In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: August 21, 2025

TANDY HAMILTON,	*	
Petitioner,	*	No. 21-2130V
v.	*	Special Master Young
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Courtney Christine Jorgenson, Siri & Glimstad, LLP, Phoenix, AZ, for Petitioner.
Ryan Nelson, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On November 3, 2021, Tandy Hamilton ("Petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program.[2] Petitioner alleged that he "suffered a Table [i]njury, specifically thrombocytopenic purpura"[3] ("ITP") after receiving the influenza ("flu")

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

[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 ("the Vaccine Act" or "Act"). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

[3] Thrombocytopenic purpura is "any form of purpura in which the platelet count is decreased." *Thrombocytopenic Purpura*, DORLAND'S MED. DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=101173&searchterm=thrombocytopenic+purpura. Platelets are "disk-shaped structure[s] . . . found in the blood of all mammals and chiefly known for [their] role in blood coagulation." *Platelets*, DORLAND'S MED. DICTIONARY ONLINE. Purpura is "any of a group of conditions characterized by ecchymoses or other small hemorrhages in the skin, mucous membranes, or serosal surfaces; causes include blood disorders, vascular abnormalities, and trauma." *Purpura*, DORLAND'S MED. DICTIONARY ONLINE. It also refers to "any of several conditions similar to the traditional purpura group, which may be caused by decreased platelet counts, platelet abnormalities,

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vaccine on October 29, 2018. Pet. at 1, ECF No. 1. After carefully analyzing and weighing all the evidence presented in this case in accordance with the applicable legal standards,[4] I find that Petitioner has not provided preponderant evidence that he "suffered the residual effects or complications of such illness, disability, injury, or condition for more than [six] months after the administration of the vaccine," pursuant to the Vaccine Act's severity requirement. § 11(c)(1)(D). Accordingly, Petitioner is not entitled to compensation.

I. Procedural History

Petitioner filed his petition and personal statement on November 3, 2021. Pet.; Pet'r's Ex 1, ECF No. 1. He filed medical records on November 14, 2021, and a statement of completion on January 12, 2022. Pet'r's Exs. 1–11, ECF Nos. 6, 9. In response to a status report filed by Respondent, Petitioner filed additional requested medical records on January 4, 2023. Pet'r's Exs. 12–14, ECF No. 18.

On February 13, 2023, Respondent filed his Rule 4(c) report and argued that "there is not preponderant evidence that [P]etitioner suffered the residual effects of his alleged vaccine injury for more than six months after his vaccination on October 29, 2018." Resp't's Report at 13, ECF No. 21. Petitioner filed an affidavit of no records and a statement of completion on February 20, 2023, and February 21, 2023, respectively. ECF Nos. 22–23. In response to Respondent's arguments, Petitioner filed a letter from his treating hematologist on August 30, 2023. Pet'r's Ex. 16, ECF No. 24. On September 6, 2023, Petitioner filed additional medical records. Pet'r's Ex. 17, ECF No. 25. Petitioner also filed a direct rebuttal to Respondent's assertion on September 21, 2023. Pet'r's Br., ECF No. 26. On December 28, 2023, I issued an order noting that "the evidence in the record is insufficient to support by preponderant evidence that residual effects or complications of Petitioner's ITP lasted for more than six months." Order at 2, ECF No. 28.

Petitioner continued to file medical literature along with a statement from Dr. Thomas Zizac and his own supplemental statement on January 29, 2024. Pet'r's Exs. 18–21, ECF No. 30. Petitioner also filed a response to my order on February 12, 2024. Pet'r's Response, ECF No. 34. Respondent filed a response on March 15, 2024, and Petitioner filed his reply on April 2, 2024. Resp't's Response, ECF No. 36; Pet'r's Reply, ECF No. 37. The parties filed another round of responses due to the emergence of additional authority with Petitioner filing on May 7, 2024, and Respondent filing his response on May 21, 2024. Pet'r's Supp. Reply, ECF No 40; Resp't's Supp. Reply, ECF No. 41. Petitioner filed a final reply on June 5, 2024. ECF No. 42. This matter is now ripe for consideration.

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vascular defects, or reactions to drugs." *Id.* An ecchymosis is "a small hemorrhagic spot[] . . . in the skin or mucous membrane forming a nonelevated, rounded or irregular, blue or purplish patch." *Ecchymosis*, DORLAND'S MED. DICTIONARY ONLINE.

[4] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

II. Summary of Relevant Evidence

a. Medical Records

Petitioner was born on November 23, 1951. Pet'r's Ex. 12 at 2. His medical history prior to the 2018 flu vaccination includes bilateral knee osteoarthritis. *See* Pet'r's Ex. 7 at 43. Medical records also indicate that Petitioner had a prior history of ITP as early as 2008. *See* Pet'r's Ex. 11 at 285. On September 4, 2018, Petitioner saw Dr. James Y. Choi, a hematologist at the Virginia Piper Cancer Center, for evaluation of normocytic anemia.[5] Pet'r's Ex. 3 at 4. Petitioner's bloodwork, dated August 15, 2018, revealed a normal white blood cell count and platelet level. *Id.* Petitioner returned to Dr. Choi on September 19, 2018, and his lab results showed both an iron deficiency and low vitamin B12. Pet'r's Ex. 3 at 35. Records from this appointment also noted a past medical history of ITP. Pet'r's Ex. 10 at 6. Dr. Choi recommended that Petitioner undergo total IV iron replacement therapy and start oral vitamin B12 supplements. Pet'r's Ex. 3 at 35. Dr. Choi also noted that Petitioner had bleeding hemorrhoids[6] which were likely the source of his iron deficiency and referred him to a colorectal surgeon. *Id.* Petitioner underwent total IV iron replacement therapy on September 24, 2018. *Id.* at 64.

On October 10, 2018, Petitioner saw a colorectal surgeon, Dr. Jason Weiss. Pet'r's Ex. 10 at 9. Petitioner reported that he had been dealing with hemorrhoids for several years and an examination revealed prolapsing left lateral and right posterior mixed hemorrhoids and weak sphincter tone. *Id.* at 9–10. Dr. Weiss recommended a hemorrhoidectomy[7] due to the large size of the hemorrhoids. *Id.* at 11.

Petitioner received an intramuscular flu vaccination on October 29, 2018. Pet'r's Ex. 2 at 2.

On November 6, 2018, Petitioner had a follow-up appointment with Dr. Choi. Pet'r's Ex. 3 at 63–64. Labs from November 1, 2018, showed improved iron levels, low vitamin B12 levels, and normal platelets. *Id.* at 64–69. Petitioner went to Banner Urgent Care on November 10, 2018, with a complaint of blood blisters in his mouth. Pet'r's Ex. 9 at 13. He was directed to follow up with his primary care provider ("PCP") and hematologist. *Id.* at 15. Two days later, on November 12, 2018, Petitioner saw nurse practitioner ("N.P"), Krista Hawkins, at his PCP's office. Pet'r's

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[5] Normocytic anemia is "anemia with erythrocytes of normal size but a proportionate decrease in hemoglobin content, packed red cell volume, and a number of erythrocytes per cubic millimeter of blood. *Normocytic Anemia*, DORLAND'S MED. DICTIONARY ONLINE. Anemia is "a reduction below normal in the concentration of erythrocytes or hemoglobin in the blood, . . . it occurs when the equilibrium is disturbed between blood loss . . . and blood production." *Anemia*, DORLAND'S MED. DICTIONARY ONLINE. An erythrocyte is "one of the elements found in peripheral blood." *Erythrocyte*, DORLAND'S MED. DICTIONARY ONLINE. Hemoglobin is "the red oxygen-carrying pigment of erythrocytes." *Hemoglobin*, DORLAND'S MED. DICTIONARY ONLINE.

[6] A hemorrhoid is a "prolapse of an anal cushion, resulting in pleading and painful swelling in the anal canal." *Hemorrhoid*, DORLAND'S MED. DICTIONARY ONLINE.

[7] A hemorrhoidectomy is the "excision of hemorrhoids." *Hemorrhoidectomy* DORLAND'S MED. DICTIONARY ONLINE.

Ex. 3 at 274. Petitioner reported a three-day history of a bleeding mouth ulcer. *Id.* Petitioner declined a blood draw at his PCP's office and planned to see his hematologist or seek emergency care. *Id.* at 276. Later that same day, Petitioner presented to the Banner Thunderbird Medical Center Emergency Department ("ED"). Pet'r's Ex. 11 at 285. His chief complaint was a three-day history of mouth blisters. *Id.* Petitioner also reported that he had ITP after a knee surgery in 2008, and that "he went to his hematologist [two] weeks ago because his platelets were low." *Id.* On examination, multiple hemorrhagic bullae[8] were noted inside his mouth. *Id.* at 286. His platelet count was low at 1 K/MM3. *Id.* at 287. Petitioner was admitted to the hospital to start intravenous immunoglobulin[9] ("IVIG") and an oral prednisone course. *Id.*

Dr. Choi enlisted his associate, hematologist and oncologist Dr. Joan M. Dahmer, for a consultation with Petitioner on November 12, 2018. Pet'r's Ex. 11 at 275. Dr. Dahmer wrote that Petitioner's ITP "was possibly triggered by the flu shot, but I am keeping an open mind." *Id*. at 276. Dr. Dahmer also noted that Petitioner's hemoglobin levels were not low enough to explain fatigue, and suspected Petitioner's low iron levels to be a contributor. *Id.* A November 14, 2018 progress note from Dr. Dahmer noted that Petitioner was "[a]sking about banding 'since they can't do surgery.' I think unless there is substantial bleeding from those hemorrhoids, that any procedure should wait for stabilization [sic] of his [platelet] count." Pet'r's Ex. 11 at 257–58. Petitioner was discharged on November 16, 2018. Pet'r's Ex. 11 at 271. His mucosal bleeding was resolved, and his platelet count had increased to 18,000. *Id.* at 271, 274.

On November 20, 2018, follow-up bloodwork at the ED recorded Petitioner's platelets had decreased to 2,000 with no present bleeding. Pet'r's Ex. 11 at 415, 622. Petitioner was admitted to the hospital for another round of IVIG and ordered to start Rituxan.[10] *Id.* at 621. Due to his hemorrhoidal bleeding, Petitioner received one unit of platelets on November 22, 2018. *Id*. at 617. Petitioner was discharged on November 24, 2018, with a platelet count of 29, 000. *Id.* at 381, 620.

Following this hospitalization, Petitioner saw Dr. Choi on November 27, 2018. Pet'r's Ex. 3 at 89. Dr. Choi described Petitioner as having "now steroid refractory ITP" and recommended that Petitioner receive rituximab weekly for four weeks. *Id.* at 90. Dr. Choi also noted that Petitioner, "ha[d] bleeding hemorrhoids and will require treatment with his colorectal surgeon once the thrombocytopenia issue is resolved." *Id.* Petitioner's rituximab therapy began on November 21, 2018, and was completed on December 12, 2018. Pet'r's Ex. 3 at 150. Records from a follow-up with Dr. Choi on December 19, 2018, documented that Petitioner's platelet counts were "now normalized," at 173,000. *Id.* at 158. Dr. Choi's office faxed a copy of this December 19, 2018 record to Petitioner's colorectal surgeon, Dr. James Weiss, later that day. *See* Pet'r's Ex. 14 at 23–

[8] A bulla is "a large blister." *Bulla*, DORLAND'S MED. DICTIONARY ONLINE.
[9] Immunoglobulin refers to "any of the structurally related glycoproteins that function as antibodies." *Immunoglobulin*, DORLAND'S MED. DICTIONARY ONLINE.
[10] Rituxan is a "trademark for a preparation of rituximab." *Rituxan*, DORLAND'S MED. DICTIONARY ONLINE. Rituximab is "a chimeric murine/human monoclonal antibody that binds the CD 20 antigen." *Rituximab*, DORLAND'S MED. DICTIONARY ONLINE. Hereinafter, I will refer to Petitioner's course of treatment as "rituximab" unless specifically quoting a source that references Rituxan.

25. Dr. Choi requested Petitioner return in two months, and Petitioner was directed to call if he developed any bruising, rashes, bleeding or petechiae.[11] *Id.* at 150.

The next day, on December 20, 2018, Petitioner received a call and voicemail from Dr. Weiss's office to schedule an appointment. Pet'r's Ex. 14 at 8. The following day, on December 21, 2018, Petitioner saw N.P. Hawkins. Pet'r's Ex. 3 at 272. N.P. Hawkins noted Petitioner's recent hospitalization and that a "specialist [was] concerned that [the flu] vaccine led to these events." *Id.* On February 20, 2019, Petitioner returned to see Dr. Choi with a platelet count that had "remain[ed] normalized" at 275,000. Pet'r's Ex. 3 at 186–88. Dr. Choi noted that Petitioner "ha[d] bleeding hemorrhoids and will require treatment with his colorectal surgeon. [Petitioner] state[d] he will contact the surgeon when he is ready." *Id.* at 187. Petitioner's ITP history was documented in PCP visit records on March 13, 2019, and he denied easy bruising or excessive bleeding. *Id.* at 269. This visit, along with others in May, was not related to Petitioner's ITP, although it was always similarly noted in his medical history. *Id.* at 270, 271; Pet'r's Ex. 4 at 6.

On August 19, 2019, Petitioner called his hematologist's office to report that he "is going to schedule his hemorrhoid surgery." Pet'r's Ex. 12 at 2. Petitioner wanted "to know if he should get his blood checked and if any other special precautions should be taken before he schedules." *Id.* Dr. Choi ordered a comprehensive metabolic panel, iron, total iron binding capacity, and iron saturation labs. *Id.* at 6–9. Petitioner saw Dr. Choi on August 20, 2019, who noted that Petitioner's platelet count "remain[ed] normalized." Pet'r's Ex. 14 at 16–17.

Petitioner underwent a left lateral hemorrhoidectomy on September 4, 2019. Pet'r's Ex. 14 at 14. Dr. Weiss noted Petitioner's ITP and that his platelet count was at "219[,000] on August 19, 2019." *Id*. at 6. On September 17, 2019, Petitioner presented for a post-hemorrhoidectomy appointment with Dr. Weiss. Pet'r's Ex. 4 at 199. Dr. Weiss noted that Petitioner's bleeding post-surgery had resolved, and that his platelets and hemoglobin were higher than before surgery. *Id.* An October 22, 2019, "phone note" indicated that Petitioner called Dr. Weiss to report some discomfort and rectal bleeding. Pet'r's Ex. 14 at 4. Petitioner was advised this could be because the wounds had not completely healed, and he deferred an in-person appointment. *Id.*

On February 6, 2020, Petitioner saw Dr. Kevin Houlihan for an annual examination. Pet'r's Ex. 13 at 34. Under his history of present illness, Dr. Houlihan recorded that Petitioner "developed a flare of ITP after receiving this season's flu vaccine. Would like to hold off on other vaccines at this time until he speaks with his Hematologist, Dr. Choi." *Id.* Dr. Houlihan further noted that Petitioner "presents with a diagnosis of thrombocytopenic purpura. This was diagnosed years ago. The course has been episodic. It is of severe intensity. Platelet counts dropped to 1[,000] with this season's flu vaccine." *Id.* Routine labs, taken at Dr. Houlihan's direction, were collected on February 6, 2020. Pet'r's Ex. 13 at 86. Petitioner's platelet count was normal at 253,000. *Id.* Petitioner also sought unrelated treatment for his left shoulder through April of 2020. *Id.* at 107. A note from Petitioner's August 17, 2020 telehealth appointment with Dr. Houlihan recorded Petitioner's ITP history and listed his status as "uncertain." *Id.* at 28–29. This call was also unrelated. *Id.*

[11] Petechia is "a pinpoint, nonraised, perfectly round, purplish red spot caused by intradermal or submucous hemorrhage." *Petechia*, DORLAND'S MED. DICTIONARY ONLINE.

About six months later, on February 8, 2021, Petitioner presented for a follow-up visit with Dr. Houlihan. Pet'r's Ex. 13 at 21. His ITP was again listed in his "Past Medical History." *Id.* Routine labs, which were collected on February 8, 2021, revealed that Petitioner's platelet count was normal at 182,000. *Id.* at 79. Labs were repeated on December 6, 2021, and Petitioner's platelet count remained normal at 227,000. *Id.* at 76. Repeat labs were completed on March 4, 2022, and Petitioner's platelet count remained in normal range at 189,000. *Id.* at 72. Petitioner's most recently filed platelet count is from September 28, 2022, and it recorded a normal platelet count at 195,000. *Id.* at 67.

b. Petitioner's Sworn Statement

Petitioner submitted a sworn statement, dated November 2, 2021. *See generally* Pet'r's Ex. 1. Petitioner averred that his "surgeon continued to delay [his] surgery for [his] hemorrhoids because of the potential complications due to ITP." *Id.* at 3. Petitioner also averred that he "continued to suffer from anemia due to the bleeding," and that even after concluding his medication, he had stiff and painful joints "for probably another six months after the infusions." *Id.* He continued that his doctor "indicated this was a side effect of the medications." *Id.* Finally, Petitioner averred that he was "not able to have the corrective surgery on [his] hemorrhoids until October 2019 – the delay of which and [his] continuing symptoms were directly attributable to [his] ITP." *Id.* at 3.

On February 12, 2024, Petitioner filed a supplemental statement to clarify the circumstances surrounding his delayed colorectal surgery. *See generally* Pet'r's Supp. Statement, ECF No. 34. Petitioner explained that although as of February 20, 2019, his "platelets were above the bottom line for normal, they were still fluctuating." *Id.* at 3. He recounted the two issues that Dr. Choi identified with Petitioner "having [his] prior scheduled surgery." *Id.* Due to Petitioner's platelet fluctuation, Dr. Choi "said he thought [Petitioner] should wait a few months before getting the surgery just to be safe." *Id.* Additionally, "the surgery was contraindicated within six months of concluding [r]ituximab therapy." *Id.* Petitioner averred that as a direct consequence of his ITP, he "waited over six months after the conclusion of [his] [r]ituximab therapy before [he] started the process to have [] surgery." *Id.* He concluded that his bloodwork on August 19, 2019, six months after the conclusion of his rituximab, showed a platelet count within normal range; and his surgery was performed on September 4, 2019. *Id.*

c. Physician Letters

On August 30, 2023, Petitioner filed a letter dated August 28, 2023, from his treating hematologist, Dr. Choi. Pet'r's Ex. 16. Dr. Choi's one page statement explained that "[d]ue to the persistent thrombocytopenia, [Petitioner] had hemorrhoidal surgery that had to be delayed until a higher level was achieved." *Id.* Dr. Choi continued that Petitioner's rituximab therapy, "was completed on 12/12/2018 with subsequent resolution of the thrombocytopenia." *Id.*

Petitioner also filed a statement from Dr. Thomas Zizac.[12] Pet'r's Ex. 21. Dr. Zizic is an Associate Professor of Medicine at Johns Hopkins University. *Id.* at 1. He was previously their

[12] Petitioner did not file Dr. Zizac's CV; however, his sworn statement details his relevant experience and authority.

Associate Director of Rheumatic Disease. *Id.* Dr. Zizac is also "a founding fellow of the American College of Rheumatology." *Id.* He received his medical degree from Johns Hopkins and completed his internship and residency there in internal medicine. *Id.* Dr. Zizac was a rheumatology post-doctoral fellow at Johns Hopkins before serving "as a flight surgeon at the School of Aerospace Medicine at Brooks Airforce Base, San Antonio, Texas." *Id.* He had a private practice in rheumatology for fifteen years before joining academia full time. *Id.* Dr. Zizac is a past President of the Maryland Society of Rheumatic Disease, and he has "published approximately 100 articles and abstracts in peer reviewed journals as well as several dozen chapters in textbooks of medicine." *Id.*

Dr. Zizac conceded that "he has not reviewed [Petitioner's] medical chart," and noted that his statement is not offered to "give an expert opinion" on causation. Pet'r's' Ex. 21 at 2. Dr. Zizac did review Petitioner's supplemental statement and asserted that "the American College of Rheumatology guidelines recommend a six-month waiting period after the last Rituximab dosage prior to undergoing elective surgery." *Id.* In support of this contention, Dr. Zizac relied on an article discussing perioperative immunosuppressive use, and guidelines for perioperative management of antirheumatic medication. *Id.* He argued that "surgery in close proximity to completion of [r]ituximab therapy is contraindicated." *Id.* (emphasis omitted).

d. Medical Literature

The Micheal & Auron[13] article filed by Petitioner, "highlight[s] the peri-operative immunosuppressive management and doses suggested for patients with rheumatic diseases." Pet'r's Ex. 19 at 1. The authors explain that rituximab is a monoclonal antibody that is used to treat many conditions, including the chronic diseases: rheumatoid arthritis, lupus, and vasculitis. *Id.* at 4. One side effect of the therapy is "B cell depletion within [two] to [three] weeks after a dose." *Id.* at 4. While B cell levels will eventually normalize after treatment, "[p]atients may experience a significant drop in immunoglobulin levels, which remains for up to six months after initiating rituximab." *Id.* This could potentially leave rituximab patients more susceptible to infection during this period if they undergo an operation. *Id.* Noting the "scant data about the use of rituximab in the perioperative period," the authors referenced the Goodman et al.[14] article's suggestion to monitor "IgG levels, at least 100 days after rituximab dose, and if levels normalize, then proceed further with elective surgery." *Id.* at 5; *see generally* Pet'r's Ex. 20. The authors caution that "[i]f levels remain abnormal, then administration of [IVIG] is advised prior to surgery." Pet'r's Ex. 19 at 5.

The Micheal & Auron article referenced "the American College of Rheumatology 2017 Guideline, recommend[ing] a [six]-month wait period after the last rituximab dose, to schedule elective hip or knee surgery." Pet'r's Ex. 19 at 5. Likewise filed by Petitioner, the evidence-based guideline is for "management of antirheumatic drug therapy for adults with rheumatoid arthritis

[13] Madonna Michael & Moises Auron, *Perioperative Immunosuppressive Use in Patients with Rheumatologic Diseases*, 3 J. XIANGYA MED. 38 (2018).

[14] Susan M. Goodman et al., *2017 American College of Rheumatology/American Association of Hip and Knee Surgeons Guideline for the Perioperative Management of Antirheumatic Medication in Patients with Rheumatic Diseases Undergoing Elective Total Hip or Total Knee Arthroplasty*, 69 ARTHRITIS CARE & RESEARCH 1111 (2017).

("RA"), spondyloarthritis ["SpA"], juvenile idiopathic arthritis ("JIA"), or systemic lupus erythematosus ("SLE")." Pet'r's Ex. 20 at 2. The authors specify that the "guideline is to be used for those who have elected and have been deemed appropriate candidates for [hip or knee surgery]. We would caution against extrapolation of this guideline to other orthopedic procedures until further data are available." *Id.* at 3. Furthermore, "[t]his guideline does not address . . . medical decisions unrelated to antirheumatic drug therapy . . . or perioperative evaluation and management of concurrent disease." *Id.* The authors explain that "[p]atients with rheumatic diseases undergoing total hip arthroplasty and total knee arthroplasty are at increased risk for periprosthetic joint infection." *Id.* "Biologic medications[, including rituximab,] should be withheld as close to [one] dosing cycle as scheduling permits prior to the elective [surgeries] and restarted after evidence of wound healing, typically 14 days, for all patients with rheumatic disease." *Id.* at 6. For example, "[p]atients treated with rituximab every [six] months would schedule their surgery, when possible, at the week after the first withheld dose during month [seven]. *Id.* at 7. In making this recommendation, the Goodman et al. explained:

> [A] systematic review, meta-analysis, and network meta-analysis revealed that infection risk for biologic agents is strongly associated with high-dose therapy (higher dose than the standard) and may not be associated with low-dose biologic agents, so serum half-life may not correspond to the duration of the immunosuppressant effect. The dosing cycle was therefore chosen as more relevant in determining the withholding interval and timing the surgery at the end of the dosing interval at the nadir of the drug effect.

Id. at 6.

III. Parties' Arguments

a. Petitioner's Six-Month Severity Requirement Brief

On September 21, 2023, Petitioner filed his brief to respond to Respondent's contention that the six-month severity requirement had not be met in this case. Pet'r's Br. Petitioner argued that generally, the six-month requirement can be met in one of multiple ways because, "residual effects or complications and symptomatic are not synonymous." *Id.* at 2 (citing *Faup v. Sec'y of Health & Hum. Servs.*, No. 12-78V, 2015 WL 443802 (Fed. Cl. Spec. Mstr. Jan. 13, 2015)). He explained that his case involves complications that lasted at least six months, due to an inability to undergo elective surgery for an unrelated symptomatic condition. *Id.* The recommended treatment for Petitioner's pre-existing hemorrhoids and anemia included elective surgery. *Id.* However, "[a]s a result of his vaccine-induced ITP, his surgery was delayed for several months beyond what it would have been." *Id.* Petitioner likened this to an injury suffered by an individual who fainted after an allergic reaction to a vaccine. *Id.* In both instances, the petitioner is "hurt[], requiring six or more months of treatment," not due to the immediate adverse effect of the vaccine, "but for the consequential injury." *Id.*

Petitioner argued that he suffered from hemorrhoids, and "[t]he surgery that would have fixed that underlying medical issue was cancelled because his platelet levels had fallen below the safe level for surgery." Pet'r's Br. at 3. Petitioner also continued "to suffer from anemia due to the

bleeding." *Id.* at 4. Petitioner stated that his hemorrhoid surgery had to be delayed until September 17, 2019, due to his ITP and treatment regimen, and thus, "he continued suffering complications directly attributable to his ITP well beyond the six-month mark" following his October 29, 2018 flu vaccination. *Id.* at 3. Petitioner acknowledged that his platelet counts "started to normalize between December 2018 and February 2019, although they continued to fluctuate." *Id.* He argued that "his surgeon continued to delay the surgery for hemorrhoids because of the potential complications due to ITP." *Id.*

On February 12, 2024, Petitioner filed a second brief in response to the Court's December 29, 2023 order. Pet'r's Response. In my order, I noted that in addition to his September 21, 2023 brief, Petitioner also filed a letter authored by his hematologist, Dr. James Choi, dated August 28, 2023. I concluded that although this letter supports that Petitioner's surgery initially needed to be delayed following his ITP onset, it does not address whether the surgery was ultimately delayed for more than six months post vaccination because of Petitioner's ITP. I then "allow[ed] Petitioner an opportunity to submit evidence in support of his contention that his surgery was delayed for more than six months as a result of his ITP." Order at 2. Petitioner recounted his sworn statement detailing a conversation he had with Dr. Choi. Specifically, Petitioner stated that Dr. Choi "thought [he] should wait a few months before getting the surgery just to be safe." Pet'r's Response at 3. Petitioner stated that Dr. Choi also "told [him] that surgery was contraindicated within six months of concluding rituximab therapy." *Id.* at 3. Lastly, Petitioner referred to Dr. Zizac's statement that asserted, "[a]s a result of his vaccine-induced ITP, his surgery was delayed for several months beyond what it would have been, based not only on doctor's recommendation, but on American College of Rheumatology guidelines as to elective surgeries following receipt of [r]ituximab." *Id.*

b. Respondent's Six-Month Severity Requirement Brief

Respondent summarized his rebuttal to Petitioner in his March 15, 2024 response:

> [First], in the instant case, there is no evidence that ITP caused a permanent or ongoing injury in [P]etitioner lasting at least six months. Second, rituximab therapy is not a complication of ITP; it is a treatment. Third, there is no reliable evidence that [P]etitioner was ever advised that he needed to wait six months for surgery due to the administration of rituximab, and [P]etitioner instead relies solely on evidence that some types of surgery could be delayed due to chronic rituximab use in patients with autoimmune diseases that does not appear to be applicable to this case.

Resp't's Response at 8–9.

Petitioner's vaccination occurred on October 29, 2018, and the six-month severity requirement would be satisfied by symptomology through at least April 29, 2019. Respondent noted that "Petitioner's platelets normalized by December 19, 2018," and "remained normal with repeat testing on February 20, 2019." Resp't's Response at 10. Respondent argued that his ITP "resolved by December 19, 2018, within two months of the subject ITP diagnosis, and repeat testing at four months post vaccination shows that his condition did not return." *Id.*

Furthermore, Respondent argued that "there is no medical record evidence that [P]etitioner was advised, at any time after December 19, 2018, that surgery would be contraindicated due to his ITP, low platelet levels, or based on the fact that he received one course of rituximab." Resp't's Response at 10. Respondent referred to Dr. Dahmer's note that "surgery was only contraindicated 'given [Petitioner's] severe thrombocytopenia' documented at 5,000 on November 14, 2018, and explained that Petitioner should wait until his platelets stabilized." *Id.* (citing Pet'r's Ex. 11 at 263).

Dr. Zizic's opinion should be entirely discounted, according to Respondent, for several reasons. As an initial matter, Dr. Zizac stated that he has "not reviewed [P]etitioner's medical chart," and he instead relies solely on Petitioner's statement. Resp't's Response at 10 (citing Pet'r's Ex. 21 at 2). Respondent noted that the medical records from Dr. Choi's office do not mention any needed delay due to Petitioner's treatment, that rituximab played any role in the surgery's delay, nor did any records from Dr. Weiss indicate a delay in the surgery was necessary due to Petitioner's ITP treatment. *Id.* at 11.

Respondent also discussed Petitioner's filed medical literature cited by Dr. Zizac. He noted that the article filed by Petitioner "cautions that it is limited to patients with RA, SpA, JIA, or SLE who take these medications and nothing in the article references ITP or acute periods of treatment with rituximab, lasting only one month." Resp't's Response at 14. The article "does not state that [P]etitioner was required to wait six months before he could have surgery." *Id.* The Goodman et al. article "recommended a patient-specific and dose-specific withholding cycle prior to surgery that is consistent with their recommendations for all other biologic agents, timing surgery at the end of the dosing interval at the nadir of the drug effect." *Id.* at 15. The Michael & Auron article referred to the Goodman et al. article for the six-month wait period, but Respondent noted that this "recommendation does not appear anywhere in Goodman et al." *Id.*

Respondent contended that "if [P]etitioner was advised that he was at serious risk for an infection, or that surgery was contraindicated for some other reason as a result of his rituximab exposure, it belies credibility that Dr. Choi would have failed to note that in his records." Resp't's Response at 19. It is also noteworthy to Respondent that Petitioner told Dr. Choi during his February 20, 2019 follow-up appointment that "he will contact the surgeon when he is ready." *Id.*

c. Petitioner's Reply Brief

Petitioner reiterated in his reply filed on April 2, 2024, that he does not claim to have suffered from residual symptoms for six months. Pet'r's Reply. "Instead, Petitioner maintains that the delay in colorectal surgery and continued symptoms are a clear complication that arises directly from the ITP." *Id.* at 2. Conceding that the medical record does not document the relevant conversation between him and Dr. Choi, Petitioner argued that the "[a]bsence of evidence is not evidence." *Id.* He noted "that any perceived inconsistencies between the testimony and the contemporaneous medical records can be overcome by clear, cogent and consistent testimony explaining the discrepancies. *Id.*

There is almost exactly six months between Petitioner's follow-up appointment with Dr. Choi on February 20, 2019, that revealed his platelet count was stable and his surgical preoperational visit on August 19, 2019. Pet'r's Reply at 3. Petitioner asserted that the only

reasonable explanation for why he would wait that specific length of time is because that is what he was told to do. *Id.* Therefore, he should not now be penalized and precluded from compensation for taking his treater's advice. *Id.* at 5.

On May 7, 2024, Petitioner filed a supplemental brief to address the Federal Circuit's decision in *Leming v. Sec'y of Health & Hum. Servs.* Pet'r's Supp. Reply (citing 98 F.4th 1107 (Fed. Cir. 2024)). He argued that "[l]ike a biopsy, an IVIG infusion is a 'surgical act or measure for diagnostic or therapeutic purposes taken to prevent harm of a patient or to improve the health of a patient.'" *Id.* at 3. While "maintain[ing] that the delay in colorectal surgery and ongoing complaints due to delay following his ITP and Rituximab satisfy the severity requirement of 42 U.S.C. § 300aa–11(c)(1)(D)(i)," Petitioner also argued that Petitioner's IVIG treatment satisfies § 11(c)(1)(D)(iii). *Id.* at 4.

Petitioner also addressed *Spooner*, a pre-*Leming* case where the special master found that IVIG treatments were interventions because they were therapeutic, but not surgical because of the nursing function of an IVIG. ECF No. 42 at 2; *see Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728 (Fed. Cl. Spec. Mstr. Jan. 16, 2014). In his final briefing, dated June 5, 2024, Petitioner asserted that the *Spooner* reasoning would not survive *Leming* because "[i]t is now controlling law that that the phrase 'surgical intervention' . . . included surgical act or measure for diagnostic or therapeutic purposes taken to prevent harm of a patient or to improve the health of a patient[]." ECF No. 42 at 2. He concluded that the nursing function should not be a factor for consideration. *Id.*

d. Respondent's Reply Brief

On May 21, 2024, Respondent filed a reply to address Petitioner's reliance on *Leming.* Resp't's Supp. Reply. Respondent asserted that a piggyback administration of IVIG is not analogous to a bone marrow biopsy as a surgical procedure. *Id.* at 2. The surgical nature of a biopsy was not contested in *Leming* as "the procedure was performed by a surgeon, involved the insertion of a specialized instrument to remove tissue, required general anesthesia and a surgical consent form, resulted in a *surgical report*, and required recovery in the post-surgical care unit." *Id.* at 3 (emphasis added). Conversely, Petitioner's IVIG was administered bedside, by a nurse, and without anesthesia. *Id.* In *Leming,* the issue was the therapeutic versus diagnostic nature of the treatment. *Id.* Respondent asserted that the therapeutic purpose of Petitioner's IVIG treatment is not at issue presently. *Id.* Therefore, *Leming* is inapplicable. *Id.*

IV. Applicable Legal Standard

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). The Vaccine Injury Table lists thrombocytopenic purpura as a compensable injury if it occurs within seven to thirty days after administration of a rubella-containing vaccine. § 300aa-14(a), as amended by 42 C.F.R. § 100.3. To establish that he suffered a Table injury of thrombocytopenic purpura, a petitioner must show that his injury is consistent with the Table's qualifications and aids to interpretation ("QAIs") for thrombocytopenic

purpura. *See* 42 C.F.R. § 100.3(c). The QAIs state that thrombocytopenic purpura "is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm^3." 42 C.F.R. § 100.3(c)(7). Alternatively, a petitioner may receive compensation by demonstrating that he suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* § 11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). This would include a petitioner alleging that any other covered vaccine, e.g. flu, caused him to suffer from thrombocytopenic purpura, even within the seven-to-thirty-day Table period.

> Under either method, however, a petitioner must also show that the injured person
>
> (i) suffered the residual effects or complications of his illness, disability, injury, or condition for more than six months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention[.]

§§ 11(c)(1)(D)(i)–(iii). Cases may appropriately be dismissed for failure to substantiate the severity requirement. *See, e.g.*, *Hinnefeld v. Secy of Health & Hum. Servs.,* No. 11-328V, 2012 WL 1608839, at *4–5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's Guillain–Barré Syndrome resolved less than two months after onset). Petitioner has not alleged, and the record does not support, that death resulted from vaccination. Thus, Petitioner must establish either that he "suffered the residual effects or complications of his illness, disability, injury, or condition for more than six months after the administration of the vaccine," or that he "suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention." *See* §§ 11(c)(1)(D)(i), (iii).

It is Petitioner's burden to prove his case, including the six-month requirement, by a preponderance of the evidence. *See* § 13(a)(1)(A). To satisfy the six-month requirement, "[a] potential petitioner must do something more than merely submit a petition and an affidavit parroting the words of the statute." *Faup v. Sec'y of Health & Hum. Servs.,* No. 12-87V, 2015 WL 443802, at *3 (Fed. Cl. Spec. Mstr. Jan. 13, 2015) (quoting *Black v. Sec'y of Health & Hum. Servs.,* 33 Fed. Cl. 546, 550 (1995), *aff'd*, 93 F.3d 784, 792 (Fed. Cir. 1996)). A petitioner cannot establish the length or ongoing nature of an injury merely through his or her own statements, but rather is required to "submit supporting documentation which reasonably demonstrates that the alleged injury or its sequelae lasted more than six months." *Black*, 33 Fed. Cl. at 550 (internal quotations omitted); *see also Lett v. Sec'y of Health & Hum. Servs.*, 39 Fed. Cl. 259, 260–61 (1997) ("Section 300–aa13(a)(1) provides that a special master may not award compensation 'based on the claims of [a] petitioner alone, unsubstantiated by medical records or by medical opinion'").

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005)). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by

health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1); *see also Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346–49 (Fed. Cir. 2010) (affirming the special master's finding that the petitioner suffered from one disease even though the petitioner's treating doctor had diagnosed the petitioner with a different disease). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record." § 13(b)(1).

The Federal Circuit has clarified the meaning of "residual effects and complications" to satisfy the six-month severity requirement in the context of ITP. *See Wright v. Sec'y of Health & Hum. Servs.*, 22 F.4th 999 (Fed. Cir. 2022). The Circuit held that a petitioner failed to satisfy the six-month requirement when her child, B.W.'s, platelet count normalized less than three months post ITP onset because his "relatively non-invasive ongoing [platelet] monitoring" was not a "residual effect" pursuant to § 300aa–11(c)(1)(D)(i). *Id.* at 1001, 1003, 1006–07. The Circuit noted that the child experienced later bruising that was not related to his vaccine injury and that his ongoing testing "did not reveal, constitute, or cause any somatic change." *Id.* at 1001. Defining the language in § 300aa–11(c)(1)(D)(i), the Federal Circuit determined that "[t]he term 'residual effects[]' . . . requires a change within the patient that is caused by the vaccine injury." *Id.* at 1004. It continued that "'[r]esidual' suggests something remaining or left behind from a vaccine injury . . . . Because vaccine injuries are somatic conditions defined by their signs and symptoms within the patient, . . . their residues are similarly defined." *Id.* at 1005–06.

The Federal Circuit stated that the use of the words "suffered" and "complication" in association with "residual effects" in § 300aa–11(c)(1)(D)(i) "suggest that Congress contemplated residual effects to be detrimental conditions within the patient, such as lingering or recurring signs and symptoms."[15] *Wright*, 22 F.4th at 1006. Complication is also defined as "[a] morbid process or event occurring during a disease which is not an essential part of the disease, although it may result from it." *Id.* (internal citations omitted); *see also Complication*, DORLAND'S ONLINE MED. DICTIONARY ("1. a disease or diseases concurrent with another diseases. 2. The concurrence of two or more diseases in the same patient."). It concluded that "[r]ead together, 'residual effects' and 'complications' appear to both refer to conditions within the patient, with 'residual effects' focused on lingering signs, symptoms, or sequelae characteristic of the court of the original vaccine injury, and 'complications' encompassing conditions that may not be 'essential part[s] of the disease' or may be outside the ordinary progression of the vaccine injury." *Wright*, 22 F.4th at 1006.

A more recent decision by the Circuit addressed the meaning of "inpatient hospitalization and surgical intervention." *Leming*, 98 F.4th 1107. The statute is silent as to the definition of surgical and relying on *Dorland's Medical Dictionary*, the Circuit understood "surgical intervention to require an act or measure taken to prevent harming of a patient or to improve the health of a patient, **and** is of the surgical variety, for either diagnostic or therapeutic purposes. *Id.*

[15] The Federal Circuit clarified that its decision "do[es] not disturb existing case law holding that a course of treatment lasting longer than six months can be a 'residual effect.'" *Wright*, 22 F.4th at 1006.

at 1111 (emphasis added). The legislative intent behind a 2000 amendment also provided a cosponsor quote that was cited in the case: "the modified program makes compensation available if the injury requires a hospital stay or surgery." *Id. (*citing 146 Cong. Rec. H8206 (daily ed. Sep. 27, 2000) (statement of Rep. Gilman)).

V. Discussion

Petitioner received the vaccine at issue on October 29, 2018. Thus, in order to fulfill the severity requirement, Petitioner must establish by preponderant evidence that he: (1) suffered the residual effects or complications for more than six months after the administration of the vaccine, until at least April 29, 2018; or (2) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention. *See* §§ 11(c)(1)(D)(i) and (iii). There is no dispute that Petitioner's ITP fully resolved prior to April 29, 2018. In his reply brief, Petitioner reiterated that he satisfies the six-month threshold, not due to residual effects of ITP, but because his ITP treatment necessitated a delay in his colorectal surgery and the continued symptoms qualify as a complication that lasted six months. Alternatively, Petitioner argued that his IVIG treatment qualifies as a surgical intervention that occurred while he was hospitalized. However, Petitioner has failed to present preponderant evidence of either prong to satisfy the severity requirement.

a. Residual Effects or Complications

Petitioner argued that based on his treater's advice, he delayed his colorectal surgery for six months after the conclusion of his rituximab treatment and continued to suffer from anemia and hemorrhoids during that time. This suffering, he contended, qualifies as a complication. Respondent does not address whether the delay in Petitioner's surgery or the symptoms that he continued to suffer would qualify as a morbid process or event that resulted from his ITP, i.e. a complication. Also, Respondent does not address generally if a delay in treatment for an unrelated disease is a morbid event that is not essential to the vaccine injury but is nonetheless a result of it. In this case, Respondent argued that the delay was not on advice of a treating medical professional, not necessary, and therefore not relevant to his claim. Setting aside the issue of whether this type of event could ever qualify as a complication, I find in this case that Petitioner has not provided preponderant evidence that it does at present.

Petitioner asserted that he waited to schedule his surgery at the behest of his treater, Dr. Choi, and offered in support of said assertion the six-month time frame between his February follow-up and his August call scheduling of the surgery. However, nothing in the records from Dr. Choi, nor the letter that he submitted suggests that he told Petitioner to wait until September for his surgery. The medical records provide the following timeline:

Date	Event	Pet'r's Ex.
November 21, 2018	Petitioner begins rituximab.	3 at 150.
December 12, 2018	Petitioner ends rituximab.	3 at 150.
December 19, 2018	Dr. Choi characterized Petitioner's platelet count as "now normalized" at 173,000. Dr. Choi faxed a record of Petitioner's count to Dr. Weiss.	14 at 23.

December 20, 2018	Dr. Weiss called Petitioner and left voicemail for him to schedule an appointment.	14 at 8.
February 20, 2019	Dr. Choi noted that Petitioner's platelet count has "remained normalized" at 275,000. Dr. Choi noted that Petitioner will require treatment with his surgeon. Petitioner stated to Dr. Choi, "he will contact the surgeon when he is ready."	3 at 187.
August 19, 2019	Petitioner called Dr. Weiss office to ask if "he should get his blood checked," because he is going to schedule his surgery.	12 at 2.
August 20, 2019	Petitioner's count "remained normalized."	14 at 16.
September 4, 2019	Petitioner underwent surgery.	14 at 14.

The letter that Dr. Choi submitted stated that "[d]ue to the persistent thrombocytopenia, the patient had hemorrhoidal surgery that had to be delayed until a higher [platelet] level was achieved. The patient underwent rituximab therapy for [four] doses which was completed on 12/12/2018 with subsequent resolution of the thrombocytopenia." Pet'r's Ex. 16 at 1. As Respondent has noted, there is nothing in Petitioner's medical record that suggests a contraindication for Petitioner's surgery for a period of several months after the conclusion of his therapy. Furthermore, when given the opportunity to clarify the effect that ITP and corresponding treatment would have on Petitioner's ability to have colorectal surgery, Dr. Choi's letter only stated that the surgery had to be delayed until a higher level was achieved. Dr. Choi first described Petitioner's platelet levels as normalized in December of 2018. Assuming Petitioner's argument, it is unclear why the six-month delay would not have started on the day that Petitioner concluded his therapy, which would have been December 12, 2018. Furthermore, the "higher level" that Dr. Choi described was first indicated in the medical record on December 19, 2018. Indeed, it was following the appointment on this date that Dr. Weiss was contacted and his office reached out to Petitioner. It is unclear why the six-month delay would not have started on the day Dr. Choi documented Petitioner's normalized platelet count and alerted his surgeon. Either of these starting points would have placed potential dates for Petitioner's surgery in June, three months sooner than the realized surgery date. Records from February 20, 2019, do not indicate Petitioner entered a new status in terms of his diagnosis. Dr. Choi noted that his platelet count remained as it was in December: normalized. Indeed, Petitioner's count had "remained normalized" for two months. It is unclear why this date would be appropriate to begin the six-month delay.

In my December 29, 2023 order, I alerted Petitioner to the lack of preponderant evidence that explains the delay, even after considering Dr. Choi's August 28, 2023 letter. In response, Petitioner submitted a statement that Dr. Choi told him to wait "a few months" before scheduling this surgery. As Respondent noted, this is inconsistent with Dr. Choi's repeated notations in Petitioner's medical record that he should undergo surgery once his platelet levels are higher, i.e. normalized. It is inconsistent with Dr. Choi immediately alerting Dr. Weiss of Petitioner's lab results, and Dr. Weiss's response in contacting Petitioner for an appointment. It is also inconsistent with Dr. Choi's record keeping of his interactions with Petitioner, including their conversations. *See* Pet'r's Ex. 3 at 187 (Petitioner stating that "he will contact the surgeon when he is ready"). Petitioner correctly noted that clear, cogent, and consistent testimony can explain inconsistencies

between a layperson's recollection and medical records. In this case, Petitioner's explanation leaves additional questions unresolved.

Lastly, Dr. Zizac's statement and accompanying medical literature are not particularly helpful given the facts in this case. It is true that Dr. Zizac did not need to review Petitioner's medical record to opine generally that rituximab therapy is a contraindication to colorectal surgery within six months. However, his reliance on Petitioner's statement and admitted unreview of Petitioner's medical record casts doubt on the applicability of his statements to the present case. For example. Dr. Zizac cited to the American College of Rheumatology guideline to conclude that a six-month waiting period should follow rituximab therapy prior to elective surgery. The literature that was filed in support of this contraindication is in the context of rheumatology patients suffering from chronic illnesses: RA, SpA, JIA or SLE, that typically affect the joints, who then undergo hip or knee (joint) surgery. The literature cautioned against expanding the guideline beyond these parameters and also note that increased infection may only be associated with high-dose treatment regiments. ITP was not mentioned in any of these articles, and Dr. Zizac did not explain how Petitioner's rituximab treatment for ITP prior to hemorrhoidal surgery is appropriately analogous to an RA patient undergoing knee surgery. Furthermore, he does not reconcile the discrepancy over whether and why the six-month delay should start at treatment conclusion, platelet normalization, or some period of time after platelet normalization. Lastly, he does not address the doctor's vague statement, according to Petitioner, to wait several months, if indeed six months is the appropriate amount of time despite Dr. Choi's less specific contraindication, notwithstanding.

After a review of all the evidence, including but not limited to Petitioner's medical records, his statements, the opinion of his expert, and filed literature, I do not find that the record contains preponderant evidence that Petitioner's treaters advised Petitioner to wait six months following his February 20, 2019 follow-up appointment with Dr. Choi to schedule his colorectal surgery. Nor is there preponderant evidence that Dr. Choi's actual recommendation—for Petitioner to wait to schedule his surgery until his platelet counts had returned to normal—resulted in Petitioner's hemorrhoid surgery being scheduled for greater than six months post vaccination. Accordingly, I do not find preponderant evidence that Petitioner's extended suffering from hemorrhoids and anemia due to his delayed surgery is a direct result of his ITP and treatment. Petitioner has not satisfied the severity requirement by establishing he suffered a residual effect or complication pursuant to the Act.

b. Surgical Intervention

Alternatively, Petitioner argued that his IVIG treatment qualifies as a surgical intervention undertaken during an inpatient hospitalization and thereby satisfies the severity requirement. Petitioner cited the Circuit's decision in *Leming* to assert that "[i]t is now controlling law that the phrase 'surgical intervention,' as used in the Act included **surgical act or measure** for diagnostic or therapeutic purposes taken to prevent harm of a patient or to improve the health of a patient, which was required to be conducted as a result of the vaccine injury, so long as the vaccine recipient was also hospitalized as an inpatient." Pet'r's Reply at 2 (emphasis added). Petitioner sought to characterize IVIG as "a measure for diagnostic or therapeutic purposes" and focus on the Circuit's rejection of previous case law that discounted medical treatments performing a nursing function. Pet'r's Supp. Reply at 3. That line of reasoning is misplaced here, however.

Petitioner's fatal error is the failure to consider that the Circuit intended "surgical" to apply to both **act and measure**. Petitioner is correct that the *Leming* analysis included the requirement of a surgical act or measure, but the analysis does not stop there. Petitioner extracted this requirement from a more comprehensive discussion of what constitutes a surgical intervention. Additional context reveals the Circuit ultimately concluded that "[r]elying on these *Dorland's* dictionary definitions taken together, we understand 'surgical intervention' to require an **act or measure** taken to prevent harming of a patient or to improve the health of a patient, **and is of the surgical variety**, for either diagnostic or therapeutic purposes." *Leming*, 98 F.4th at 1111 (emphasis added). The significance and placement of "surgical" is determinative. Assuming that Petitioner's IVIG is a measure taken to improve the health of a patient, and is for a therapeutic purpose, it must still be of a surgical variety. The Circuit noted "the hospitalization and the surgery must both be casually related to the recipient's negative reaction to the vaccine." *Id.* at 1113. Surgery is defined by *Dorland's* as treatment done "by manual or operative means," and "work performed by a surgeon." *Surgery*, DORLAND'S MED. DICTIONARY ONLINE.

As noted by Respondent, in *Leming,* the procedure in question was performed by a surgeon, in a hospital room, under anesthesia, and entailed the manual removal of tissue. While all of those factors need not be present for an operation, IVIG administration requires none. In *Elvira v. Sec'y of Health & Hum. Servs.*, the special master noted that the Circuit left "unaddressed the question of what factors or circumstances would allow for the conclusion that a given act or measure is of the surgical variety." No. 17-531V, 2024 WL 4966035 at *15 (Fed. Cl. Spec. Mstr. Nov. 6, 2024) (internal citations omitted). Historically, "special masters have typically examined in each instance whether a needle-based procedure was considered by the treating hospital to have been a surgical procedure." *Id.* Notably, the special master in *Elvira* specifically cited to the conclusion in *Spooner* that IVIG is not surgical when framing his analysis of *Leming*. *Id.* (citing *Spooner*, 2014 WL 504728 at *12–13). Here, there is no evidence that the hospital considered Petitioner's IVIG therapy to be of the surgical variety. Further, the *Spooner* analysis continues to provide guidance related to the surgical nature of an act or measure, specifically in relation to IVIG treatments. *See generally* 2014 WL 504728. After consideration of the parties' arguments and applicable case law (cited and reviewed), Petitioner has not presented preponderant evidence that his IVIG therapy qualifies as a surgical intervention in satisfaction of the Act's severity requirement.

VI. Conclusion

After a careful review of the record, Petitioner has failed to prove by preponderant evidence that his injury lasted for six months after his October 29, 2018 vaccination, pursuant to the Vaccine Act's severity requirement. Accordingly, I **DENY** Petitioner's claim and **DISMISS** his petition.[16]

IT IS SO ORDERED.

s/Herbrina D. S. Young
Herbrina D. S. Young
Special Master

[16] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.