surface of right forearm, [and] extensor surface of left upper arm ranging from 1.5cm - 2.5cm;" a "[s]mall bruise [] on bridge of nose;" and "3 petechiae in left armpit as well as 5-10 single, scattered petechiae [] on arms and legs." Id. at 39. Impression was ITP. Id. J.F. was admitted and given WinRho.[23] Id. at 39-40.

J.F.'s urine tests on admission and post-WinRho were negative for blood. Pet. Ex. 1 at 41. CBC on February 12, 2015 revealed a "stable" platelet level of 12 (low panic). Id. at 41, 147. J.F. was discharged home. Id. at 41. His discharge diagnosis was thrombocytopenia and ITP. Id.

Blood work taken on February 16, 2015 showed platelets of 30 (low panic). Pet. Ex. 1 at 147. On February 24, 2015, J.F.'s platelets were 32 (low panic). Id. at 148.

On March 3, 2015, J.F. returned to ACH for a follow-up examination with Dr. Pettee. Pet. Ex. 1 at 43. J.F. had "some residual bruising/petechiae in small amount but no other bleeding i.e. [n]osebleeds, mouth bleeding." Id. at 44. J.F. also had no fever, and his energy and appetite improved. Id. Dr. Pettee's physical examination revealed a "[s]mall 1 cm healing bruise [on J.F.'s] left forearm" and "[f]ew petechiae [on] left supraclavicular area and right axilla." Id. CBC showed a platelet count of 27 (low panic). Id. at 45, 148. J.F.'s diagnosis remained ITP. Id. at 45. Dr. Pettee noted J.F.'s [p]latelet count [was] stable/slightly decreased though he is doing clinically well." Id. Dr. Pettee planned to continue monitoring J.F. counts monthly, and have J.F. follow up in four months with the hope that J.F.'s ITP would be resolved by then. Id. J.F. was ordered to continue to avoid anti-inflammatories and be cautious regarding high risk activities, although he was permitted to participate in gym. Id. at 45-46.

CBC on March 27, 2015 showed that J.F.'s platelets were 20 (low panic). Pet. Ex. 1 at 149. On April 6, 2015, J.F. had a platelet count of 27 (low panic). Id. at 150. On April 20, 2015, J.F.'s platelets decreased to 23 (low panic). Id. His platelets were 34 (low panic) on May 4, 2015. Id. at 151.

J.F. presented to the ED at ACH for right ear pain for 1-2 days on May 12, 2015. Pet. Ex. 1 at 46. Dr. Jeffrey Jinks conducted a physical examination that revealed no petechiae, purpura, or rash. Id. at 47. Dr. Jinks' diagnosis was eustachian tube dysfunction. Id. On June 1, 2015, J.F.'s platelets remained at a low panic level of 25. Id. at 151. On June 7, 2015, J.F. returned to the ED at ACH for a sore throat for at least one week. Id. at 48. Dr. Michael A. Billow's physical examination did not reveal bruising or petechiae. Id. at 49. J.F. was diagnosed with pharyngitis/croup. Id.

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[23] WinRho is a Rh_0(D) immune globulin "used as a platelet count stimulator in the treatment of [ITP]." WinRho, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=53699 (last visited Aug. 23, 2021); Rh_0(D) Immune Globulin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=78981 (last visited Aug. 23, 2021).

On June 10, 2015, J.F. presented to Dr. Jinks at the ACH ED for a "rash on trunk starting today." Pet. Ex. 1 at 49-50. Physical examination revealed rash, but no petechiae or purpura. Id. at 51. Dr. Jinks described the rash as red and pimply on J.F.'s back and upper chest, some of which was with whiteheads. Id. Dr. Jinks diagnosed J.F. with folliculitis. Id. J.F. was prescribed Augmentin. Id.

J.F. returned to ACH complaining of leg pain for one month on June 18, 2015. Pet. Ex. 1 at 51, 53. Dayne M. Adkins, CNP, conducted a physical examination and found no petechiae or purpura. Id. at 53. J.F. platelets remained low at 54 on June 29, 2015. Id. at 152.

On July 14, 2015, J.F. followed up with Dr. Pettee for his ITP. Pet. Ex. 1 at 54. J.F. reported "feeling well" with "no significant bleeding." Id. at 55. J.F. "[was] having normal bruises with play or minor injury and no spontaneous bruising in other places. He report[ed] for the last 2-3 months he has had pain in [bilateral] thighs, lower legs, and ankles that [was] worse in AM, improves with [T]ylenol, and [was] slowly getting better." Id. J.F. had no back pain, weight loss, or significant fatigue. Id. He was "playing actively and running long distances (up to 2 miles)." Id. Dr. Pettee's physical examination found a "2.5 cm bruise inside of left leg" and a "few small 1 cm bruises scattered on [bilateral] lower extremities." Id. at 56. Blood work revealed a platelet count of 47 (low panic). Id. at 56, 152. Diagnosis remained ITP. Id. at 57. Dr. Pettee noted J.F.'s platelet count was "stable and historically higher than previous 3 months," and he opined J.F.'s "ITP should resolve on its own and will need 2 consecutive normal counts to consider it completely resolved." Id. He planned to recheck blood work in three months, and ordered J.F. to continue to avoid high risk activities and anti-inflammatories, although he permitted J.F. to participate in non-contact activities. Id.

On September 30, 2015, J.F.'s platelet count was 32 (low panic). Pet. Ex. 1 at 152. His platelets increased to 45 (low panic) on October 16, 2015. Id. at 153.

On October 26, 2015, J.F. presented to Dr. Erin M. Donley at ACH for his annual well-child examination. Pet. Ex. 1 at 57. Dr. Donley's physical examination was normal. Id. at 59-60. At this visit, J.F. received a flu vaccine and his first human papillomavirus ("HPV") vaccine. Id. at 58; Pet. Ex. 2 at 1. On November 27, 2015, blood work revealed a platelet count of 37 (low panic). Pet. Ex. 1 at 153.

J.F. returned to Dr. Pettee for an ITP follow-up examination on January 20, 2016. Pet. Ex. 1 at 60. J.F. "[was] at the 12 month mark from ITP diagnosis with no current evidence of bleeding." Id. at 62. J.F. was still not wrestling due to a platelet count under 50 on his prior CBC. Id. On physical examination, no significant bruising was found. Id. at 62-63. Bloodwork showed a platelet count of 55 (low). Id. at 63, 154. J.F.'s diagnosis remained ITP. Id. at 64. Dr. Pettee wrote, "[g]iven [J.F.] is now 12 months from diagnosis [and] ITP [] has not resolved, a bone marrow [biopsy] is indicated to rule out ongoing myelodysplasia." Id. Further immune work up was also pending. Id. Dr. Pettee permitted J.F. to participate in gym if his parents desired. Id.

J.F.'s immune work up results were completed on January 22, 2016. Pet. Ex. 1 at 154. His Immunoglobulin G, A, and M levels were all normal, but he tested positive for antinuclear antibodies ("ANA").[24] Id. at 154, 156.

On February 2, 2016, a bone marrow biopsy and aspiration was conducted by Dr. Pettee. Pet. Ex. 1 at 64-65, 218. Pathologist Dr. Mark A. Steele's final diagnosis was "[n]ormocellular to hypercellular bone marrow with megakaryocytic hyperplasia." Id. at 162. Dr. Steele commented that "[t]he finding of megakaryocytic hyperplasia does not suggest a platelet production problem and suggests that [J.F.'s] thrombocytopenia is due to peripheral platelet destruction, consumption, or sequestration." Id. Diagnosis remained ITP. Id. at 218.

During physical examination on February 2, Dr. Pettee noted no significant bruising. Pet. Ex. 1 at 67-68. Bloodwork revealed a platelet count of 56 (low), and positive ANA with a titer of 1:320, speckled. Id. at 68, 156. Dr. Pettee referred J.F. to Dr. Mary Toth in rheumatology to get her opinion regarding J.F.'s positive ANA. Id. at 69.

J.F. saw Dr. Toth on March 3, 2016 for a consultation regarding his positive ANA. Pet. Ex. 1 at 69. Physical examination was normal. Id. at 72. Dr. Toth "explained that 5% of healthy children can have a positive ANA without risk or present autoimmune disease. Diagnosis of the conditions associated with a positive ANA are made based on clinical diagnosis in addition to the laboratory testing." Id. at 74. Her diagnosis was ANA positive and ITP. Id. She recommended more testing, including CBC, urinalysis, and comprehensive metabolic panel, and if they were normal, further work up or evaluation would not be necessary. Id. Testing ordered by Dr. Toth revealed a platelet count of 76 (low), normal urinalysis, and positive ANA with titer of 1:640. Id. at 163-68. The additional testing ordered by Dr. Toth was normal.[25] See id.

On June 1, 2016, J.F. presented to Dr. Pettee for follow-up. Pet. Ex. 1 at 76. J.F. reported bruising on bilateral knees, thighs, and left forearm from baseball. Id. at 77-78. J.F. was not having any spontaneous bleeding and his leg pain reported during prior visits was gone. Id. at 78. On physical examination, Dr. Pettee noted "[m]ultiple small 1 cm bruises [bilateral] knees. 1-2 small 2 cm fading bruises on right thigh. Few small [] bruises on left forearm. No petechiae." Id. J.F.'s platelet count was 40 (low panic). Id. at 169. Dr. Pettee's diagnosis was chronic ITP. Id. at 79. He noted J.F. "[was] doing well with no spontaneous bruising." Id.

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[24] Antinuclear antibodies ("ANA") are "antibodies directed against nuclear antigens; ones against a variety of different antigens are almost invariably found in systemic lupus erythematosus and are frequently found in rheumatoid arthritis, scleroderma (systemic sclerosis), Sjögren syndrome, and mixed connective tissue disease." Antinuclear Antibodies, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=56804 (last visited Aug. 23, 2021);

[25] Urinalysis was normal. Pet. Ex. 1 at 165. Metabolic panel was normal. Id. at 166-67. Immunoglobulins G and M Cardiolipin antibody blood tests were negative. Id. at 167. Beta-2 Glycoprotein antibodies were negative. Id. DRVVT screening was within normal limits. Id. at 168. Strep A antigens were not detected. Id. Throat swab strep culture was negative. Id.

Because his platelets were 40, treatment was not needed. Id. J.F.'s only restrictions were to avoid contact sports and anti-inflammatories. Id. J.F. was ordered to follow up in six months for labs and examination. Id. Additional blood work taken on June 30, 2016 showed a low platelet count of 37 (low panic). Id. at 170.

J.F. returned to the ED at ACH on July 5, 2016 for a left leg injury. Pet. Ex. 1 at 80. While playing baseball, J.F. was hit on the leg by the ball. Id. J.F.'s primary care physicians recommended an X-ray if the pain continued. Id. Physical examination conducted by Dr. Michael A. Billow found "[c]ircular bruising to left medial lower leg over mid tibia with mild edema. Tenderness to palpation over bru[i]sing. Pulses, sensation, and strength intact distal to injury." Id. at 81. Discharge diagnosis was contusion to left lower leg. Id. at 82.

On October 28, 2016, J.F.'s platelet level was 33 (low panic). Pet. Ex. 1 at 171.

J.F. had his 12-year well-child examination with Dr. Jacqueline Lickliter on November 4, 2016. Pet. Ex. 1 at 82. Physical examination was normal. Id. at 85. J.F. was cleared for basketball. Id. at 83. He received his second HPV vaccination and a flu vaccination at this visit. Id.

J.F. followed up for his ITP on December 5, 2016 with Dr. Stephanie Savelli. Pet. Ex. 1 at 87. J.F. reported he was playing basketball, had experienced bruising generally related to trauma, and had "one episode of epistaxis after being hit on the nose which lasted only 5 minutes." Id. at 88. J.F. "denie[d] petechiae, hematuria, blood in his stool[,] and oral mucosal bleeding except for some bleeding from a loose tooth when brushing his teeth." Id. Physical examination noted "[n]o significant bruises, rashes, petechiae[,] or jaundice," as well as "some fading bruises on his bilateral elbows and a fading bruise on his distal shin on the [right lower extremity]." Id. at 89. Blood work taken that day revealed a platelet count of 60 (low). Id. at 89, 172. J.F.'s diagnosis remained chronic ITP. Id. at 90. J.F.'s only restriction was again to avoid contact sports. Id. Dr. Savelli discussed other treatment options, but "[did] not recommend any treatment if [asymptomatic] and platelet number in a range to allow him to participate in desired activities." Id. J.F. was ordered to follow up in six months for labs and examination. Id.

On April 5, 2017, J.F. saw Dr. Pettee for new bleeding, bruising, and petechiae. Pet. Ex. 1 at 96-97. J.F. indicated "[h]e has had bruising since Monday, mostly on his legs. Since this AM he has developed petechiae on his neck." Id. at 97. Physical examination noted, "Large 4 cm hematoma left shin. Multiple other large bruises in various stages of healing on arms, legs. 6 x 6 cm patch of petechiae on right lower neck." Id. at 98. Blood work from April 3, 2017 revealed a platelet count of 16 (low panic). Id. at 173. On April 5, 2017, platelet count was 14 (low panic). Id. at 98, 174. Dr. Pettee started J.F. on dexamethasone[26] pulses for four days, repeating monthly for three months. Id. at 99. He ordered repeat blood work in five days, and

[26] Dexamethasone is "an anti-inflammatory and immunosuppressant in a wide variety of disorders." Dexamethasone, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=13599 (last visited Aug. 23, 2021).

J.F. was instructed to follow up in one month for a re-evaluation. Id. Blood work from April 10, 2017 showed improved platelets of 93 (low). Id. at 175.

J.F. returned to Dr. Pettee on May 15, 2017. Pet. Ex. 1 at 99. Physical examination revealed a 4-5 cm bruise on his right knee, a 3-4 cm bruise on his left knee, and no petechiae. Id. at 101-02. He had a platelet level of 17 (low panic). Id. at 102, 176. Diagnosis remained chronic ITP. Id. at 102-03. Dr. Pettee ordered J.F. to start his next dexamethasone treatment for four days, and follow up in one month. Id. at 103.

On June 21, 2017, J.F. returned to Dr. Pettee for a follow up. Pet. Ex. 1 at 103. J.F. reported "[b]ruising recurred after 1 week post [dexamethasone] and has been bruising ever since." Id. at 105. Physical examination noted "[d]iffuse upper and lower extremity [bruises] 1-4 cm in size in various stages of healing with patches of petechiae on arms, trunk from minor abrasions." Id. J.F.'s platelet levels were 14 (low panic). Id. at 105, 177. Dr. Pettee opined that J.F. was "somewhat steroid resistant" and diagnosed him with steroid side effects along with chronic ITP. Id. at 106. Dr. Pettee had J.F. begin his next dexamethasone pulse and started him on eltrombopag[27] daily. Id. J.F. was ordered to follow up in two weeks. Id.

J.F.'s July 7, 2017 CBC showed low platelets of 34. Pet. Ex. 1 at 178-79. On July 11, 2017, J.F.'s platelets were 9 (low panic). Id. at 180-81. On July 25, 2017, J.F.'s platelets were at 18 (low panic). Id. at 182. J.F.'s next CBC done on August 22, 2017 showed platelets at 5 (low panic). By August 31, 2017, J.F.'s platelets increased, but remained low at 81. Id. at 112, 185.

On September 1, 2017, J.F. saw Dr. Kathryn Phillippi Cook, a rheumatologist, on referral from Dr. Pettee. Pet. Ex. 1 at 108. She noted J.F. had been treated with steroids, IVIG, WinRho, and eltrombopag, but his platelets still remained low. Id. at 109. "Given that [J.F.'s] platelets have been resistant to the treatments, Dr. Pettee wanted [J.F.] to be seen again by rheumatology as their next option is for splenectomy." Id. J.F. "denie[d] any spontaneous bleeding, alopecia, mouth/nose sores, chest pain, trouble breathing, abdominal pain, nausea, vomiting, diarrhea, blood in his stool or urine, rashes, morning stiffness, joint pain, swelling, erythema[,] or increased warmth." Id. Physical examination revealed "[m]ultiple bruises on his upper and lower extremities" and a "[h]ealing scar on his right shin." Id. at 112. Diagnosis was ITP and a positive ANA. Id. at 113. Dr. Phillippi Cook wrote that although different conditions, diseases, infections, and drugs can be associated with a positive ANA, "[a] low titer ANA can be found in 5-10% of individuals without evidence of connective tissue disease. This makes it difficult to use ANA alone to rule in or rule out any particular disease." Id. She opined that J.F. did not exhibit findings to suggest an associated rheumatic disease, but given his persistent ITP, additional labs were ordered. Id. She suggested that if the labs were normal, other than the

[27] Eltrombopag olamine "stimulates platelet production" and is "used for the treatment of thrombocytopenia in patients with chronic [ITP] who have had an insufficient response to other treatments." Eltrombopag Olamine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15982 (last visited Aug. 23, 2021).

positive ANA, it "might be worth consider[ing] rituximab[28] for his refractory ITP prior to doing a splenectomy." Id. at 113-14.

Subsequent lab work conducted in September 2017 revealed a positive ANA with a titer of 1:640, along with low platelets. Pet. Ex. 1 at 185-94, 198. Throughout September, J.F.'s platelet levels fluctuated between 12 and 18 (low panic), until September 29, 2017, when his platelets increased to 45 (low panic). Id. J.F. received a pneumococcal vaccine on September 25, 2017. Pet. Ex. 10 at 3.

J.F. had a pediatric surgery consult with Dr. Oliver Soldes at ACH on October 1, 2017. Pet. Ex. 1 at 114. Dr. Soldes agreed that a laparoscopic splenectomy was indicated. Id. at 117. J.F. presented for his pre-operative consultation on October 4, 2017. Id. Physical examination by Lindsay Schroeter, CNP, was normal. Id. at 120-21. Surgery was ordered to be scheduled. Id. at 123.

October 6, 2017 blood work revealed J.F.'s platelets were 151 (normal). Pet. Ex. 1 at 199. One week later, on October 13, 2017, J.F.'s platelets decreased to 75 (low). Id. at 200. The following week, on October 20, 2017, his platelets further decreased to 28 (low panic). Id. at 201. J.F. received a flu vaccine on October 20, 2017. Pet. Ex. 10 at 3. On October 23, 2017, his blood work was normal, including his platelet level of 210. Pet. Ex. 1 at 202.

Dr. Soldes conducted a laparoscopic splenectomy without complications on October 25, 2017. Pet. Ex. 1 at 124. After surgery, J.F. did well and had no bleeding. Id. at 129. The day following surgery, October 26, 2017, J.F. platelets were 249 (normal). Id. at 203. ITP steroid treatment was discontinued. Id. at 129. J.F. was discharged home on October 28, 2017. Id.

J.F.'s CBC on November 8, 2017 revealed a platelet level of 710 (high). Pet. Ex. 1 at 204. The following week, on November 15, 2017, his platelets were 495 (high). Id. at 205.

On November 27, 2017, J.F. saw to Dr. Pettee for a follow up. Pet. Ex. 1 at 134. J.F. reported "[b]ruising on legs with mild injuries," but "[n]o fresh petechiae or other bruising." Id. at 135. He was "feeling much better since his splenectomy." Id. at 136. Physical examination found no petechiae and a few faded bruises on J.F.'s bilateral shins. Id. Blood work that day revealed a platelet count of 466 (high). Id. at 136, 205. Dr. Pettee "recommend[ed] [J.F.] follow up with Dr. Soldes for post[-]operative care and clearance for sports, but from [his] perspective [J.F.] [was] clear to resume contact sports as his platelets [were] normal." Id. at 137. Dr. Pettee discussed with J.F. and petitioner "that [J.F.'s] chronic ITP may still be present but if [J.F.] maintains normal platelets[,] [there are] no active concerns." Id.

J.F. saw Dr. Soldes on December 4, 2017 for a post-operative visit. Pet. Ex. 1 at 138. J.F. was doing well following surgery with an excellent platelet response. Id. at 139.

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[28] Rituximab is "a chimeric murine/human monoclonal antibody that binds the CD 20 antigen; used as an antineoplastic in the treatment of CD20-positive, B-cell non-Hodgkin lymphoma; administered intravenously." Rituximab, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=43977 (last visited Aug. 23, 2021).

J.F. returned to Dr. Pettee on January 15, 2018. Pet. Ex. 7 at 3. J.F. reported no bruising or petechiae. Id. Physical examination was normal. Id. at 4-5. Blood work revealed a platelet level of 376 (normal). Id. at 5. Dr. Pettee ordered J.F. to follow up in one year. Id. at 6. On January 29, 2018, during a visiting to ACH for unrelated complaints, petitioner noted J.F. had begun wrestling again. Id. at 6-7. Physical examination noted no bruising or petechiae. Id. at 7.

Throughout 2018, J.F. presented to ACH for unrelated complaints, including pharyngitis, facial injury,[29] and pectus carinatum.[30] Pet. Ex. 7 at 8-14. Physical examinations at these visits did not note any bruising or petechiae. Id. at 9-11, 13.

J.F. presented to Dr. Lickliter for his 14-year annual visit on November 28, 2018. Pet. Ex. 10 at 1. Physical examination did not reveal bruising or petechiae. Id. at 12.

J.F. presented to the ACH ED complaining of eye redness, sore throat, cough, and runny nose on December 7, 2018. Pet. Ex. 10 at 21, 23. Physical examination did not show "rashes, petechiae[,] or bruising." Id. at 25. He was discharged home with a diagnosis of unspecified conjunctivitis and unspecified acute upper respiratory infection. Id. at 21, 26.

He returned to the Dr. Pettee on January 2, 2019 for a follow-up examination. Pet. Ex. 10 at 45. J.F. reported "[n]o bleeding, bruising, or petechial rashes." Id. at 47. Physical examination was normal. Id. Blood work taken that day revealed a normal platelet level of 341. Id. at 47, 51. J.F. received a flu vaccine at this visit. Id. at 3, 50, 52. J.F.'s diagnosis remained chronic ITP. Id. at 48. Dr. Pettee reported J.F. was doing well and ordered him to follow up in one year. Id.

J.F. followed up with Dr. Pettee next on January 3, 2020. Pet. Ex. 10 at 87. J.F. was doing well with no bleeding or bruising. Id. at 88-89. He was participating in wrestling. Id. at 89. Physical examination revealed "[n]o rash, bruising, or petechiae." Id. J.F.'s platelet levels were normal at 271. Id. 89, 91. J.F. received a flu vaccine at this visit. Id. at 3, 90, 93. Dr. Pettee directed J.F. to follow up in one year. Id. at 90.

On January 17, 2020, J.F. presented to the Mahoning Valley ED for a right hand injury during a wrestling match. Pet. Ex. 10 at 109, 111. He was diagnosed with a displaced fracture of shaft of fifth metacarpal bone in right hand. Id. at 107, 115. Physical examination did not reveal any bruising or petechiae. Id. at 113.

On January 25, 2021, J.F. saw Dr. Pettee for a follow-up examination. Pet. Ex. 10 at 140. J.F. reported "[n]o bleeding, bruising, or petechial rashes." Id. at 141. Physical examination did

[29] J.F. did complain of nosebleeds due to the facial injury, but "[d]enie[d] epistaxis between nasal injury." Pet. Ex. 7 at 9, 11.

[30] Pectus carinatum is "a group of deformities of the anterior chest wall characterized by convex protrusion of the sternum and of the costal cartilages on one or both sides." Pectus Carinatum Olamine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=96922 (last visited Aug. 23, 2021).

not reveal any bruising. Id. at 142. J.F.'s platelets were 235 (normal). Id. at 142, 144. Dr. Pettee's diagnosis remained chronic ITP. Id. at 143. He reported J.F. was doing well and ordered him to follow up in one year. Id.

No additional medical records were filed.

D. Affidavits

1. Petitioner

Petitioner is J.F.'s mother. Pet. Ex. 3 at ¶ 1. In the weeks following J.F.'s October 23, 2014 vaccinations, petitioner and J.F.'s father "started noticing bruises on J.F.," but "didn't think too much about it considering he was young and active." Id. at ¶ 4.

J.F. began his fourth year of wrestling in the beginning of November 2014. Pet. Ex. 3 at ¶ 5. One of J.F.'s wrestling coaches, Tony Winterburn, commented on J.F.'s numerous bruises to petitioner and J.F.'s father. Id. Mr. Winterburn told them that "the bruises [could not] be from wrestling because they were only doing conditioning at that time." Id. Petitioner thought "J.F. wasn't drinking enough milk or eating enough vegetables, that his body could be lacking something." Id. at ¶ 6. Petitioner's mother-in-law bought J.F. vitamins. Id. Petitioner added that J.F. would get bloody noses before wrestling matches, which she thought were due to the dry air in the gymnasium. Id. at ¶ 7. She discussed J.F.'s bruising with her mother in November 2014 when her mother pointed out bruises on the back of J.F.'s arms. Id. at ¶ 8.

In early January 2015, J.F. was vomiting, had diarrhea, and his stomach hurt. Pet. Ex. 3 at ¶ 9. Petitioner took J.F. to the doctor. Id. She did not mention J.F.'s bruising because she was worried about J.F.'s vomiting. Id. And because it was the winter, J.F. was wearing pants and a long sleeve shirt. Id.

In late January 2015, J.F. had a rash on his head. Pet. Ex. 3 at ¶ 11. While at the doctor's office for the rash, petitioner asked the physician about J.F.'s bruising and blood work was ordered. Id. Petitioner received a phone call from a nurse, who indicated that J.F.'s platelet levels were "extremely low" and that he needed to go to ACH. Id. at ¶ 12. J.F. was started on IVIG. Id. at ¶ 14.

Six months later, J.F. had a bone marrow biopsy because his platelet levels were still very low. Pet. Ex. 3 at ¶ 15. After numerous blood infusions and steroids, petitioner decided to have J.F.'s spleen removed in October 2017 because his platelet levels were still low. Id. at ¶¶ 15-17. Because J.F. had a splenectomy, he now must take penicillin twice a day for the rest of his life. Id. at ¶ 17. "J.F. will always have chronic ITP." Id.

2. Jolie MacDougall

Jodie MacDougall is the grandmother of J.F. Pet. Ex. 4 at ¶ 2. She first noticed unusual bruising on J.F. in November 2014. Id. at ¶ 3. She lived across the street and he would come over for help with his homework. Id. "J.F. had bruises on the back of his arms and in other odd

places." Id. at ¶ 4. Around Christmas 2014, She noticed bruises on the top of J.F.'s feet when he was watching a movie at her house. Id. at ¶ 5.

3. Vanessa Ferguson

Vanessa Ferguson is the grandmother of J.F. Pet. Ex. 5 at ¶ 2. She first noticed bruising on J.F. in November 2014. Id. at ¶ 3. She would pick J.F. up from school and take him to wrestling practice. Id. She mentioned J.F.'s bruising to her son, J.F.'s father, who told her that he and petitioner noticed the bruising and thought it was from J.F. not eating enough vegetables or drinking enough milk. Id. at ¶ 4. Ms. Ferguson thereafter bought J.F. vitamins. Id. On Thanksgiving 2014, she saw bruises on J.F.'s feet. Id. at ¶ 6. J.F.'s bruising continued to get worse, and he began to develop bloody noses. Id. at ¶ 8.

4. Tony Winterburn

Tony Winterburn was one of J.F.'s wrestling coaches in 2014. Pet. Ex. 6 at ¶ 2. Practices began on November 3, 2014. Id. For the first two weeks of practice, they were working on conditioning. Id. at ¶ 3. During the second week of conditioning, he noticed bruising on J.F. "in odd places like the back of his calves." Id. He thought this was odd and made a comment to J.F.'s parents. Id. at ¶¶ 3-4. After the first two weeks, "live wrestling" began, which is "where the kids would have a partner to wrestle with, but it was not yet full on wrestling." Id. at ¶ 5.

The first wrestling match was on December 7, 2014. Pet. Ex. 6 at ¶ 6. At this match or the following match on December 14, 2014, "J.F. got a bloody nose on the side line before the match started." Id. Mr. Winterburn also believed J.F. had another bloody nose before another match during that season. Id.

E. Expert Reports

1. Petitioner's Expert, Dr. Edwin Forman

a. Background and Qualifications

Since 2009, Dr. Forman has worked as a Professor of Pediatrics at Mount Sinai School of Medicine as well as an Attending Physician in the Department of Pediatrics at Mount Sinai Hospital. Pet. Ex. 9 at 1. Prior to those appointments, he held various teaching and hospital positions, including Director of Pediatric Hematology/Oncology at the Warren School of Medicine at Brown University. Id. at 1-3; Pet. Ex. 8 at 1. After receiving his M.D. in 1960 from University of Pennsylvania School of Medicine, he completed an internship and residency in pediatrics at Johns Hopkins Hospital. Pet. Ex. 9 at 3-4. Thereafter, he completed a fellowship in pediatric hematology and oncology. Id. at 4. He is board-certified in pediatrics and pediatric hematology/oncology. Id. He is a member of and has served on various societies and boards focused on pediatric hematology and oncology. Id. at 6-9, 12-13; Pet. Ex. 8 at 1. Dr. Forman has also authored or co-authored over 80 publications. Pet. Ex. 9 at 16-23.

b. Opinion

Dr. Forman agreed with J.F.'s treating physicians that J.F.'s proper diagnosis is ITP. Pet. Ex. 8 at 2-3. He opined that more likely than not, one or more of J.F.'s October 23, 2014 vaccines caused J.F. to develop ITP. Id. at 3; Pet. Ex. 11 at 2.

According to Dr. Forman, "[i]mmune thrombocytopenia is an autoimmune bleeding disorder" that "involves a dysfunctional proliferation of autoreactive T cells, which inappropriately adhere to platelets. Macrophages (B cells) then attack the T cell carrying platelets" that "leads to persistent anti-platelet autoimmunity." Pet. Ex. 11 at 1. He opined that the mechanism underlying this autoimmune illness is molecular mimicry, stating, "[m]olecular mimicry between antigens from the immune challenge (in this case [flu], Tdap, or meningococcus vaccines) and platelet membranes is the likely trigger for this disorder." Id.

In support of his opinion as to the mechanistic theory, Dr. Forman cited relevant medical texts and articles. In Cecinati et al., the authors reviewed the literature on the subject of ITP following vaccine administration. Pet. Ex. 22 at 1. They explained that ITP "following vaccine administration depends on the development of autoantibodies that cross-react with the naturally present antigenic targets on platelets. It is more frequent in young children because the idiotypic network is still forming, and this increases the likelihood of post-vaccination, cross-reactive autoantibody expression." Id. A "defective immune regulation" caused by genetic abnormality also "may play a role in the pathogenesis of the disease." Id. at 2.

Dr. Forman also cited Nathan and Oski's Hematology and Oncology of Infancy and Childhood Textbook, which stated that "ITP is caused by autoantibodies that interact with membrane glycoproteins on the surface of platelets and megakaryocytes. These antibodies result in accelerated platelet destruction." Pet. Ex. 15 at 1. Hamiel et al. stated that while the cause of ITP is not usually known, "it can be triggered by . . . vaccination, most likely by the mechanism of molecular mimicry." Pet. Ex. 12 at 3. "The formed autoantibodies are directed against platelet membrane antigens. The antibody-coated platelets are rapidly cleared by tissue macrophages, resulting in a shortened half-life. In addition, the antibodies may also inhibit platelet production." Id.

The paper by Consolini et al.,[31] cited by Dr. Forman, provides a more detailed and technical review of the "complex dysregulation of the immune system" thought to cause ITP. Pet. Ex. 13 at 1. Generally, the authors described ITP as "an autoimmune disease resulting from platelet antibody-mediated destruction and impaired megakaryocyte and platelet production." Id. They stated that the mechanism of molecular mimicry as applied to the "cross-reactive nature of [] autoantibodies" was identified as a cause of ITP in 1996 by Wright et al.[32] Id. at 2. Since then, antibody platelet destruction, megakaryocyte abnormalities, and T helper (Th) cell defects have all been implicated as playing a role in the persistence of ITP. Id. The authors conclude

[31] Rita Consolini et al., The Centenary of Immune Thrombocytopenia – Part 1: Revising Nomenclature and Pathogenesis, 4 Frontiers Pediatrics 1 (2016).

[32] The Wright et al. article was not filed in the record.

that "[a]lthough the accelerated platelet destruction by platelet autoantibodies is considered the hallmark of ITP pathogenesis, research advances highlight the complex immune mechanism underlying the disease." Id. at 8.

Vaccines, primarily the MMR vaccine, "ha[ve] [] been associated with an increased risk of developing [ITP].[33] Pet. Ex. 12 at 1; see also Pet. Ex. 22 at 2-3; Pet. Ex. 32.[34] Cecinati et al. explained that the difficulty of obtaining reliable information about the risk of developing ITP following vaccination is due to the nature of surveillance programs, the difficulty confirming diagnosis, the presence of confounding viral infections, and the co-administration of multiple vaccines. Pet. Ex. 22 at 2. They noted that the MMR vaccine is the only vaccine with a documented causal association. Id.

Dr. Forman opined that the vaccines J.F. received have been associated with the development of ITP, and cited supportive studies and case reports. Pet. Ex. 8 at 3. In a large retrospective cohort study by O'Leary et. al., data was obtained from five large healthcare systems in the United States from 2000 to 2009. Pet. Ex. 14 at 1. The study encompassed "[a] total of 1.8 million children [who] received a total of 15 million vaccine doses during the study period." Id. at 3. Surprisingly, "[t]he risk of ITP after Hep[atitis] A, [Varicella], and [Tdap] was significantly elevated in three discrete age categories." Id. at 4. For Tdap, there was a significantly increased risk of ITP in children 11 to 17 years of age. Id. at 5 tbl.2. The authors of O'Leary noted that the study was limited by methodologies used to study rare adverse events and recommended further studies to explore the observed associations. Id. at 5. "[A]lthough it is important to consider that the findings showing an elevated risk of ITP after Hep[atitis] A, [Varicella], and Tdap in older children may be real, these results must be interpreted with caution." Id.

Sauvé et al.[35] reported the results of a Canadian cases series study, which reviewed data from its Immunization Monitoring Program, Active (IMPACT) from 12 Canadian hospitals. Pet. Ex. 31 at 1. There were 107 children hospitalized with post-vaccination ITP. Id. The most frequently associated vaccine was MMR, followed by DTP/diphtheria-tetanus-acellular-pertussis ("DTaP"). Id. at 2 tbl.1. Of the cases of ITP, 77 (72%) children received the MMR vaccine and 28 (26%) received the DTP/DTaP vaccine. Id. A majority of the children "had an alternate potential cause," including medications associated with ITP or a preceding viral illness. Id. at 2. The authors explained that "[t]here [was] no specific test to determine the etiology of [ITP]." Id. While they acknowledged that "[t]here [was] increasing evidence to support a link between vaccinations and thrombocytopenia," they were unable to reach any conclusions as to vaccine causation. Id. at 1-3.

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[33] A presumption of causation is afforded under the Vaccine Injury Table for cases of ITP following MMR if onset is between 7 and 30 days. 42 C.F.R. § 100.3(a)(V)(A).

[34] Vasiliki Vlacha et al., Recurrent Thrombocytopenic Purpura After Repeated Measles-Mumps-Rubella Vaccination, 97 Pediatrics 738 (1996).

[35] Laura J. Sauvé et al., Postvaccination Thrombocytopenia in Canada, 29 Pediatric Infectious Disease J. 559 (2010).

Another retrospective study cited by Dr. Forman was published by Hsieh and Lin.[36] Pet. Ex. 26. The authors studied the medical records of 20 children age 3 and under, who had been hospitalized at Cathay General Hospital in Taipei, Taiwan from 1989 to 2010. Id. at 1-2. They identified 12 cases of post-vaccination ITP. Id. at 2. Four of the children had received the DTaP vaccine. Id. In this study, "[t]he most frequent cause of post-vaccination [ITP] . . . was [Hepatitis B] vaccination, followed by DTaP, and then MMR." Id. at 3.

In addition to the studies described above, Dr. Forman also cited a number of case reports of post-vaccination ITP. Arya et al.[37] reported ITP following diphtheria-pertussis-tetanus ("DPT") vaccination in two young children, ages 18 months and 4 years of age. Pet. Ex. 25 at 2-3. Onset was three days after the first booster in one child, and eight days in the other, with repeat occurrences after subsequent doses of the vaccine. Id. Both children were ultimately diagnosed with chronic ITP. Id. at 4.

As for the flu vaccine, Dr. Forman cited the Hamiel et al. case report, where the authors concluded "with high probability, the [flu] vaccine [was] a cause for ITP in a pediatric patient." Pet. Ex. 12 at 1. The article summarized the clinical course of a four-year-old child who was diagnosed with ITP, treated with IVIG, and improved. Id. at 1-2. Upon review of the child's past medical record, "it became apparent that he had been hospitalized twice previously, at 1.5 and 3.5 years of age, with similar signs and symptoms," including low platelet counts, all within one week of receipt of the seasonal flu vaccine. Id. at 2. "Symptoms appeared within 7 days of the first vaccination at age 1.5 years and within 6 days of the second and third vaccinations at age 3.5 years and 4.5 years, respectively." Id. It was recommended that the child not have any further flu vaccinations and "no further recurrences" were documented. Id. The authors concluded "with a high degree of confidence an association between the trivalent [flu] vaccine and the development of ITP. The response to IVIG therapy strongly suggests an immunologic mechanism rather than a cytotoxic one." Id. at 3.[38]

The other vaccination at issue here is the meningococcal conjugate vaccine. Dr. Forman cited a French study by Lafaurie et al.[39] that reported an increased risk of ITP after MMR and

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[36] Yuh-Lin Hsieh & Lung-Huang Lin, Thrombocytopenic Purpura Following Vaccination in Early Childhood: Experience of a Medical Center in the Past 2 Decades, 73 J. Chinese Med. Ass'n 634 (2010).

[37] L. S. Arya et al., Letter to the Editor, Thrombocytopenic Purpura Following DPT Vaccination, 10 Pediatric Hematology & Oncology 381 (1993).

[38] For a summary of additional studies investigating the risk of ITP after flu vaccination, see Pet. Ex. 12 at 3.

[39] Margaux Lafaurie et al., Risk of Vaccine-Induced Immune Thrombocytopenia in Children. Nationwide Case Cross-Over and Self-Controlled Case Series Studies in France, 132 Blood 738 (2018).

meningococcal C vaccines.[40] Pet. Ex. 24 at 2. Dr. Forman also cited a paper by the World Health Organization ("WHO")[41] that discussed the safety of a Norwegian meningococcal B vaccine administered in France, based on information obtained from a questionnaire completed by parents. Pet. Ex. 33 at 6. Eight cases of purpura were reported including one case of ITP. Id. However, the committee that conducted the evaluation[42] was unable to evaluate the significance of the findings due to the lack of data on background rates of ITP in the population. Id. at 6-7.

Moving to Dr. Forman's discussion of the temporal association between vaccination and onset of symptoms, he explained that generally, the interval between antigen presentation (via infection or immunization) and antibody production is one to two weeks. Pet. Ex. 11 at 1-2. Dr. Forman explained that the antigen presents to immune cells, which process the antigen and release antibodies. Id. at 2. The number of antibodies released rises until a certain level is reached. Id. When this level is reached, either the clinical picture of disease or immunity occurs. Id.

Dr. Forman opined that "post-immunization . . . [ITP] generally occurs 1 to 6 weeks after exposure, with the peak time of development being 1 to 3 weeks." Pet. Ex. 8 at 3. Dr. Forman cited O'Leary et al. to support his opinion. In O'Leary et al., the authors "defined the exposed period as 1 to 42 days after vaccination for all vaccines." Pet. Ex. 14 at 3. Further, the cases of ITP following vaccination occurred in a risk window that fell within 6 weeks of vaccination, and a risk period as far out as to 12 weeks following vaccination. See Pet. Ex. 14 at 5 fig.1. Other articles cited by Dr. Forman also reference a similar onset time frame following vaccination. For example, in the Sauvé et al. study, all of the cases of ITP occurred within a month of vaccination. Pet. Ex. 31 at 2.

Based on petitioner's affidavits, Dr. Forman concluded that "J.F. developed unusual and excessive bruising [] in early November [2014], 2 to 3 weeks after the vaccinations." Pet. Ex. 8 at 1-2. Wrestling coach, Tony Winterburn observed bruising in odd places approximately November 11 to November 17, 2014. Id. at 2. Dr. Forman opined that the timing is medically appropriate because "[t]he onset of spontaneous bleeding manifestations (abnormal bruising, epistaxis) . . . occurred approximately 2 to 3 weeks after the immunizations given on October 23, 2014." Id. at 3.

Dr. Forman opined that there was no immune challenge other than J.F.'s vaccinations that could explain his condition. Pet. Ex. 8 at 3; Pet. Ex. 11 at 2. J.F. did not have a viral infection prior to his vaccinations or prior to the onset of his bruising and epistaxis. Pet. Ex. 8 at 3. J.F. had gastroenteritis on January 10, 2015, approximately 11 weeks post-vaccination, and after the onset of J.F.'s bruising and epistaxis. Id. Thus, Dr. Forman concluded that gastroenteritis could not be a possible cause of J.F.'s ITP. Pet. Ex. 11 at 2. Further, diagnostic studies, including the

[40] This study did not find an increase in ITP after the diphtheria-tetanus-poliomyelitis vaccine. Pet. Ex. 24 at 2.

[41] Weekly Epidemiological Record, 83 World Health Org. 37 (2008)

[42] This was the Global Advisory Committee on Vaccine Safety, or GACVS.

bone marrow biopsy and labs, were normal, which Dr. Forman opined is evidence that J.F. does not have an underlying disorder that could have caused his condition. Pet. Ex. 8 at 3.

2. Respondent's Expert, Dr. John Strouse

a. Background and Qualifications

Dr. Strouse is board certified in pediatrics, hematology, and pediatric hematology/oncology. Resp. Ex. A at 1. He currently works as an Associate Professor of Medicine and Pediatrics at Duke University School of Medicine. Id. He received his A.B. from Princeton University and his M.D. and Ph.D. from Johns Hopkin University. Resp. Ex. B at 1. His "clinical practice includes the care of children, adolescents[,] and adults with both acute and chronic autoimmune thrombocytopenia" and he sees approximately 100 patients from thrombocytopenia per year." Resp. Ex. A at 1. Dr. Strouse has authored or co-authored over 90 publications, held various editorial positions, and participated in numerous organizations and societies. Resp. Ex. B at 2-14.

b. Opinion

Dr. Strouse concurred with the diagnosis in J.F.'s medical records and Dr. Forman's expert reports. Resp. Ex. A at 2. Although Dr. Strouse agreed that ITP was caused by "immune mediated destruction of platelets," he opined that "the specific trigger . . . is not identified in the majority of patients." Id. at 3. Further, while a number of viral infections have been linked with ITP,[43] Dr. Strouse stated that he was not aware of any association between "[flu], diphtheria, tetanus, pertussis, or meningococcal infections" and ITP. Id. With regard to the known association of the MMR vaccine and ITP, Dr. Strouse pointed out that it was a "live attenuated virus" vaccine, unlike the flu, Tdap, and meningococcal vaccines given to J.F. Id.

While he agreed that the MMR vaccine was "consistently associated with ITP," he disagreed that any of the vaccinations administered to J.F. on October 23, 2014 were "consistently associated" with ITP. Resp. Ex. A at 3. Instead, Dr. Strouse opined that the more likely cause of J.F.'s ITP was "a viral infection," or that it was idiopathic, noting that "[c]hildren with chronic ITP such as [J.F.] often do not have a specific known trigger." Id.

Dr. Strouse cited an English study by Miller et al.,[44] which confirmed the previously reported causal association between the MMR vaccine and ITP. Resp. Ex. A, Tab 9 at 2. The authors briefly explained the history of ITP after MMR vaccinations. Id. at 1. The association was initially reported in Swedish medical literature in the 1980s. See id. In the 1994 report authored by the Institute of Medicine, now the National Academy of Sciences, a causal relationship between the MMR vaccine and ITP was "accepted . . . , apparently on the grounds of

[43] Dr. Strouse identified the viral infections that have been associated with ITP as "HIV, hepatitis C, measles, rubella, Epstein-Bar Virus, and varicella." Resp. Ex. A at 3.

[44] E. Miller et al., Idiopathic Thrombocytopenic Purpura and MMR Vaccine, 84 Archives Disease Childhood 227 (2001).

biological plausibility." Id. In the Miller et al. study, the absolute risk occurred within six weeks of vaccination, "with two of every three cases being vaccine attributable." Id. at 2.

As for the vaccines at issue here, Dr. Strouse opined that none have "consistent associations with ITP in epidemiological studies." Resp. Ex. A at 2. He acknowledged the existence of case reports of ITP associated with the flu vaccine but stated they "are to be expected given the large numbers of [flu] vaccinations given in the United States." Id. Dr. Strouse also recognized a German study[45] that found adults who received a flu vaccination were four times more likely to develop ITP. Id. (citing Resp. Ex. A, Tab 2 at 9). He explained, however, that larger studies, including O'Leary et al. and Grimaldi-Bensouda et al.,[46] have not found a significantly increased risk of ITP after flu vaccination. Id. (citing Pet. Ex. 14; Resp. Ex. A, Tab 3).

In Garbe et al., the German study referenced above, a medication/vaccine history was obtained for adults with newly diagnosed ITP between 2000 and 2009. Resp. Ex. A, Tab 2, at 1, 3. A total of 619 patients with ITP were identified; of these, 169 were included in the study. Id. at 4. Criteria from the WHO was used to perform a standardized causality assessment. Id. at 3. A drug reaction was classified as "probably" causal when ITP occurred within a reasonable time after administration of the drug or vaccine, other causes were unlikely, and "a positive dechallenge reaction was observed on drug withdrawal." Id. at 3-4. The authors found that the flu vaccine had a "probable" causal relationship with ITP.[47] Id. at 9. They concluded that "[i]n the case-control analysis, [flu] vaccination was associated with a statistically significant 4-fold risk." Id.

Specifically related to the Tdap vaccine, Dr. Strouse acknowledged that the O'Leary et al. epidemiologic study reported an association between Tdap and ITP in children "between 11 and 17 years of age." Resp. Ex. A at 2 (citing Pet. Ex. 14 at 1). However, he stated that it was "a single study" and the "association was based on only 2 exposed cases." Id. at 2-3 (citing Pet. Ex. 14 at 5 tbl.2). Dr. Strouse filed another case-control study, not of children but adults (ages 18 to 79), by Grimaldi-Bensouda et al., which used data from a nationwide registry in France to study ITP after vaccination. Resp. Ex. A, Tab 3 at 1-2. There was an increase in ITP within two months of vaccination, most notably for the diphtheria-tetanus-pertussis-poliomyelitis ("DTPP") vaccine. Id. at 4. The authors concluded, however, that "this increase was not statistically significant" because "the study lacked power" to draw conclusions, "particularly for DTPP." Id.

[45] Edeltraut Garbe et al., Drug-Induced Immune Thrombocytopaenia: Results from the Berlin Case-Control Surveillance Study, 68 Eur. J. Clinical Pharmacology 821 (2012).

[46] Lamiae Grimaldi-Bensouda, A Case-Control Study to Assess the Risk of Immune Thrombocytopenia Associated with Vaccines, 120 Blood 4938 (2012).

[47] Pneumococcal and poliomyelitis vaccines were also assessed as probably causal. Resp. Ex. A, Tab 2 at 9.

Further, Dr. Strouse asserted that "DTaP vaccination was rarely associated with [ITP] in [the] Vaccine Adverse Event Reporting System (VAERS)."[48] Resp. Ex. A at 2. He cited a U.S. Post-licensure study of Tdap vaccines published by Chang et. al.,[49] which reviewed VAERS reports submitted from 2005 to 2007. Resp. Ex. A, Tab 5 at 1. During that time period, there were 2090 adverse event reports related to Tdap. Id. Five were reports of "petechiae, easy bruising, ecchymosis, or epistaxis, and 3 were diagnosed with [ITP]." Id. at 4. The onset range was 13 to 30 days. Id.

With regard to the third vaccine administered to J.F., the meningococcal vaccine, Dr. Strouse stated that it "has not been associated with ITP." Resp. Ex. A at 3.

With regard to temporal association, Dr. Strouse opined that "based on the published studies on MMR vaccination," onset in the majority of cases "occurred between 14 and 28 days after administration of the vaccine." Resp. Ex. A at 3. For support, Dr. Strouse cited to Miller et al., a study that "confirm[ed] a causal association between MMR vaccine and ITP." Resp. Ex. A, Tab 9, at 2. The authors examined 35 cases of children under the age of five who received an MMR vaccine and were admitted to the hospital for ITP. Id. at 1-2. They found "the highest relative incidence in the six weeks after MMR was found between 15 and 28 days." Id. at 2.

Dr. Strouse opined that J.F.'s vaccinations occurred approximately three months prior to his diagnosis, and therefore outside the appropriate timeframe. Resp. Ex. A at 3. He opined that J.F.'s gastroenteritis, which he described as a typical trigger for ITP, occurred two weeks prior to diagnosis and within the timeframe seen for ITP post-viral infection. Id.

Dr. Strouse agreed with Dr. Forman that J.F.'s "initial symptoms of increased bruising and some mild increased bleeding" began approximately two to three weeks after J.F. received the vaccinations at issue. Resp. Ex. A at 3. However, Dr. Strouse could not "definitely attribute this to a decreased platelet count without testing of the platelet count." Id.

III. DISCUSSION

A. Standards 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

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[48] VAERS is "the U.S. national, passive surveillance system for vaccine [adverse events]" that "was established in 1990 and is jointly managed by [the Food and Drug Administration ("FDA")] and [Centers for Disease Control and Prevention ("CDC")]." Resp. Ex. A, Tab 5 at 2. "Passive surveillance systems such as VAERS are subject to many limitations, including underreporting, incomplete information . . . , inadequate data regarding the number of doses administered, and lack of unbiased comparison groups. Causality between reported [adverse events] and vaccines cannot usually be assessed from individual reports to VAERS." Id.

[49] Soju Chang et al., U.S. Postlicensure Safety Surveillance for Adolescent and Adult Tetanus, Diphtheria and Acellular Pertussis Vaccines: 2005-2007, 31 Vaccines 1447 (2013).

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). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379

(Fed. Cir. 2009); Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Causation

To receive compensation through the Program, petitioner must prove either (1) that J.F. suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that J.F. received, or (2) that J.F. 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 J.F. suffered a Table Injury, she must prove a vaccine J.F. received caused his injury. To do so, petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." 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). Petitioner cannot establish entitlement to compensation based solely on her 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 special master must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in her 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).

IV. CAUSATION ANALYSIS

In large measure, the outcome here depends on a finding that onset was within an appropriate time frame following vaccination. Therefore, the undersigned starts with an analysis of Althen Prong Three, followed by Althen Prongs One and Two.

A. Althen Prong Three

Althen Prong Three requires petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That phrase has been defined as a "medically acceptable temporal relationship." Id. The petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease's etiology, it is medically acceptable to infer causation-in-fact." de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542 (2011), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

The undersigned finds the temporal association of the onset of J.F.'s ITP following vaccination is appropriate given the mechanism of injury for the reasons explained below.

The events leading up to J.F.'s diagnosis of ITP are described in the affidavits of petitioner and other lay witnesses. Persuasive lay witness testimony was given by Tony Winterburn, J.F.'s wrestling coach in 2014. J.F. received the Tdap vaccination at issue on October 23, 2014. Wrestling practice began on November 3, 2014. During the second week of practice, Coach Winterburn, observed that J.F. had bruising in unusual places, including the back of his calves. The first and second wrestling matches were December 7 and 14, 2014, respectively. At one of these events, J.F. had a nosebleed before the match started.

Coach Winterburn's testimony was corroborated by J.F.'s grandmother, Vanessa Ferguson. She picked up J.F. from school and took him to wrestling practice. She noticed bruising on J.F. in November 2014. She also recalls seeing bruises on J.F.'s feet on Thanksgiving 2014. She averred that the bruises continued and J.F. also began to have bloody noses.

Petitioner, J.F.'s mother, began noticing bruises on J.F. in the weeks following his vaccinations, but she was not concerned because her son was young and active. J.F. began his fourth year of wrestling in early November 2014. J.F.'s wrestling coach, Tony Winterburn, commented on J.F.'s numerous bruises, telling J.F's parents that "the bruises [could not] be from wrestling because they were only doing conditioning at that time." Pet. Ex. 3 at ¶ 5. Petitioner attributed the bruising to J.F.'s diet.

In early January 2015, petitioner took J.F. to ACH for vomiting, diarrhea, and stomachache. Petitioner did not mention J.F.'s bruising at that visit because she was worried about J.F.'s vomiting. Petitioner attributed the lack of references to J.F.'s bruising to the fact that it was winter, and J.F. was wearing pants and a long sleeve shirt.

In late January 2015, petitioner took J.F. to ACH because he had a rash on his head. While at the doctor's office, petitioner also told J.F.'s physician about the bruising and blood

work was ordered. Petitioner received a call from a nurse, who told her that J.F.'s platelet levels were "extremely low" and that he needed to go to ACH. Pet. Ex. 3 at ¶ 12. The medical records establish that J.F.'s initial platelet count was drawn on January 29, 2015, and showed that J.F.'s platelets were extremely low at 10. He was subsequently diagnosed with ITP.

Dr. Forman opined that the onset of ITP following vaccination generally occurs within one to six weeks. The O'Leary et al. study used a time frame of one to 42 days after vaccination as the period of exposure, or the appropriate interval between vaccination and onset of symptoms. In the Sauvé et al. study, the cases of ITP occurred within a month of vaccination. The onset of ITP is usually characterized by "the abrupt onset of bruising and bleeding in an otherwise healthy child." Pet. Ex. 15 at 1. Nosebleeds may also occur. Based on the testimony set forth in petitioner's affidavits, Dr. Forman opined that "J.F. developed unusual and excessive bruising [] in early November [2014], 2 to 3 weeks after the vaccinations." Pet. Ex. 8 at 1-2.

Dr. Strouse agreed with Dr. Forman that J.F.'s initial symptoms of bruising and mild increased bleeding began two to three weeks after vaccination. However, Dr. Strouse could not "definitely attribute" this to an abnormally low platelet count without testing. Resp. Ex. A at 3. Because there was no testing done at the time that J.F. had initial symptoms, Dr. Strouse placed onset on the date of testing, and the date that J.F. was formally diagnosed with ITP, January 29, 2015. Dr. Strouse opined that this date is approximately three months post-vaccination, too long to be temporally associated with J.F.'s vaccines.

There are two problems with Dr. Strouse's approach to onset. The first is his use of the phrase "definitely attribute." The word "definitely" is defined as "without doubt" or "clearly."[50] However, the applicable burden of proof here is preponderant evidence, more likely than not. § 13(a)(1); Moberly, 592 F.3d at 1322 n.2. The burden is not "without doubt." Proof of medical certainty is not required. Bunting, 931 F.2d at 873. Dr. Strouse's opinion, if adopted, would impose a more rigid standard than that required under the Vaccine Act.

The second problem with Dr. Strouse's approach, requiring definite proof of onset verified by a lab result instead of placing onset at the time J.F. had clinical symptoms of bleeding, is that he pushes onset out to the date of diagnosis. By doing so, he conflates onset with the date of diagnosis. Given the facts of this case, the date of onset (bleeding symptoms) and the date of diagnosis (verified lab result) are not the same.

The undersigned finds the lay witness testimony and opinion of Dr. Forman, supported by medical literature, more persuasive. Onset in early November, within 30 days of vaccination, is consistent with the bruising and nosebleed described by Coach Winterburn, as well as the other witnesses. Dr. Forman's opinion is consistent with the medical literature that describes the initial manifestations and clinical course of the illness. Moreover, Dr. Strouse does not disagree that bleeding symptoms were present in early November 2014.

[50] Definitely, Merriam-Webster, https://www.merriam-webster.com/dictionary/definitely (last visited Dec. 1, 2021).

Therefore, undersigned finds that onset occurred within 30 days of vaccination, and that this time frame is appropriate given the mechanism of molecular mimicry. Therefore, the petitioner has met her burden of proof as to Althen Prong Three.

B. Althen Prong One

Under Althen Prong One, petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

For the following reasons, the undersigned finds petitioner has provided by preponderant evidence a sound and reliable theory that the Tdap vaccine can cause ITP, and therefore, petitioner has satisfied the first Althen prong.

Dr. Forman's expert reports and cited medical literature establish that ITP is known to be an autoimmune condition "in which autoantibodies inhibit platelet production and impair the circulating ones, leading to thrombocytopenia." Pet. Ex. 20 at 1. Petitioner cited a number of articles which establish the mechanisms by which the condition may occur after vaccination. While the cause of ITP is not known, the authors of the medical texts and articles cite molecular mimicry as the "most likely" causal mechanism. Pet. Ex. 12 at 3.

For example, Cecinati et al. state that ITP after vaccination is caused by the "development of autoantibodies that cross-react with the naturally present antigenic targets on platelets." Pet. Ex. 22 at 1. Nathan & Oski's Hematology and Oncology Textbook states that "ITP is caused by autoantibodies that interact with membrane glycoproteins on the surface of platelets and megakaryocytes. These antibodies result in accelerated platelet destruction." Pet. Ex. 15 at 1. And the paper by Consolini et al. provided a thorough overview of the potential mechanisms, acknowledging that the "hallmark of ITP pathogenesis" is "accelerated platelet destruction by platelet autoantibodies." Pet. Ex. 13 at 8.

As compared with the paucity of medical literature regarding many alleged post-vaccination adverse conditions, there is a wealth of medical literature that supports an association between vaccinations and ITP. Further, there is a known causal association between the MMR

vaccine and ITP, and that association is reflected in the Vaccine Injury Table.[51] The presumption of causation for ITP following the MMR vaccine has not been extended to other vaccines. The evidence filed in this case, however, supports vaccine causation as to the Tdap vaccine administered here.

The epidemiology study authored by O'Leary et al., confirmed the causal association of MMR and ITP. The study also found a significantly elevated risk of ITP after hepatitis A, Varicella, and Tdap vaccinations in older children. Chart review confirmed 197 cases of ITP within the 42-day risk window selected. In younger children, the majority of cases were acute. However, in the older children (ages 11 to 17), one-third of the cases were diagnosed as chronic ITP. There were six cases of ITP following MMR vaccination in children 12 to 19 months old, as compared to five in the control group (unexposed cases). The researchers concluded that "there was a significant association of ITP with MMR." Pet. Ex. 14 at 3. There were two cases of ITP following Tdap compared with three in the control group. The authors found "[t]he risk of ITP after . . . Tdap[] was significantly elevated." Id. at 4-5.

The authors of the O'Leary study issued several caveats, primarily warning that because ITP is very rare, "there is the possibility that significant associations could surface by chance alone." Pet. Ex. 14 at 4. They also questioned why, from a biological point of view, ITP would occur in older children but not younger children. They stated, "although it is important to consider that the findings showing an elevated risk of ITP after Hep[atitis] A, [Varicella], and Tdap in older children may be real, these results must be interpreted with caution." Id. at 5. The undersigned acknowledges the cautionary guidance, but notes that these same caveats apply to most epidemiology studies dealing with very rare events, which is true for many cases filed in the Vaccine Program.

Respondent asserts that "the limited data in O'Leary does not establish a preponderant causal connection between the Tdap vaccine and ITP, especially chronic ITP." Resp. Response at 13. Acknowledging the limits of the study, however, does not mean that the results are not real. Standing alone one study may not establish preponderant proof, but when combined with other epidemiology studies, case reports, and expert reports, the resulting weight can satisfy the requisite burden of proof. Here, in addition to the O'Leary et al. study, two other studies reported the occurrence of ITP following DTaP vaccination: Sauvé et al. and Hsieh and Lin. The methodology of these two studies did not allow for conclusions to be made about causation; however, the findings are consistent with O'Leary et al.

In addition to these studies, Dr. Forman cited to case reports of post-vaccination ITP, including two children who developed the illness following DPT vaccination in Arya et al. Respondent takes the position that "case reports are entitled to little weight in assessing causation." Resp. Response at 13. Respondent cites Loyd, where the Chief Special Master found that "[p]etitioner's causation theory [] relied heavily on case reports—a category of evidence inherently given less weight in the Program, especially when contrasted with on-point and reliable epidemiologic proof." Loyd ex rel. C.L. v. Sec'y of Health & Hum. Servs., No. 16-811V, 2021 WL 2708941, at *30 (Fed. Cl. Spec. Mstr. May 20, 2021). However, in this case,

[51] See 42 C.F.R. §§ 100.3(a)(V)(A), (c)(7).

respondent has not cited "on-point and reliable epidemiologic proof" to rebut the O'Leary et al. study. Therefore, respondent's argument carries little weight. Especially here, where there are supportive epidemiological studies, case studies can add to the weight of the evidence.[52]

With regard to the flu vaccine, the Hamiel et al. case report provides strong evidence of causation. The child had three episodes of ITP, and each episode occurred within one week of a flu vaccine. The authors concluded "with a high degree of confidence an association between the trivalent [flu] vaccine and . . . ITP." Pet. Ex. 12 at 3. Moreover, the authors stated that the child's response to IVIG "strongly suggest[ed] an immunologic mechanism." Id. However, the facts specific to this case do not support causation for J.F.'s flu vaccination, for reasons described below in the analysis of Althen Prong Two. Therefore, the undersigned does not reach a finding as to whether the flu vaccine can cause ITP. Additionally, the undersigned does not make a finding as to whether the meningococcal conjugate vaccine can cause ITP.

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 F.3d 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. The Vaccine Act specifically provides that the "diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court." § 13(b)(1)(B).

The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and

[52] The undersigned acknowledges that Sauvé et al., Hsieh and Lin, and Arya et al. discuss DTaP and DPT vaccinations, and not the Tdap vaccine at issue here. However, each of these vaccines contain the same or similar contents, although the whole cell pertussis vaccine (DTP) differs from the acellular version. See Diphtheria, Tetanus, and Pertussis Vaccine Recommendations, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/recommendations.html (last reviewed Jan. 22, 2020) ("CDC recommends diphtheria, tetanus, and acellular pertussis vaccination across the lifespan. Children younger than 7 years of age receive DTaP or DT, while older children and adults receive Tdap and Td.").

effect." Capizzano, 440 F.3d at 1325. Instead, petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

For the following reasons, the undersigned finds there is preponderant evidence of a logical sequence of cause and effect establishing that the Tdap vaccination administered to J.F. on October 23, 2014 was the cause of his ITP. See Althen, 418 F.3d at 1278.

J.F.'s clinical course is consistent with post-vaccination ITP. There is no evidence here to suggest that J.F. had symptoms of ITP prior to vaccination. He received his Tdap vaccination on October 23, 2014. At the time of vaccination, he was approximately 10-and-one-half years of age. His symptoms of unusual bruising and nosebleeds began two to three weeks after vaccination. This clinical course is consistent with ITP following vaccination as described in the medical literature.

For example, in O'Leary et al., "a case was defined as a child aged 6 weeks to 18 years with a platelet count of [less than] 50,000/μL, with normal red and white blood cell indices, and the presence of clinical signs and symptoms of ITP, such as petechiae, significant bruising, or spontaneous bleeding." Pet. Ex. 14 at 2. Chronic ITP was defined as "thrombocytopenia lasting [more than] 6 months."[53] Id. "The majority of cases of ITP in younger children were classified as acute, whereas over one-third in the 11- to 17-year-old age group were chronic." Id. at 3. In the children ages 11 to 17, 59 cases were acute and 38 were chronic. Id. at 4 tbl.1. Based on the findings, the authors concluded that "ITP after vaccination may have a similar clinical course as ITP from other causes." Id. at 6.

J.F.'s case is consistent with the cases described in O'Leary et al. The fact that his condition persisted, and he developed chronic ITP, is also consistent with the findings in O'Leary et al., that older children had a higher incidence of chronic ITP as compared with younger children.

Respondent argues that because J.F. had chronic ITP, his course is inconsistent with post-vaccination ITP. Respondent relies on Loyd in support of his position. See Resp. Response at 11-13 (citing Loyd, 2021 WL 2708941). In Loyd, the Chief Special Master found that petitioner was not entitled to compensation because there was insufficient evidence that the pneumococcal vaccine caused the child's ITP. Loyd, 2021 WL 2708941, at *1. One of the reasons for the Chief Special Master's decision was based on the fact that the child in Loyd had chronic and not acute ITP. Id. at *23, 29-32. Notably, Loyd involved a young child. Id. at *1. The facts here are different, as this case involves an older child. O'Leary et al. specifically stated that younger children most often had acute ITP following vaccination, but that a notable percentage of older children had chronic ITP. Based on the O'Leary et al. article, it appears that respondent's reliance on Loyd is misplaced, as respondent does not take into account the difference between the clinical course of younger children when compared to older children who have ITP following vaccination.

[53] O'Leary et al. noted that after the study was conducted, "an expert panel [] recommended a definition of chronic ITP as lasting [more than] 12 months." Pet. Ex. 14 at 2.

Further, while O'Leary et al. studied younger and older children, other studies only focused on younger children. Sauvé et al. studied the MMR vaccine, usually given at 12 months, 18 months, or 4 to 6 years of age, and the varicella vaccine, usually given by age 7. Therefore, by design, the study focused on younger children. Out of 107 children with vaccine-associated ITP, only 11 (10%) were older than 5 years of age. They noted that "most of the children had a rapidly resolving, benign course;" however, there were two children with severe complications, and one who died. Pet. Ex. 31 at 2. The authors did not address the subject of acute versus chronic ITP or suggest that chronic ITP was inconsistent with vaccine-associated ITP.

The Hsieh and Lin study evaluated ITP in children under the age of 3 years. They stated that "[a]lthough childhood ITP has an 85% recovery rate, it will sometimes relapse months or years later." Pet. Ex. 26 at 3. All of their cases, however, were benign, and the children "recovered and did not experience recurrence." Id. However, the authors did not discuss older children. Further, based on the results of the O'Leary et al. study, it does not appear that results in younger children (relative to an acute versus a chronic clinical course) can be extrapolated to older children.

Another study only focused on adults. Grimaldi-Bensouda et al. studied only adult vaccine-associated ITP. They noted that "[o]nset is frequently insidious and low platelet counts often last beyond 6 months." Resp. Ex. A, Tab 3 at 1. These findings suggest that in general, the adults had chronic ITP. However, the authors did not offer any observations about the distinction between acute versus chronic ITP, as pertaining to the question of whether ITP was vaccine-related.

Moreover, Dr. Strouse did not opine that because J.F. had chronic instead of acute ITP, that it was unlikely to be vaccine-related. Dr. Strouse stated that "[c]hildren with chronic ITP . . . often do not have a specific known trigger." Resp. Ex. A at 3. Dr. Strouse's statement is consistent with the medical literature filed here which establishes that the cause of ITP is unknown in the majority of cases. But respondent stretched this point by asserting that the difference between acute and chronic ITP is an important factor, and that if a child has chronic ITP, that finding weighs against a finding of vaccine causation. Resp. Response at 12. Simply put, the evidence establishes that younger children usually have acute ITP, whereas the majority of older children have acute ITP, but some have chronic ITP.

Even if respondent correctly interpreted the medical literature and their expert report as to the significance of the fact that J.F. had chronic ITP, the facts of the Loyd case are so dissimilar that there can be no meaningful comparison. In Loyd, the child received the haemophilus influenza type b and pneumococcal vaccines, not the Tdap, flu, and meningococcal vaccines. Loyd, 2021 WL 2708941, at *1. She was under the age of one at the time of vaccination. See id. And there was an eight to nine month gap between vaccination and onset of bleeding symptoms, during which blood work showed a completely normal platelet count. Id. at *24-28.

Another reason that the undersigned finds that petitioner has met her burden as to Althen Prong Two, is that there is no evidence of an alternative cause of J.F.'s ITP. J.F.'s records do not document any illness between the date that he received his Tdap vaccination on October 23, 2014, and the onset of his bleeding symptoms that occurred in early November 2014. J.F. did

have an illness prior to diagnosis, but this illness occurred well after his bleeding symptoms had been observed. As explained by Dr. Forman, J.F.'s "episode of gastroenteritis [] occurred on January 10, 2015 . . . , well after the unusual bruising and epistaxis occurred." Pet. Ex. 8 at 3. Therefore, Dr. Forman concluded that it was "more likely than not the vaccines, singly or in combination, were the cause of J.F.'s ITP." Id. The undersigned agrees and finds Dr. Forman's opinions persuasive.

J.F.'s treating health care providers did not note an association between his vaccinations and his ITP. However, it does not appear that they were aware of the onset of J.F.'s unusual bruising and nosebleeds that occurred in November 2014. CNP Julia Golden saw J.F. on January 29, 2015, after his blood work revealed an abnormally low platelet count and documented that her impression was "post viral thrombocytopenia with a likely diagnosis of acute [ITP]." Pet. Ex. 1 at 29. Dr. Pettee stated that J.F. had been "ill approximately 1.5-2 weeks [prior] with fever, nausea/vomiting[,] and diarrhea." Id. at 35. Dr. Pettee did not opine that J.F's. ITP was caused by the prior illness. Neither Ms. Golden nor Dr. Pettee included J.F.'s vaccination history in their respective history of J.F.'s illness. They also did not include the complete history of his bruising and nose bleeds described by J.F.'s wrestling coach, grandmothers, or mother. After considering all of the evidence, the statement made by Ms. Golden that J.F. had "post viral thrombocytopenia" appears to be based on incomplete knowledge of the facts, and therefore, the undersigned gives it less weight.

With regard to the flu vaccine, J.F. received the seasonal flu vaccine in 2014, as well as from 2015 to 2017. His platelet counts were monitored frequently during these years due to his ongoing ITP. It does not appear that J.F.'s platelet counts worsened or that he had any significant relapse of his thrombocytopenia within 30 days to 6 weeks following receipt of these annual flu vaccinations. However, J.F. had low platelet counts that fluctuated from the time of his diagnosis in January 2015, until his splenectomy in October 2017. The question of whether J.F. had any adverse effect caused by his annual flu vaccinations prior to and after his splenectomy cannot be answered without expert opinion. Neither Dr. Forman nor Dr. Strouse specifically analyzed the effect of the annual flu vaccinations on J.F.'s clinical course. Further, petitioner has not claimed that the annual flu vaccines he received since the vaccinations administered in 2014 (at issue here) significantly worsened his condition. For these reasons, and because there is insufficient evidence on this issue, the undersigned makes no finding as to whether the flu vaccine caused or contributed to J.F.'s ITP. Additionally, the undersigned does not make a finding as to whether the meningococcal conjugate vaccine caused or contributed to J.F.'s ITP.

In conclusion, the undersigned finds petitioner has proven by preponderant evidence a logical sequence of cause and effect establishing that the Tdap vaccination caused J.F.'s ITP, and has satisfied the second Althen prong.

D. Alternative Causation

Because the undersigned concludes that petitioner has established a prima facie case, petitioner is entitled to compensation unless respondent can put forth preponderant evidence "that [J.F.'s] injury was in fact caused by factors unrelated to the vaccine." Whitecotton v. Sec'y

of Health & Hum. Servs., 17 F.3d 374, 376 (Fed. Cir. 1994), rev'd on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007). As discussed above in the analysis related to Althen Prong Two, the undersigned found the respondent failed to establish evidence to show that J.F.'s ITP was caused by a source other than vaccination. Thus, respondent did not prove by a preponderance of evidence that petitioner's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

V. CONCLUSION

Based on the record as a whole and for the reasons discussed above, the undersigned finds there is preponderant evidence to satisfy all three Althen prongs and to establish J.F.'s October 23, 2014 Tdap vaccination caused his ITP. Thus, the undersigned finds that petitioner has established by preponderant evidence that she is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master