In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-489V

(not to be published)

* *	Special Master Corcoran
SONJA PEARSON, *	
*	
Petitioner, *	Filed: February 7, 2019
*	
v. *	
*	Dismissal; Lack of Expert;
SECRETARY OF HEALTH *	Influenza Vaccine; Allergic
AND HUMAN SERVICES, *	Reaction; Lack of Causation
*	Theory; Anaphylaxis.
Respondent. *	
*	
* *	

Steven H. Jesser, Glenview, IL, for Petitioner.

Adriana Teitel, U.S. Dep't of Justice, Washington, DC, for Respondent.

RULING ON THE RECORD DISMISSING CLAIM[1]

On April 6, 2017, Sonja Pearson filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] She alleged that she experienced an immediate allergic reaction (with associated symptoms thereafter including itching, hives, pains, aches, and muscle weakness) to an influenza ("flu") vaccine she received on December 19, 2014. Pet. at ¶¶ 5, 9–10 (ECF No. 1).

Petitioner filed medical records and an affidavit in support of her claim but was unable to obtain an expert report. She nevertheless has requested a ruling on the record—and to that end, I received briefs from both parties setting forth their respective positions as to the appropriateness of an entitlement award in this case. *See* Pet'r's Br., dated Oct. 14, 2018 (ECF No. 22) ("Mot.");

[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its current form. *Id.*

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

Resp't's Br., dated Nov. 9, 2018 (ECF No. 23) ("Opp."). Having reviewed those briefs as well as all evidentiary filings in this case, I hereby DENY Petitioner's motion for an entitlement award. For the reasons stated in more detail below, Petitioner has failed to show that any reaction she immediately had to the flu vaccine upon its administration had any relationship to her subsequent symptoms (not all of which are evidentiarily substantiated), nor did she establish that the vaccine *could* have caused an immediate reaction that months later manifested as leg pain and skin rashes.

I. Summary of Medical Record[3]

Pre-Vaccination History

Petitioner was fifty years old at the time she received the flu vaccine in December 2014. Pet. at ¶1. She alleges a medical history of various allergies to certain foods and other substances, although substantiation for some of these preexisting allergies comes from records in which *she* provided medical histories to treaters, rather than from actual independent medical confirmation. *See, e.g.*, Ex. 3 at 11, filed Apr. 24, 2017 (ECF No. 7) (history provided on December 19, 2014). The same is true for her allegation that she has a family history of "autoimmune disorders" (Mot. at 2)—the representations made to treaters about family member diseases may be correct, but do not constitute substantiation of the broader suggestion that Ms. Pearson was prone to autoimmunity *per se*. *See* Ex. 5 at 12 filed Apr. 24, 2017 (ECF No. 7).

In the months immediately prior to receipt of the flu vaccine at issue in this case, Ms. Pearson was treated by her primary care provider, Dr. Donna Williams, on several occasions. On August 14, 2014, she saw Dr. Williams to discuss her current medications for diabetes and blood pressure control. Ex. 2 at 13, filed Apr. 24, 2017 (ECF No. 7). At that time, she was recovering from two different eye surgeries performed within a few days and months of the visit. *Id.* Lab tests run later that fall revealed elevated A1C levels, indicative of Type II diabetes, although Dr. Williams opined this result might be attributable to eye drops Petitioner was taking at the time. *Id.* at 5; Ex 14 at 18, filed Apr. 24, 2017 (ECF No. 7). She was nevertheless encouraged to follow up with a specialist about her diabetes. Ex. 2 at 3.

Vaccination and Alleged Reaction

Right before noon on December 19, 2014, Ms. Pearson received the flu vaccine in her left deltoid at the RML Employee Health Clinic. Ex. 18 at 1, filed Jan. 1, 2018 (ECF No. 14-3). Within the next hour, she went to the RML Specialty Hospital Emergency Room ("ER") reporting that her throat was closing up, and that she had developed "sensations in her throat" and difficulties breathing after receiving the vaccine. Ex. 1 at 2–3, filed Apr. 24, 2017 (ECF No. 7). Examination

[3] Petitioner also submitted in support of her claim a short declaration which merely confirms her receipt of the flu vaccine on December 19, 2014, and then reiterates her allegations of an immediate reaction that same day. *See generally* Ex. 7, filed Apr. 24, 2017 (ECF No. 7). And she filed a single-page document reflecting a workers' compensation case she pursued beginning in the fall of 2015; that case is referenced in some of the medical records. *See generally* Ex. 6, filed Apr. 24, 2017 (ECF No. 7).

revealed "significant" bilateral tonsillar swelling with no exudate or erythema, and no visible rash or stridor. *Id.* at 2. In addition, Petitioner was neurologically intact and her strength was assessed as normal. *Id.*

Petitioner was administered Solu-Medrol (an anti-inflammatory immunosuppressant drug) before being transferred to Mount Sinai Hospital in Chicago. Ex. 2 at 3. There, she recounted to treaters that ten minutes after her flu shot she felt "SOB [shortness of breath] and her throat closing," although the medicine administered at the ER had alleviated her symptoms. Ex. 3 at 11. On exam, she denied having any current shortness of breath, chest pain, throat swelling, or rash. *Id.* at 12. Ms. Pearson was diagnosed with an allergic reaction and discharged with oral steroids and Benadryl. *Id.* at 13.

The next day (December 20, 2014), Ms. Pearson went back to Dr. Williams for "follow up on allergic reaction to flu vaccine." Ex. 4 at 1, filed Apr. 24, 2017 (ECF No. 7). She recounted her experience but indicated to Dr. Williams that she now felt well. Her physical exam was normal, and Dr. Williams provided reassurance that nothing appeared wrong. *Id.* at 3. Dr. Williams nevertheless informed her that she should not again receive the flu vaccine. Ex. 13 at 145, filed Apr. 24, 2017 (ECF No. 7).

Purported Sequelae in 2015

There is a subsequent gap of several months in the medical records before Ms. Pearson next sought treatment for what she now alleges to be sequelae from her initial vaccine reaction. She does maintain, however, that she experienced recurrent hives and itching, as well as increased allergic sensitivity to fruit, in the months following vaccination, although she offered no contemporaneously-recorded evidence corroborating this assertion. *See* Mot. at 3. She relies instead on statements made to treating physicians many months later. *See, e.g.*, Ex. 5 at 6 (Petitioner asserting that she had experienced recurrent hives, itching, and developed additional fruit allergies since flu vaccination at August 31, 2015 visit with allergist Dr. James Thompson).[4]

Prior to the August 2015 visit with an allergist, Petitioner saw Dr. Williams on April 8, 2015, more than three months after the December 19, 2014 vaccination. Ex. 13 at 139–42. At this visit, she reported having "cold symptoms for several weeks," with respiratory symptoms evident on exam. *Id.* at 139. The rest of the examination was normal, however—and significantly, she neither revealed nor reported any rashes, hives, itching, or muscle weakness at this time. *Id.* at 141 (noting "normal skin color and pigmentation and no rash"). Ms. Pearson nevertheless currently maintains that "around this time" she noticed persistent weakness in her calves, which she initially attributed to orthopedic issues. Mot. at 3–4 (citing Ex. 5 at 10). The record referencing onset of such leg weakness, however, comes from a history conveyed by Petitioner more than one year after vaccination at a January 29, 2016 doctor's visit. Ex. 5 at 10 (describing Petitioner's "history

[4] For this and some other citations in her brief, Petitioner cites to "Supp. Ex. 1." *See, e.g.*, Mot. at 3. I cannot, however, identify from the docket in this case to what she is referring.

of leg pains going for approximately 10 months time"). Ms. Pearson similarly alleges that she received a tuberculosis ("TB") test in the spring of 2015 that caused a hive reaction at its administration site, accompanied by the same itching she had been experiencing since receiving the flu vaccine—but the substantiation for this assertion is again found in her self-reported history at the August 31, 2015 visit with Dr. Thompson (months after the purported TB test) rather than in contemporaneous records. Mot. at 4 (citing Ex. 5 at 7).

On July 27, 2015, Petitioner went to the Mount Sinai Hospital ER with a chief complaint of high blood pressure complications, informing treaters that while at work she began to experience high blood pressure, blurry vision, a headache, and a general feeling of malaise. Ex. 12 at 22. She demonstrated no muscle pain or skin problems at this visit. *Id.* at 22–23. Because of concerns for subarachnoid bleed, she was admitted for further work-up. *Id.* at 25–26. A head CT scan performed at this time was negative for ischemia, and Ms. Pearson's headache improved by the following day. *Id.* at 54, 61. Her treaters concluded, however, that her accelerated hypertension was most likely due to her failure to take medications already prescribed for her condition (due to a personal aversion), as her symptoms resolved once she actually took the medication. *Id.* at 64. Petitioner's concurrent symptoms were attributed as secondary to her hypertension, and she was discharged on July 28, 2015, with an instruction to follow up with Dr. Williams. *Id.*

On July 30, 2015, Ms. Pearson went back to Dr. Williams for the requested follow-up. Ex. 13 at 122. The history from the relevant medical record noted Petitioner's ongoing difficulties in controlling her diabetes and its impact on her work. *Id.* Her physical exam was normal, although her blood pressure readings remained elevated. *Id.* at 124–25. Dr. Williams completed forms to help Petitioner get medical leave from work. *Id.* at 125. The following month, Ms. Pearson saw Dr. Williams again, reporting continued high blood pressure based upon at-home monitoring. *Id.* at 109. She was prescribed additional medication and referred for nutritional counseling. *Id.* at 112. She saw Dr. Williams another time later that same month (August 25, 2015) and was advised to continue medication and self-monitoring of her blood pressure. *Id.* at 96–97. At all three visits with Dr. Williams, Petitioner did not complain of any muscle weakness or pain, hives, or itching. *Id.* at 97, 111, 125.

Treater Inquiries into Alleged Vaccine Reaction

The earliest record in this matter in which a treater opines that Petitioner's December 2014 vaccine might have had some longer-term impact on her health comes from her evaluation with allergist Dr. Thompson on August 31 2015, more than eight months post-vaccination. Ex. 5 at 3–7. Notably, she had no identifiable skin rash as of the date of this evaluation. *Id.* at 7. In addition, skin testing Dr. Thompson performed did confirm some of her history claims (for example, reactivity to shellfish and grass pollen), but was inconclusive or negative for other possible allergies (such as pork and fruit). *Id.*

Following the evaluation, Dr. Thompson summarized the visit in a letter addressed to Dr. Williams. Ex. 5 at 6–7. Based upon his discussion with Petitioner (including her self-reported medical history), Dr. Thompson concluded that she had "a history of adverse reactions to f1u vaccine." *Id.* at 6. He proposed researching whether some component of the vaccine was to blame, and counseled against "further exposure" to the it (as well as the TB test, based on her reported reaction). *Id.* at 7.

That fall, Petitioner again saw Dr. Williams to address her high blood pressure. Ex. 13 at 85. She noted at a late September appointment that she was experiencing leg fatigue, although her physical exam was normal. *Id.* at 85, 87–88. She reported similar symptoms again at a mid-October visit, with examination revealing no joint swelling and a normal range of motion and strength. *Id.* at 76, 79. At a subsequent visit on October 21, 2015, Ms. Pearson complained more of leg pain than weakness, especially when walking, and testing of creatine kinase levels (which, if high, can evidence muscle damage or injury) displayed abnormal amounts. Ex 13 at 73; Ex. 14 at 6.

Besides muscle-related complaints, Petitioner also reported skin issues to treaters in the fall of 2015. Thus, at a follow-up visit with Dr. Thompson on October 27, 2015, Ms. Pearson stated that she was experiencing itching, although she speculated it could be chemically-associated (due to work with oil-based paint), and also reported what she believed was a rash caused by eating or touching bananas. Ex. 5 at 2. Dr. Thompson diagnosed her with chronic dermatitis. *Id.* She also reported "very itchy" skin to Dr. Williams at around the same time. Ex. 13 at 52 (October 29, 2015 visit).

On November 13, 2015, Ms. Pearson saw rheumatology fellow Dr. Stacy Weinberg. Ex. 19 at 1, filed Jan. 1, 2018 (ECF No. 14-4). She reported her December 2014 vaccine reaction as well as subsequent leg pain. *Id.* Examination, however, revealed no muscle weakness or other focal neurologic deficits. *Id.* at 7. Dr. Weinberg proposed a differential diagnosis ("meds (no new), idiopathic inflammatory myopathy, diabetic amyotrophy, LPD [Lymphoproliferative disease]/malignancy"), which an attending physician, Dr. Joel Block, characterized as "broad" due to a lack of evidence pinpointing the source of Petitioner's reported symptoms. *Id.* at 8. Dr. Block added that a "drug-or toxin-mediated" cause for Petitioner's symptoms seemed "unlikely without a clear offending agent; viral should have resolved after 7 months." *Id.* at 8–9.

2016 Records and Beyond

More than a year after vaccination, Ms. Pearson continued to seek treater input as to the cause of her leg pain and weakness, and her skin-related symptoms. On January 29, 2016, she saw a neurologist, Dr. John-Michael Li. Ex. 10 at 15, filed Apr. 24, 2017 (ECF No. 7). She reported to Dr. Li that she has been experiencing leg pains for ten months, or since March 2015, to the point where walking was becoming difficult, and also mentioned her creatine kinase testing. *Id.* at 15–16. On exam, however, Dr. Li could find no evidence of atrophy or fasciculations, and noted normal muscle strength, gait, sensation, and deep tendon reflexes. *Id.* at 18. Dr. Li deemed the

etiology for Petitioner's condition unclear, but expressed concern for "an underlying systemic process given her worsening control of diabetes and new onset allergies." *Id.* He ordered several labs and recommended petitioner undergo electromyography and nerve conduction velocity ("EMG/NCV") testing[5] to see whether she had an underlying myopathy. *Id.*; *see also id.* at 20–52 (lab results).

On February 26, 2016, Petitioner was seen by rheumatologist Dr. Sarah Everakes, now complaining of more severe pain (in her arms as well as legs) and walking difficulties, as well as "uncontrolled" pruritis.[6] Ex. 19 at 55. But examination did not confirm these symptoms, although Dr. Everakes diagnosed Petitioner with myalgia and myositis. *Id.* Dr. Everakes added that there was "no obvious autoimmune illness or drug exposure outside of the flu vaccine last year." *Id.* at 63.

In March 2016, Ms. Pearson returned to Dr. Li for a follow-up visit, complaining again of leg pain. Ex. 10 at 9. Dr. Li, however, observed that Petitioner's creatine kinase testing revealed normal levels, and because her prior exam was "overall normal," he felt the etiology for her symptoms remained unclear. *Id.* at 15. Despite the above, Dr. Li also speculated that the "time correlation" between Ms. Pearson's December 2014 vaccination and her immediate reaction plus subsequent symptoms might point to "a possible autoimmune reaction." *Id.* But Dr. Li did not provide any explanation for how Petitioner's overall history in the fifteen months since vaccination reflected an autoimmune course, or when he proposed her onset occurred. *Id.*

Since the spring of 2016, Ms. Pearson has continued to see the same treaters mentioned above, both for symptoms unrelated to her claimed injuries (such as high blood pressure) and her purportedly vaccination-related symptoms, including skin allergies, pruritis, and leg pain and associated weakness. *See, e.g.*, Ex. 13 at 1 (May 13, 2016 visit with Dr. Williams); Ex. 5 at 29 (May 23, 2016 appointment with Dr. Thompson). None proposed any additional opinions about her receipt of the flu vaccine as connected to her symptoms. She also saw Dr. Li again in June 2016. Ex. 10 at 2. He noted than electrocardiogram she received earlier that year produced abnormal results, but did not confirm a neuropathy. *Id.* at 7. Her exam was otherwise normal, except for evidence of reduced deep tendon reflexes, and he also observed that her creatine kinase readings had fluctuated over time. *Id.* at 8. Dr. Li recommended pursuing a muscle biopsy, with further work-up to be discussed pending the biopsy results (although such results were never filed in this case). No additional medical records after this time have been filed.

[5] EMGs measure extracellular activity of skeletal muscles at rest. *Dorland's Illustrated Medical Dictionary* 602 (32nd ed. 2012) (hereinafter "Dorland's"). NCVs measure the speed at which impulses move along peripheral nerves. *Id.* at 2037.

[6] An itching sensation. *Dorland's* at 1540.

II. Parties' Respective Arguments

A. *Petitioner's Brief*

Petitioner's brief in support of her request for a ruling on the record asserts that she has met her preponderant burden of proof. Mot. at 1. She maintains that the medical record establishes that she experienced an immediate allergic reaction to the flu vaccine, consistent with her existing allergies (as well as a likely family propensity for autoimmune illnesses). *Id.* at 2–3. Thereafter came the symptoms in 2015 that she maintains were also vaccine-caused (as reflected in the diagnostic opinion of allergist Dr. Thompson) and related to her initial reaction. *Id.* at 3–6.

Petitioner has not filed an expert report in support of her claim. But her brief references two possible causal mechanisms by which her immediate reaction and subsequent symptoms could have come about. First, she identifies the concept of molecular mimicry, in which antigens contained in vaccines sufficiently resemble self-structures in the body to trigger an autoimmune attack by way of a cross-reaction between the antigens and self-structures. Mot. at 6–7. Second, she references the "by-stander theory," which she explains as "the APC activation of the vaccine dose leads to the potential activation of pre-primed and auto-reactive T cells initiating autoimmune symptoms." *Id.* at 7. In support of both theories, her brief cites several medical articles, although none were filed in the case. *Id.* at 6–8.

Petitioner also maintains that certain case studies and other items of literature demonstrate that "[a]utoimmune responses" to the flu vaccine can include persistent itching, myositis, and/or muscle myalgia. Mot. at 8–9. Some of these items of literature include articles on the concept of "autoimmune/inflammatory syndrome induced by adjuvants" (or "ASIA"), which propose that adjuvants in vaccines can heighten their autoimmune potentiality—although the flu vaccine that Petitioner received did *not* contain any adjuvant. *Id.* at 8; Ex. 18 at 1; Centers for Disease Control and Prevention, *Adjuvants Help Vaccines Work Better*, CDC (Oct. 22, 2018), https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html.[7] And she cites additional articles that she maintains support the proposition that individuals of certain races, or who have a family history of allergy or autoimmunity, are more likely themselves to experience an autoimmune vaccine reaction (although these articles are premised on the same ASIA theory). *See, e.g.*, Mot. at 9 (citing Y. Shoenfeld, et al., *Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA) 2013: Unveiling the Pathogenic, Clinical and Diagnostic Aspects*, 47 J. Autoimmunity 1 (2013)).

[7] The records filed in this case do not specify precisely which seasonal flu vaccine Petitioner received. However, as noted by the CDC, *all* flu vaccines administered in the United States (except for one) contain no adjuvant. Centers for Disease Control and Prevention, *Adjuvants Help Vaccines Work Better*, CDC (Oct. 22, 2018), https://www.cdc.gov/vaccinesafety/concerns/adjuvants html. Petitioner's vaccination consent form indicates that she received a vaccine manufactured by Sanofi Pasteur (Ex. 18 at 1), while the single adjuvanted flu vaccine in the United States (FLUAD) is manufactured by Seqirus. Centers for Disease Control and Prevention, *Flu Vaccine With Adjuvant*, CDC (Oct. 18, 2018), https://www.cdc.gov/flu/protect/vaccine/adjuvant htm. It is thus reasonable to infer that whatever flu vaccine Petitioner received was unadjuvanted.

Based upon all of the above, Petitioner maintains she has met the three prongs of the test enumerated by the Federal Circuit in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005). She argues that the literature cited establishes that the flu vaccine can cause the reaction she experienced in a person with her preexisting susceptibility; that the record shows that this did occur in her case, as reflected by Dr. Thompson's diagnostic opinion; and that her immediate reaction, followed by pruritis over time that eventually progressed into muscle issues, occurred in a medically acceptable timeframe. Mot. at 11–12.

B. *Respondent's Brief*

Respondent disputes the sufficiency of Petitioner's evidentiary showing. First, he notes that Petitioner has not clearly defined the nature of her vaccine injury. Opp. at 14–15. He then asserts that the "can cause" prong of the *Althen* test is not met, because Petitioner has attempted to propose a causation theory in a conclusory way, relying simply on invoking concepts or literature relating to autoimmunity but failing to link such evidence to her case with a persuasive expert opinion. *Id.* at 17–18. He also notes that the ASIA theory has not met success in the Program. *Id.* at 19 (citing *Johnson v. Sec'y of Health & Human Servs.*, No. 10-578V, 2016 WL 4917548, at *8–9 (Fed. Cl. Spec. Mstr. Aug. 18, 2016); *Rowan v. Sec'y of Health & Human Servs.*, No. 10-272V, 2014 WL 7465661 (Fed. Cl. Spec. Mstr. Dec. 8, 2014), *mot. for review denied*, 2015 WL 3562409 (Fed. Cl. May 18, 2015); *D'Angiolini v. Sec'y of Health & Human Servs.*, No. 99-578V, 2014 WL 61678145, at *60 (Fed. Cl. Spec. Mstr. Mar. 27, 2014) (characterizing the ASIA theory as lacking "sufficient current support to be a reliable basis for compensation in the Vaccine Program")).

Beyond the above, Respondent argues that the facts of Petitioner's medical history do not support the conclusion that the flu vaccine did in fact cause an autoimmune reaction as alleged, maintaining that Dr. Thompson's opinion is not well-founded or supported by a sufficient causal explanation to give it much weight. Opp. at 20 n.8. And he proposes that the timeframe in which Petitioner's symptoms actually unfolded—an immediate reaction, followed by purported itching not fully supported by the record, and lapses in treatment before Petitioner began reporting muscle symptoms nearly nine months later—has not been established to be medically reasonable based on Petitioner's theory. *Id.* at 21–22.

III. Applicable Legal Standards

A. *Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 11(c)(1), 13(a)(1)(A), 14(a); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440

F.3d 1317, 1320 (Fed. Cir. 2006).[8] In this case, Petitioner does not assert a Table claim. Furthermore, a petitioner must show that he has "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 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." Section 11(c)(1)(D).

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

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

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009)

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

(citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017).

In discussing the evidentiary standard applicable to the first *Althen* prong, many decisions of the Court of Federal Claims and Federal Circuit have emphasized that petitioners need only establish a causation theory's biological plausibility (and thus need not do so with preponderant proof). *Tarsell v. United States*, 133 Fed. Cl. 782, 792–93 (2017) (special master committed legal error by requiring petitioner to establish first *Althen* prong by preponderance; that standard applied only to second prong and petitioner's overall burden); *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)); *see also Andreu*, 569 F.3d at 1375. At the same time, there is contrary authority from the Federal Circuit suggesting that the same preponderance standard used overall in evaluating a claimant's success in a Vaccine Act claim is also applied specifically to the first *Althen* prong. *See, e.g.*, *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010) (affirming special master's determination that expert "had not provided a 'reliable medical or scientific explanation' *sufficient to prove by a preponderance of the evidence a medical theory* linking the [relevant vaccine to relevant injury]") (emphasis added). Regardless, petitioners always have the ultimate burden of establishing their Vaccine Act claim *overall* with preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell*, 133 Fed. Cl. at 793 (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

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

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be

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

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

B. *Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied sub. nom. Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight")).

In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Consideration of Medical Literature*

Although neither party actually filed medical or scientific literature in this case, both parties discussed such material. However, not every item of literature factors into the outcome of this decision. While I have reviewed the medical literature referenced[9] in this case, I discuss only those

[9] It is common practice for petitioners to *file* those items of medical literature deemed significant, so that they will be treated as evidence, like medical records or other pieces of proof. Here, however, although the Petitioner *cited* fifteen articles, she filed none. Despite the fact that they were not properly filed, I have looked at those items relevant to

articles that are most relevant to my determination or are central to Petitioner's case. *Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

D. *Determination to Resolve Case Without Hearing*

I have opted to decide entitlement in this case (without the objection of the parties) based on written submissions and evidentiary filings, including the expert reports filed by each side, rather than after a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers when, in the exercise of their discretion, they conclude that such a means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Tiole v. Sec'y of Health & Human Servs.*, 726 F. App'x 809, 812 (Fed. Cir. 2018); *Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.,* No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

Based on the records filed and the arguments of the parties, I do not find that Petitioner has established by a preponderance an entitlement to a Program award.

First, Ms. Pearson has not satisfied the "can cause" *Althen* prong with a plausible, reliable medical or scientific theory that the flu vaccine could cause both an initial reaction (similar in presentation to an allergic response), followed by a diffuse series of skin rashes and muscle pain. Her failure to offer an expert report was a threshold obstacle to her success in establishing this *Althen* prong. Admittedly, a claimant is not required to offer an expert *at all* to prevail in a non-Table case, as "evidence in the form of scientific studies" can be offered in the alternative to "expert medical testimony" to show causation. *Wilson v. Sec'y of Health & Human Servs.*, No. 02-1797V, 2005 WL 6117474, at *4–5 (Fed. Cl. Spec. Mstr. June 27, 2005) (citing H.R. Rep. No. 99-908, pt. 1, at 15 (1986)). Certainly some kinds of claims (for example, a claim that is exceedingly common in the Program, such as one alleging Guillain-Barré syndrome as the vaccine injury) could

Petitioner's claim (in particular, those dealing with the flu vaccine in the nonadjuvanted form, as well as articles pertaining to injuries comparable to that alleged in this case).

be successfully established simply on the basis of well-accepted science, along with reference to prior persuasive Vaccine Program decisions.[10] But this is not such a case—and the absence of an expert to provide an overarching, learned explanation for how the flu vaccine could have produced the injuries alleged herein greatly limited the effectiveness of the arguments she did make via her motion on the "can cause" prong.

Despite the lack of an expert report, Petitioner did cite (although she did not also *file*) a number of items of scientific or medical literature, which purportedly supported her causation theory. But this scientific evidence did not come close to establishing a scientifically/medically *reliable* theory. The smattering of items of literature Petitioner referenced at best established how vaccines could be associated with *some* of the symptoms she experienced individually, *not* that the flu vaccine has been shown to cause an immediate allergic reaction resembling anaphylaxis that then could progress into myopathy or some other muscle-related presentation by way of a skin rash or pruritis.[11] The same is true of those referenced items pertaining to mechanisms of causation, like molecular mimicry or bystander activation,[12] by which autoimmunity has been demonstrated to occur. Such literature does not stand for the proposition that (a) an injury akin to what Petitioner alleges to have experienced is likely autoimmune in origin, or (b) that such an injury would unfold over many months by these mechanisms.

The six articles Petitioner cites involving ASIA as a pathologic mechanism not only apply only to vaccines containing adjuvants (and thus are irrelevant to this case, as the flu vaccine administered in the U.S. is *not* adjuvanted), but invoke a mechanism that has been consistently deemed unpersuasive and unreliable. *Morris v. Sec'y of Health & Human Servs.*, No. 12-415V, 2016 WL 3022141, at *12 (Fed. Cl. Apr. 1, 2016) (discussing lack of reliability of ASIA theory (citations omitted)); *see also Rowan*, 2014 WL 7465661, at *16; *D'Angiolini*, 2014 WL 1678145, at *60. I have in fact not permitted petitioners to go to hearing based upon the ASIA theory, given my reasoned doubts about its reliability. *See, e.g.*, *Johnson*, 2018 WL 2051760, at *7 n.11. This mechanism could not prop up Petitioner's causation theory.

[10] While past special master decisions do not determine the outcome in any individual case, they can suggest persuasive views about how a particular kind of theory should be analyzed. The collective wisdom of the special masters in resolving Vaccine Act injury cases over the past twenty-five years should not be ignored where relevant—especially where certain claims meet the same fate over and over.

[11] Petitioners alleging autoimmune illnesses that affect the skin have been successful in prior Vaccine Program cases. *See, e.g.*, *Sanchez v. Sec'y of Health & Human Servs.*, No. 04-1361V, 2008 WL 3174348 (Fed. Cl. Spec. Mstr. July 18, 2008). But the medical record establishes no instance in which a treater proposed or opined that *Ms. Pearson* suffered from such an autoimmune condition (for example, dermatomyositis, which involves the skin and muscles as well). This omission gains significance from the fact that she saw rheumatologists (the practice specialty that would treat dermatomyositis and other like conditions) in November 2015 and February 2016, *none* of whom proposed such an autoimmune condition as a possible diagnosis. *See generally* Ex. 19.

[12] Bystander activation occurs when T lymphocytes are activated by a foreign antigen as a secondary effect, thus "resulting in a 'nonspecific' activation of those immune system cells in a disease process." *Bender v. Sec'y of Health & Human Servs.*, No. 11-693V, 2018 WL 3679637, at *15 (Fed. Cl. Spec. Mstr. July 2, 2018), *mot. for review denied*, 2019 WL 2882280 (Fed. Cl. Jan. 23, 2019).

The case reports Petitioner offers are somewhat more relevant (for example, establishing pruritis or myositis after the flu vaccine). *See, e.g.*, Mot. at 8 (citing Y. Qin, et al., *Prolonged Pruritic Rash Following Influenza A (H1N1) Vaccination*, 54 Singapore Med. J. e117 (2013); C. Ferri, *Polymyositis Following Pandemic Influenza A (H1N1) and 2009–10 Seasonal Trivalent Vaccines*, Case Reports in Rheumatology (2012)). But because they only *suggest* an association, the probative weight given to this kind of evidence in Program cases is limited. *See Harris v. Sec'y of Health & Human Servs.*, No. 10-322V, 2014 WL 3159377, at *18 (Fed. Cl. Spec. Mstr. June 10, 2014) (noting that "case reports are generally not a valuable form of evidence"). They therefore cannot make up for the deficiencies discussed above that weaken Petitioner's showing on *Althen* prong one overall.

Second, even if I found that the scattered citations offered in Petitioner's brief, devoid of the harmonization an expert could have provided, were sufficient to constitute a reliable and plausible causation theory, her claim would still founder on the second, "did cause" *Althen* prong. The medical record does not support the conclusion that Petitioner's ultimate symptoms course—beginning with her immediate, post-vaccination reaction, then progressing to her alleged pruritis and eventual muscle symptoms—was vaccine-caused. While preponderant evidence does suggest Petitioner may have had an initial reaction[13] that could credibly be linked to her receipt of the flu vaccine, that reaction was short-lived, and there followed a several-month hiatus in the records revealing no subsequent issues. Ms. Pearson did not see any physician until Dr. Williams in April 2015, with her purported muscle symptoms only beginning later that fall. Petitioner has not persuasively explained how this disease course is consistent with her causation theory—for example, by pointing to evidence from the record beyond the temporal relationship between her immediate symptoms and vaccination as confirming the theory. This record does not provide evidence that would corroborate the causal contention that Petitioner experienced an autoimmune "hit" as of December 2014 that lingered on for months into the next year and eventually resulted in muscle symptoms, however properly characterized.[14]

[13] Petitioner has not alleged a Table claim based upon anaphylaxis after receipt of the flu vaccine. *See* Mot. at 11–12 (pleading her claim as caution-in-fact under *Althen*); *see also* 42 C.F.R. § 100.3(a)(XIV)(A) (2018) (anaphylaxis beginning no more than four hours after receipt of seasonal flu vaccine is a Table claim). But if she had pled her claim in such a manner and were found to satisfy the qualifications and aids to interpretation set forth in the Table (*see* 42 C.F.R. § 100.3(c)(1)), such a claim would still have failed. Table claims must satisfy the statutory requirement set forth in Section 11(D) of the Vaccine Act, which requires that a petitioner suffer the residual effects or complications of her injury for more than six months after vaccine administration (or, alternatively, die or require inpatient hospitalization and surgical intervention as a result of her vaccine injury, neither of which (thankfully) occurred in the present case). *See, e.g.*, *Price v. Sec'y of Health & Human Servs.*, No. 11-442V, 2015 WL 7423070, at *7 (Fed. Cl. Spec. Mstr. Oct. 29, 2015) (awarding compensation to petitioner who experienced Table anaphylaxis that caused ongoing seizures for more than six months). Ms. Pearson has not persuasively linked the skin symptoms and muscle pain she felt many months after vaccination to whatever initial anaphylaxis-type reaction she may have had, so these symptoms cannot satisfy the six-month severity requirement.

[14] In addition, Petitioner's after-the-fact statements to treaters that her symptoms began earlier than what the contemporaneous records establish are not enough to counter the presumptive accuracy of those initial medical records that do *not* record the symptoms she later reported to treater. *See, e.g.*, *Burns*, F.3d at 417.

It also does not appear that any treater has proposed that Ms. Pearson's course reflected an ongoing autoimmune disease process initiated by the flu vaccine. Dr. Li may have allowed for the possibility in 2016, but did so long after the fact, did not cite to records supporting the potential etiologic diagnosis, and ultimately does not seem to have embraced this as a favored causal explanation. Petitioner also points to Dr. Thompson's views, but while these are entitled to some weight, they are not sufficiently anchored in a reliable theory explaining *how* the flu vaccine could initiate one kind of allergic reaction that overtime morphed into two other kinds, especially absent record proof corroborating that this occurred. And the fact that Petitioner's *initial* reaction could well have been allergic (for example, to some vaccine ingredient other than the absent adjuvant) does not explain how that one-time transient reaction would evolve over months, as Petitioner maintains. Such an explanation would more credibly come from an immunologist, not an allergist like Dr. Thompson. I therefore do not give these treater opinions much weight.

Finally, Ms. Pearson has done no more than conclusorily assert that the timeframe in which her symptoms evolved and progressed was medically acceptable. But she has not *shown* this to be the case—in particular, by linking her causation theory to the facts arising from the medical records, or by offering reliable evidence to support the contention that a reaction to the flu vaccine could credibly follow such a course. Again, even if the flu vaccine Petitioner received *did* cause an initial and understandably-frightening reaction, nothing in Petitioner's referenced items of literature persuasively explains how it would be plausible for that reaction to morph over many months into muscle symptoms, especially when the record shows those secondary symptoms began no sooner than *nine* months post-vaccination, in September 2015. Records from subsequent doctor's visits in which Petitioner recalled the skin and muscle symptoms beginning sooner do not persuasively rebut the presumption that the earlier-in-time records in which she first complained of such symptoms are correct. Ultimately, the course of Petitioner's complained-of symptoms has not been demonstrated to have occurred in a medically-reasonable timeframe as measured from her December 2014 vaccination.

Conclusion

Petitioner has not carried her burden of proof. Accordingly, I am compelled to **DISMISS** her claim. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk **SHALL ENTER JUDGMENT** in accordance with this decision.[15]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[15] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.