In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-1302V

(not to be published)

JEFFREY PREPEJCHAL,	*	Special Master Corcoran
Petitioner,	*	Filed: October 5, 2018
v.	*	Decision on Record; Influenza ("Flu") Vaccine; Deep Vein Thrombosis ("DVT"); Six Month Residual Effects Requirement; Nicolau Syndrome ("NS").
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Mark T. Sadaka, Mark T. Sadaka, LLC, Englewood, NJ, for Petitioner.

Claudia B. Gangi, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION GRANTING MOTION TO DISMISS CASE[1]

On November 2, 2015, Jeffrey Prepejchal filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Mr. Prepejchal alleged that his November 7, 2012 influenza ("flu") vaccine caused deep vein thrombosis ("DVT") in his left arm. Pet. at 1, ECF No. 1.

[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012).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 Internet access.** 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 "pf 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. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10–34 (2012) (hereinafter "Vaccine Act" or "the Act"). Individual section references hereafter shall refer to §300aa of the Act.

Once the medical records, statement of completion, and Respondent's Rule 4(c) Report were filed, on March 5, 2018, Respondent filed a motion for a decision dismissing the petition on the record. *See* Mot. for Decision Dismissing Pet. on Record, ECF No. 37 ("Mot."). Petitioner responded to that motion on May 2, 2018, arguing for a decision in his favor. *See* Resp. to Mot. for Ruling on Record, ECF No. 40 ("Resp."). Having completed my review of the evidentiary record and the parties' filings, I hereby **GRANT** Respondent's Motion for a Ruling on the Record Dismissing the Case and **DISMISS** Petitioner's claim, for the reasons stated below.

I. Factual Background

A. *Pre-Vaccination History*

Mr. Prepejchal was born on June 5, 1968. Ex 18 at 1, ECF No. 35-1. His pre-vaccination medical records reflect a history of right hip and left shoulder pain. Ex. 1 at 23, ECF No. 9-1. In particular, medical records from May 2, 2012—six months before the flu vaccination at issue—show that Petitioner suffered from chronic pain in his left shoulder, which his primary care physician posited might be tendinitis. *Id.* He had no personal history of DVT before the vaccination at issue, although his father has previously experienced an upper extremity DVT. *Id.* at 21–22.

At all relevant times, Petitioner has been employed as a medical charter pilot. Ex. 18 at 1. His work schedule is such that he alternates seven-day on-call periods with seven-day free periods. *Id.* He flies one or two days during a typical week on call, sometimes handling multiple flights per day. *Id.* All his flights are local, usually lasting less than one hour, and his "ground time" (time spent in the airplane while on the ground) typically ranges from fifteen to forty-five minutes per flight. *Id.*

Petitioner flew on four separate days during the two weeks preceding his receipt of the flu vaccine. Ex. 18 at 1–2. Including ground time, he flew 1.4 hours on October 25, 2012; 3.5 hours on October 31, 2012; 2.3 hours on November 4, 2012; and 3.5 hours on November 5, 2012. *Id.* at 2.

B. *Vaccination and DVT Discovery*

Petitioner received the flu vaccine in his left deltoid on November 7, 2012. Ex. 3 at 1, ECF No. 9-3; Ex. 18 at 1. He claims to have experienced "soreness and mild pain" an hour after the vaccination. Ex. 18 at 2. His precise condition in the days immediately following the vaccination is not clear from the record, however.

On November 16, 2012—nine days after vaccination—Mr. Prepejchal visited his primary care physician, Dr. Walter Meeker, with complaints of swelling in his left arm. Ex. 1 at 21.

However, while Petitioner's January 29, 2018 affidavit alleges that his initial soreness worsened over the days following the vaccination, ultimately becoming "unbearable" and driving him to visit his doctor (*see, e.g.*, Ex. 18 at 2), records from the November 16th visit with Dr. Meeker merely characterize Petitioner's arm as "a little sore." Ex. 1 at 21. Moreover, records from a December 3, 2012 visit with Dr. Darryl Lesoski, an occupational health specialist, indicate that Mr. Prepejchal had been prompted to visit Dr. Meeker two weeks prior by his father, who noticed—while bowling with Petitioner—that Petitioner's left bicep was so swollen as to appear approximately two inches larger in circumference than his right bicep, with some swelling also visible in his left forearm. Ex. 2 at 11, ECF No. 9-2. It is thus difficult to ascertain whether Petitioner personally noted any significant arm soreness or swelling before his father pointed it out during the pair's bowling excursion (thus raising some questions as to the severity of the problem in November).

At the November 16, 2012 visit with Dr. Meeker, an ultrasound revealed that Petitioner had a DVT in his left arm. Ex. 1 at 21. The radiology report indicated that Petitioner suffered from "near-complete occlusion" of the subclavian, axillary, and basilic veins. Ex. 2 at 38. Dr. Meeker characterized Petitioner's left arm as having "diffuse mild swelling with venous distention." Ex. 1 at 22. He prescribed two anticoagulants, Coumadin and Lovenox, and noted that he was "unsure how this is related to recent flu shot." *Id.* at 21. Petitioner's December 3rd visit with Dr. Lesoski confirmed Dr. Meeker's ultrasound findings. Ex. 2 at 12. Externally, Dr. Lesoski also observed a small bruise on Petitioner's left anterior bicep, but noted that his left arm now appeared "normal compared to the right," and thus that his swelling had resolved. Ex. 2 at 12.

Following the December 3rd visit, Dr. Lesoski looked into possible links between the flu vaccine and upper extremity DVT. Ex. 2 at 10. But his investigation—which included librarian-aided literature research, discussion with a hematologist, and an inquiry to an Occupational Health & Medicine list serve group—found "no association" between the flu vaccine and DVTs, and he even suggested that "administration of the influenza vaccine *was actually prophylactic* or protective of DVTs." *Id.* (emphasis added). Dr. Lesoski otherwise noted that "25% of [DVTs] are deemed idiopathic," and ultimately concluded that in light of Petitioner's symptoms and medical history, "there is no significant evidence that would tell me that this is related to the administration of the influenza vaccine and is more than likely idiopathic." *Id.*

Following the November 16, 2012 visit, Petitioner saw Dr. Meeker regularly for international normalized ratio ("INR") tests, which measure the blood's clotting tendency.[3] Ex. 1 at 11–15, 17, 19. Immediately following the DVT diagnosis on November 16th, such tests were performed multiple times per week. *See id.* at 15, 17, 19. They subsequently decreased in

[3] *PT*, Lab Tests Online, https://labtestsonline.org.uk/tests/pt.

frequency, and the last recorded test before cessation of treatment occurred on January 31, 2013—less than three months from Petitioner's receipt of the flu vaccine. *Id.* at 11–14.

C. *Subsequent Medical History*

There is a gap of nearly six months in the medical records in this case after January 2013. Records from a June 6, 2013 visit with Dr. Meeker, however, reflect that Petitioner had completed "greater than 6 months therapy" of anticoagulant medication by that date. Ex. 1 at 8. Dr. Meeker recommended "no further therapy" at this time because of the low risk of DVT recurrence (although he did suggest avoiding the flu vaccine in the future). *Id.* The record is otherwise silent as to whether Petitioner experienced continuing swelling, soreness, or any other symptoms of DVT between November 2012 and June 2013.

On October 23, 2013, Petitioner again saw Dr. Meeker, who opined at this time that Petitioner's previous "intramuscular deep tissue reaction likely was related to DVT." Ex. 1 at 6. Notes from another visit with Dr. Meeker in the following year, on January 27, 2014, state that his left arm DVT was "possibly related to influenza vaccine being given," but provide no explanation for this assertion. *Id.* at 3. Petitioner has not experienced any DVT recurrence since the episode diagnosed by Dr. Meeker on November 16, 2012. *Id.* at 6.[4]

II. Witness Affidavits

The only affidavit filed in this matter is that of Mr. Prepejchal. *See generally* Ex. 18. It addresses in detail his work as an airline pilot and briefly describes his post-vaccination symptoms. *See generally id.* He executed the affidavit on January 29, 2018. *Id.* at 2.

III. Expert Reports

A. *Dr. M. Eric Gershwin*

Dr. Gershwin prepared three reports for Petitioner. The first lays out his basic theory of causation of Petitioner's injury. Ex. 5, May 3, 2017, ECF No. 25-1 ("Gershwin First Rep."). The second discusses which categories of specialists would be best-suited to opine in this case. Ex. 17, June 16, 2017, ECF No. 29-1 ("Gershwin Second Rep."). The third responds to the report submitted by Respondent's expert, Dr. Megha Tollefson. Ex. 19, Feb. 2, 2018, ECF No. 36-1

[4] Petitioner filed other medical records not directly relevant to his claimed vaccine injury (although, as discussed below, he did allege at one point in the case's life that such records reflected sequelae of his injury). For example, nearly two years after the vaccination at issue, Petitioner visited his doctor on October 28, 2014, following several episodes of dizziness in a one-week span. Ex. 1 at 1. Records indicate that his vertigo could be reproduced through the Dix-Hallpike maneuver, however, indicating that the condition was likely peripheral—that is, caused by inner ear problems, rather than anything else. *Id.*; *Dorland's Illustrated Medical Dictionary* 2054 (32nd ed. 2012) (hereinafter "Dorland's").

("Gershwin Third Rep."). Based on his review of Petitioner's medical records and his own expertise, Dr. Gershwin opines that Petitioner's receipt of the flu vaccine caused a "mechanical injury" that led to Petitioner's DVT. Gershwin First Rep. at 1. He characterizes Petitioner's condition as analogous to a rare condition known as Nicolau Syndrome ("NS;" also known as embolia cutis medicamentosa or livedo-like dermatitis). *Id.*

As reflected by his curriculum vitae, Dr. Gershwin serves as a Distinguished Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology at the University of California, Davis. Ex. 16 at 1, ECF No. 27-1 ("Gershwin CV"). He received his M.D. from Stanford University in 1971 and his M.S. in Astronomy and Astrophysics from the Centre for Astrophysics and Supercomputing in Melbourne, Australia, in 2002. *Id.* He completed a residency at the Tufts-New England Medical Center, then went on to serve as a Clinical Associate in Immunology at the National Institutes of Health. *Id.* at 2. He is board certified in Internal Medicine with the subspecialty of Rheumatology, as well as in Allergy and Clinical Immunology. *Id.* Dr. Gershwin has served as a professor at UC Davis since 1975. Gershwin CV at 2. During that time, he has served on the editorial boards of many scientific and medical journals. *Id.* at 5–7. He has authored hundreds of books, monographs, experimental papers, book chapters, and book reviews, primarily writing in the fields of immunology and rheumatology. *Id.* at 8–128.

i. *Dr. Gershwin's First Expert Report*

Dr. Gershwin's first report takes great care in distinguishing between immunological and mechanical causes of injury. Gershwin First Rep. at 1. He forthrightly admits that he finds no association between the components of the flu vaccine and DVT (a condition he otherwise did not define) by which the two could be immunologically linked, emphasizing that he "do[es] not believe that there is *any* component of the influenza vaccine that would produce venous thrombosis." *Id.* (emphasis added). "In other words," he writes, "there is no immunological basis to associate the vaccine components with a clotting abnormality." *Id.* He also does not opine that any subsequent symptoms Petitioner might have experienced (such as the dizziness reported two years post-vaccination) could be vaccine-related. *Id.* at 2. Instead, Dr. Gershwin concludes that Petitioner's DVT was caused by "a mechanical injury from the injection [that] led directly to the swelling and subsequent deep venous thrombosis." Gershwin First Rep. at 1.

To make this argument, Dr. Gershwin analogizes Petitioner's DVT to an injury he unquestionably was not diagnosed with: NS. Gershwin First Rep. at 1 (Petitioner's DVT "is most consistent with a local reaction *similar to* NS" (emphasis added)). NS, he explains, is a rare dermatological condition associated with intramuscular injections. *See id.*; *see also* M. Corazza, et al., *Five Cases of Livedo-Like Dermatitis (Nicolau's Syndrome) Due to Bismuth Salts and Various Other Non-Steroidal Anti-Inflammatory Drugs*, 15 J. Eur. Acad. Dermatology & Venereology 585, 585–86 (2001), filed as Ex. 10, ECF No. 25-6 ("Corazza"). NS generally

begins with instantaneous, severe pain at the site of injection, followed shortly thereafter by development of skin lesions. P. Bégin, et al., *Nicolau Syndrome May Be Caused by Intravascular Vaccine Injection*, 30 Vaccine 2035, 2035 (2011), filed as Ex. 15, ECF No. 26-1 ("Bégin"); Corazza at 586. While the exact presentation of NS may vary, it generally includes large areas of purplish plaque on the skin, and can include erythema (skin redness caused by capillary congestion), chronic ulcers, and scarring. K. Luton, et al., *Nicolau Syndrome: Three Casesa and Review*, 45 Int'l J. Dermatology 1326, 1327 (2006), filed as Ex. 7, ECF No. 25-3 ("Luton"); Corazza at 586. Ultimately, tissue in the affected area may become necrotic and require surgical removal. Corazza at 586.

Dr. Gershwin states in his first report that NS can "affect deeper tissue, veins and nervous tissue," though he cites nothing to directly support this proposition. Gershwin First Rep. at 1. His first report does not, however, explain the mechanism by which a vaccination could result in DVT, or otherwise explain the association between DVT and NS beyond his personal comparison (which, it bears mentioning, is not based on his own direct experience diagnosing or studying DVT).

The literature Dr. Gershwin relies on in his first report provides some clarification of the basis for his analogy to NS. One item explains that NS can occur "when an intramuscular medication is inadvertently injected directly in an arterial lumen or wall." Bégin at 2035. Another notes that "the pathogenesis of Nicolau Syndrome is not clear but the most reasonable hypothesis is that of a vascular origin." Luton at 1328. Luton proceeds to lay out six different theories for NS's relation to intramuscular injections. *Id.* These six possible mechanisms of causation all involve "occluded peripheral 'arterial' vessels, either through true emboli or through vessel damage and then occlusion." *Id.*

ii. *Dr. Gershwin's Second Expert Report*

Dr. Gershwin filed a second, one-page report in response to my inquiry as to which medical specialty had sufficient expertise to opine on NS. Gershwin Second Rep. at 1. Emphasizing the rarity and varied presentation of NS, he maintains that internists—such as himself—are well-qualified to assess NS and its comparability to DVT. *Id.* Emphasizing NS's varied presentation, he states that it may be referred to practitioners in many specialties, often including internists as well as allergists. *Id.* He points out that he was once qualified to testify in federal court on the question of whether a patient's NS was related to subsequent osteonecrosis, and further noted that "[a]s Chief of Rheumatology at the University of California, [he has] been the 'go-to guy' for patients with a large variety of rare syndromes in medicine for more than half of [his] 42-year career." *Id.*

Dr. Gershwin's third report was filed in direct response to Dr. Tollefson's report. For this reason, it will be discussed below.

B. *Dr. Megha Tollefson*

Respondent filed one expert report from Dr. Tollefson. Ex. A, Jan. 8. 2018. ECF No. 32-1 ("Tollefson Rep."). Dr. Tollefson contests Dr. Gershwin's conclusion that Petitioner's flu vaccine caused his DVT. *Id.* at 2. Interpreting Dr. Gershwin's first report to state that Petitioner actually did develop NS as a result of his flu vaccination, Dr. Tollefson disputes the counter-diagnosis. *Id.*

As reflected in her curriculum vitae, Dr. Tollefson is an Associate Professor of Pediatrics and an Associate Professor of Dermatology at the Mayo Clinic College of Medicine in Rochester, Minnesota. Ex. B at 1, ECF No. 32-2. She also received her M.D. from Mayo Clinic College of Medicine in 2003. She completed residencies in pediatrics and dermatology, also at the Mayo Clinic, and is board certified in dermatology and pediatrics. *Id.* She completed a one-year fellowship in pediatric dermatology at Stanford University and has published over forty articles, largely in the field of dermatology. *Id.* at 1, 25–27.

As noted, Dr. Tollefson contests the applicability of NS in explaining Petitioner's condition. Emphasizing that NS presents with local and immediate changes in the skin accompanied by intense pain at the site of injection, Dr. Tollefson explained that Petitioner's condition—no pain during or immediately following the vaccine injection, and no visible changes on his skin—was entirely *inconsistent* with NS. Tollefson Rep. at 2.

Dr. Tollefson proceeds to address whether Petitioner's DVT could be vaccine-caused, concluding that it was most likely idiopathic in origin—something she terms "not uncommon." Tollefson Rep. at 2. She argues against a possible causal link between Mr. Prepejchal's flu vaccine and DVT on the basis of the distinct locations of the two, observing that "[t]he injection from the influenza vaccine would not have been placed anywhere near the site of the DVT as the influenza vaccine is given intramuscularly, which is quite a bit more superficial than the deep blood vessel at the location of Mr. Prepejchal's DVT." *Id.* She also observes that Petitioner was likely genetically predisposed to DVT, as seen through his father's medical history. *Id.* And she highlights Petitioner's work as an airline pilot, postulating that his frequent air travel, in conjunction with his genetic predisposition, was more likely to be the cause of his DVT than the flu vaccine, citing an item of literature linking the two. *Id.* (citing S. Kuipers et al., *Travel and Venous Thrombosis: A Systematic Review*, 262 J. Internal Med. 615 (2007), filed as Ex. C, ECF No. 32-3 ("Kuipers")). Kuipers, however, only observed a relationship between DVT and flights longer than four hours—but Petitioner's flights were generally no more than one hour in duration. Kuipers at 615; Ex. 18 at 1.

C. *Dr. Gershwin's Third Expert Report*

Dr. Gershwin's third report (two pages in length like the first) responds to Dr. Tollefson's arguments. *See generally* Gershwin Third Rep. In it, he takes direct issue with Dr. Tollefson's emphasis on Petitioner's work as a pilot as a possible cause of his DVT, as well as with her contention that Petitioner could not have experienced NS absent "skin findings." *Id.* at 1.

Regarding Petitioner's frequent air travel as a possible explanation for his DVT, Dr. Gershwin stated that he "do[es] not view [that] air travel as prolonged or tedious and therefore unrelated to his subsequent development of thrombosis," especially given that Petitioner's DVT was in his arm and on the same side as the vaccination. Gershwin Third Rep. at 1. While he does not expound on these views, presumably Dr. Gershwin means to suggest that (1) only prolonged, tedious air travel could reasonably be linked to the development of DVT; (2) air travel would more reasonably be linked to lower than upper extremity DVT; and (3) development of DVT in the same arm in which Petitioner received the flu vaccination was an unlikely coincidence.

Turning to the issue of whether Petitioner experienced NS rather than DVT and/or the overall propriety of the comparison, Dr. Gershwin's position is not entirely clear. *See* Gershwin Third Rep. at 1. Although he never specifically argues that Petitioner actually developed NS (an argument that lacks record support), he points out that NS "is, by definition, a syndrome and there is an enormous degree of variation in the clinical features of patients," thus suggesting that Petitioner's presentation could be viewed as consistent with NS. *Id.*[5] He also notes that "there has been a previous report of thrombosis in a patient with Nicolau's syndrome." *Id.* (citing N. Gormus et al., *Successful Surgical Treatment of Nicolau's Syndrome Combined with Intravenous Iloprost*, 38 Zeitschrift für Gefässkrankheiten [VASA] 378, 378–81 (2009), filed as Ex. 20, ECF No. 36-2 ("Gormus")). This would presumably bulwark the possibility that Mr. Prepejchal's DVT was just an alternative presentation of NS.

Finally, Dr. Gershwin allows Dr. Tollefson's point that Petitioner was genetically predisposed to develop DVT, but interpreted the significance of this differently. Gershwin Third Rep. at 2. In his view, any predisposition would at most merely make Petitioner "more likely to develop thrombosis *following* an injury." *Id.* He cites nothing to support his unstated implication that DVT requires some kind of injury as a trigger, however. He concludes by affirming his earlier view that Petitioner's DVT is "secondary to his vaccination and reflects a significant local injury." *Id.*

[5] It is unclear what Dr. Gershwin means by emphasizing that NS is "by definition, a syndrome." Gershwin Third Rep. at 1. Dorland's Medical Dictionary defines *syndrome* as "a set of symptoms that occur together; the sum of signs of any morbid state; a symptom complex." *Dorland's* at 1819. He may mean to suggest that a syndrome, by definition, can vary in presentation, though he still does not explicitly state nor indirectly support the contention that Petitioner's symptomology fits within even a broad definition of NS.

IV. Procedural History

As noted above, this action was commenced on November 2, 2015. Pet. at 1. Petitioner filed medical records designated as Exhibits 1–4 on February 3, 2016 and his statement of completion on February 12, 2016. *See* Ex. 1; Ex. 2; Ex. 3; Ex. 4, ECF No. 9-4; Statement of Completion, ECF No. 10.

I suspended the deadline for Respondent's Rule 4(c) Report to allow the parties to engage in settlement negotiations. *See* Non-PDF Scheduling Order, filed May 12, 2016. Following approximately eight months of negotiations, the parties reported that their settlement efforts had been unsuccessful. *See* Joint Status Report, Jan. 11, 2017, ECF No. 21. Accordingly, I reinstated a deadline for Respondent's Rule 4(c) Report, which was filed on February 10, 2017.

Petitioner subsequently filed an expert report from Dr. Gershwin and accompanying medical literature on May 4, 2017. *See* Gershwin First Rep. Following a May 9, 2017 status conference, Petitioner filed a second report from Dr. Gershwin on July 31, 2017. *See* Gershwin Second Rep. Respondent thereafter filed Dr. Tollefson's expert report and accompanying medical literature on January 9, 2018, as well as a status report requesting a ruling on the record. *See* Tollefson Rep.; Status Report, ECF No. 33. Petitioner filed an affidavit regarding his employment history on January 29, 2018, and the third and final report from Dr. Gershwin on February 5, 2018. Ex. 18; Gershwin Third Rep.

Respondent filed his motion requesting that I dismiss Petitioner's claim on the record on March 5, 2018. Mot. at 1. Petitioner responded on May 2, 2018. Resp. at 1. This matter is now ripe for decision.

V. Parties' Respective Arguments

A. *Respondent's Motion*

The thrust of Respondent's position is that Petitioner has failed to put forth a scientifically reliable theory of causation. *See* Mot. at 14. In light of Dr. Gershwin's concession that there is no immunological association between the flu vaccine and DVT, Respondent argues that his "mechanical injury" theory of causation is "speculative" and "lacks a reasonable scientific basis." *Id.* Rather than explaining or providing support for his theory, Respondent contends that Dr. Gershwin "relies on the 'analogous' condition of NS, which, in fact, is not at all analogous to petitioner's injury." *Id.*

In so arguing, Respondent details the ways in which Petitioner's condition was distinguishable from NS. Most notably, Respondent highlights several articles on NS filed by Petitioner in which NS patients experienced intense and immediate pain at the site of injection.

Mot. at 18–19. Petitioner, by contrast, "did not experience pain during or immediately after the injection of the flu vaccine," in Respondent's reading of the records, despite his complaints of subsequent soreness over time. *Id.* at 19.

Respondent further contends that, because Petitioner has failed to put forth a tenable theory of causation, it necessarily follows that Petitioner cannot demonstrate that his injury was actually caused in this case by the flu vaccine. Mot. at 15. Respondent also takes issue with the alleged severity of Petitioner's symptoms following his vaccination, arguing that the medical records belie his claim that he experienced "unbearable pain" before visiting Dr. Meeker on November 16, 2012. *Id.* at 16.

Furthermore, Respondent contends that even if Dr. Tollefson overstated the role Petitioner's frequent air travel may have played in bringing about his DVT, Respondent does not bear the burden of explaining an alternate cause of Petitioner's injury, and therefore such arguments still have some evidentiary value even if they do not dispositively explain the cause of his DVT. Mot. at 17.

B. *Petitioner's Response*

Much of Petitioner's argument hinges on his contention that DVT requires an isolated and identifiable triggering event. Resp. at 4. To support this proposition, Petitioner makes three subpoints. First, Petitioner characterizes Dr. Tollefson's statement that Petitioner's "genetic predisposition, in addition to his frequent airline travel, is far more likely than the influenza vaccination to be causative in the development of his DVT" as "a tacit recognition by Respondent that DVTs do not just form but require an environmental trigger." *Id.* at 5 (citing Tollefson Rep. at 2). Second, Petitioner baldly asserts that DVT requires a trigger because genetic predisposition alone cannot *cause* DVT, a concept which he explains by way of the following illustration: "a person who walks alone at night on an unlit street in a known dangerous neighborhood has an increased susceptibility to being robbed. Yet, those factors do not cause the theft they increase susceptibility to it." *Id.* Finally, Petitioner points to an overview of DVT from the Mayo Clinic website, which states that "the blood clots of [DVT] can be caused by anything that prevents your blood from circulating or clotting normally, such as injury to a vein, surgery, certain medications and limited movement." *Id.* (citing Ex. 21 at 2, ECF No. 39-1). Petitioner again reads this to mean that there must be some unique, identifiable event—in his words, a "tipping point"—that triggers the development of DVT. *See id.* at 6.

Petitioner then explains why, in his view, his work as a pilot cannot have contributed to his development of DVT. He asserts that he "did not fly during the time period that could have potentially triggered the clots, and, even if he did, his flight times are likely too short to be a trigger for DVT." Resp. at 6. Petitioner provides no further explanation as to what would constitute a sufficiently close temporal nexus to the development of DVT or what duration of

flights could possibly cause DVT. He does not, in fact, cite any authority for this contention whatsoever.

Petitioner next turns to the crux of his theory of causation: because "[i]t is common knowledge that blood flows to tissues through arteries and back to the heart through veins," it follows naturally that "an injury to a superficial vein causing a clot in that vein can cause additional clots further down." Resp. at 10. Therefore, "[i]t is completely logical to accept that the intramuscular injection injured one or both superficial veins running through the site of injection causing a clot that spread to adjacent veins with the natural flow of blood." *Id.* at 11. Looking to evidence of blood clots in Petitioner's cephalic and basilic veins—identified in Respondent's Exhibit D as superficial veins—Petitioner argues that, in the course of receiving the flu vaccine, he received an injury in one or both of these veins that caused blood clots, which in turn flowed to the deeper adjacent veins. *Id.* at 12 (citing Ex. D, ECF No. 37-1).

Petitioner concludes by asserting that the onset of his injury occurred within a medically reasonable period of time after his vaccination. Resp. at 14–15. Reasoning again by analogy to NS, Petitioner asserts that onset of thrombosis caused by mechanical injury generally occurs within twenty-four hours of the triggering injury. *Id.* at 15 (citing generally Bégin; Corazzo; Gormus; *see also* G. Okan, et al., *Nicolau Syndrome and Perforator Vessels: A New Viewpoint for an Old Problem*, 29 Cutaneous & Ocular Toxicology 70 (2010), filed as Ex. 12, ECF No. 25-8). While acknowledging that Petitioner did not seek medical attention until his father observed the swelling in his left arm several days after the vaccination, Petitioner nonetheless contends that he must have experienced some soreness immediately following the vaccination "based on common knowledge of what typically happens for 99.9% of people after they receive the influenza vaccine" and Petitioner's assertion in his affidavit that he experienced pain shortly after the vaccination. *Id.* at 14. In sum, Petitioner seems to argue that he likely experienced the ordinary post-injection soreness typically associated with uneventful vaccinations, but this soreness simultaneously reflected the onset of his DVT.

While Petitioner initially claimed that the episodes of dizziness he experienced in October 2014 may have been related to the November 2012 flu vaccination, Pet. at 4, he did not reiterate this argument following Dr. Gershwin's assessment that there is no basis for linking the two. Moreover, while he initially claimed to "continue[] to suffer from arm pain [and] arm soreness" *id.*, he provided no medical records or sworn statement to that effect. *See generally* Ex. 18 (no mention of ongoing symptoms); Resp. (no mention of ongoing symptoms).

Finally, although Petitioner does not expressly request a hearing, he argues that if I do not find he is entitled to compensation at this point, then a hearing should be scheduled. Resp. at 17. In particular, he asserts that if I decide against him on the basis of a factual issue, then hearing testimony from Mr. Prepejchal himself or Dr. Gershwin is necessary. *Id.*

VI. 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).[6] 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 by the Federal Circuit in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of

[6] 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).

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." *Id.* 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) (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 Fed. 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.* at 1352; *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.*, 2013 WL 1896173 (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. *Analysis of Expert Reports*

Establishing a sound and reliable medical theory often requires a petitioner to present statements from medical experts in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has been employed to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert reports, a special master's decision may be

"based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination or are central to Petitioner's case. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 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").

E. *Determination to Resolve Case Without Hearing*

I have opted to decide entitlement in this case 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 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

Below, I address the *Althen* prongs relevant and dispositive herein, in order of their significance.[7]

A. *Althen Prong One*

Petitioner has failed to offer a cogent and reliable theory of causation. An initial stumbling block is the overall character of the expert opinion offered (in the absence of scientific or medical literature connecting the flu vaccine to DVT). Petitioner's own expert, Dr. Gershwin, is highly qualified to opine on the subject of immunology—yet he concedes that there is *no immunological connection* between the flu vaccine and DVT. Gershwin First Rep. at 2. Accordingly, accepting Petitioner's causation theory requires adoption of an opinion about a potential mechanism for injury that is outside of Dr. Gershwin's area of expertise, even if he has some familiarity with NS.[8] While I have considered his opinion, it does not gain credibility under such circumstances merely because Dr. Gershwin is a credentialed expert with direct experience on topics *not* relevant to the disposition of this case.

Moreover, the theory itself is predicated on analogizing Petitioner's DVT to a wholly different condition, NS. This comparison is faulty on several levels. It cannot be disputed that Petitioner did not suffer from NS; no treaters ever proposed otherwise, and (again) Dr. Gershwin's expertise does not render such an alternative diagnosis credible, even for comparison's sake only (whereas, in contrast, Dr. Tollefson's dermatologic expertise pertains more directly and thus imbues her opinion with added heft). In addition, as the literature filed makes clear, NS is sufficiently distinct from DVT in terms of presentation and associated symptoms to make it a poor comparison. As noted in literature submitted by Petitioner, NS includes severe and immediate pain at the injection site (Luton at 1327), which Mr. Prepejchal did not experience. It also presents with necrosis of skin tissue (Corazza at 585; Luton at 1326),

[7] Because this claim fails on the first two *Althen* prongs, I do not include an extended discussion of the third. The timing of onset of Petitioner's alleged soreness and post-vaccine administration pain is consistent with that theory, and somewhat consistent with the timeframe in which NS has been observed to begin. *See, e.g.*, Corazza at 586. It is also consistent with a SIRVA Table onset (within 48 hours). Absent a reliable, plausible causation theory, however, the reasonableness of onset *under* that evidentiarily-deficient theory is not enough to save the claim. *Caves v. Sec'y of Health & Human Servs.*, No. 07-443, 2010 WL 5557542, at *21–22 (Fed. Cl. Spec. Mstr. Nov, 29, 2010), *aff'd*, 100 Fed. Cl. 119 (2011).

[8] As a point of comparison, experts who opine in Vaccine Program cases on Shoulder Injury Related to Vaccine Administration ("SIRVA") claims—a well-recognized kind of mechanical injury associated with vaccination—are often orthopedists. *See*, e.g., *Tenneson v. Sec'y of Health & Human Servs.*, No. 16-1664V, 2018 WL 3083140, at *3 (Fed. Cl. Spec. Mstr. Mar. 30, 2018).

which Mr. Prepejchal similarly did not experience. As a result, the fact that NS has been associated with intramuscular injection does not aid Petitioner, since NS is not sufficiently comparable to DVT.

Petitioner's theory of causation is further weakened by the fact that it hinges on his unsupported assertion that DVT requires a known triggering event. Petitioner argues that "there must be a tipping point that triggers the development of a DVT," and "the only potential trigger of Mr. Prepejchal's DVT supporter by evidence was the intramuscular injection he received in the exact spot in which the clots developed." Resp. at 6. In so reasoning, Petitioner effectively conflates two questions of causation: (1) whether DVT, as a general matter, arises spontaneously or as a result of some cause, and (2) whether the onset of DVT can, in every case, be linked to an identifiable and discrete causal event. While Petitioner provides slight evidence on the first question, his position on the second—that *every* case of DVT can be linked to a specific and identifiable trigger—is utterly unsupported. The fact that a disease such as DVT generally has a cause and does not occur spontaneously does not necessarily imply that, in every case, a discrete trigger is identifiable. Indeed, Petitioner's reasoning entirely disregards the well-documented occurrence of idiopathic diseases—that is, those of unknown origin. *Dorland's* at 912. It is consistent with past Vaccine Program decisions to find that a petitioner's injury may have been idiopathic in origin. *See, e.g.*, *Morgan v. Sec'y of Health & Human Servs.*, No. 12-77V, 2017 WL 6893079, at *23 n.32 (Fed. Cl. Spec. Mstr. Dec. 6, 2017). The possibility of an idiopathic DVT is further bolstered by Dr. Lesoski's statement that 25 percent of DVT cases are idiopathic. Ex. 2 at 10.

The medical literature filed in this matter otherwise did very little to advance Petitioner's theory of causation. All articles filed by Petitioner concern NS only. In my own review of that literature, I found nothing to support Petitioner's contention that it would be reasonable to analogize NS to some other mechanical injury. And Petitioner has not offered any other sufficiently reliable evidence upon which it could be concluded that DVT could be caused by the mechanical results of vaccine administration. Dr. Gershwin's reports provide no meaningful explanation of the mechanics of his theory, and nothing suggesting that DVT could have the same etiology as NS.[9] At best, his speculative arguments about the potentiality of clots caused by vaccine administration to result in a down-stream DVT are intellectually interesting and perhaps the subject of future research—not a basis for finding that a plausible, scientifically-reliable causation theory has been established.

[9] The plausibility of Dr. Gershwin's theory of causation is further undermined by the fact that a survey of past Vaccine Program decisions revealed no meritorious DVT claims whatsoever.

B. *Althen Prong Two*

Absent a plausible theory of causation under *Althen* prong one, there is very little to be said regarding *Althen*'s second prong—whether the flu vaccine actually did cause Mr. Prepejchal's DVT. However, even if the causation theory had been plausible, I would still be unable to find on this record that Petitioner's DVT was vaccine-associated.

As the record indicates, two of Petitioner's treating doctors (Drs. Meeker and Lesoski) considered whether the flu vaccine may have caused Petitioner's DVT, reaching somewhat contrary determinations. *See* Ex. 1 at 3, 21; Ex. 2 at 10–12. Dr. Meeker did propose an association in January 2014, but that opinion must be weighed against his earlier assessment—"unsure how [Petitioner's DVT] is related to recent flu shot"—which was far more equivocal, and close in time to vaccination as well. Ex. 1 at 21. He otherwise has not explained the basis of his view (although I nevertheless give it some evidentiary weight). Dr. Lesoski's independent research and consultation with other physicians, by contrast, renders the views he expressed in the medical record on Petitioner's condition more persuasive, and he concluded that "there is no significant evidence that would tell me that this is related to the administration of the influenza vaccine." Ex. 2 at 10. Accordingly, this is not a case where treater views preponderate in the Petitioner's favor, even if there is *some* treater evidence favorable to his claim.

The factual record otherwise does not support an etiology consistent with a mechanically-triggered DVT, whether based upon an analogy to NS, or simply attributed to the vaccination without comparison to injuries known to be mechanical in origin. Mr. Prepejchal may have experienced the ordinary soreness associated with vaccine administration within the day following vaccination, but the extent of any additional pain, soreness, or swelling he experienced subsequently is unclear. The only meaningful link between the flu vaccine Petitioner received and his DVT is a temporal association, which does not suffice to prove causation-in-fact under Vaccine Program law. *McCarren v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 142, 147 (1997).[10]

Although this action does not involve a Table claim, a comparison with the Vaccine Injury Table's treatment of vaccine-caused Shoulder Injury Related to Vaccine Administration ("SIRVA") further illustrates the deficiencies in Petitioner's *Althen* two showing. SIRVA is "not a neurological injury," but rather "is caused by an injury to the musculoskeletal structures of the shoulder (*e.g.* tendons, ligaments, bursae, etc.)." 42 CFR § 100.3(c)(10). It presents with

[10] The parties also addressed Petitioner's work as a pilot as a possible alternative explanation for his DVT, given literature associating the two. While the science offered on this topic supported Respondent's argument, the fact that Mr. Prepejchal's flights were short in duration undercuts the conclusion that his DVT could be attributed to his occupation. But absent an initial showing by a petitioner that the vaccine in question could have caused his injury, there is no need for the special master to determine whether any other environmental factor could have been a superseding cause of the injury. *McCarren*, 40 Fed. Cl. at 147.

shoulder pain and limited range of motion in the shoulder joint. *Id.* To be compensable as a Table claim, SIRVA onset must occur within forty-eight hours of vaccination. *Id.* at § 100.3(a). Thus, the kind of vaccine-caused mechanical injury that is deemed legitimate in the Program involves a fairly immediate response coupled with quickly-identifiable physical deficiencies. Here, by contrast, Mr. Prepejchal did not experience a sudden severe reaction, and the post-vaccination swelling (which it is not clear he even noticed at first) took several days to manifest. The facts of this case are thus not comparable even to the vaccine-caused mechanical injuries that the Program presently recognizes.

C. *Six-Month Residual Effects Requirement*

In addition to the above, there is another deficiency in Petitioner's claim—the sufficiency of his showing that the sequelae of his DVT lasted more than six months.

Program claimants not asserting a vaccine-related death or other injury requiring a specific kind of medical intervention generally must demonstrate that they suffered the residual effects or complications from their vaccine-related injury for more than six months. Section 11(c)(1)(D). Here, it appears that Petitioner's DVT had mostly resolved by January 31, 2013—less than three months after vaccination. *See* Ex. 1 at 11. In the subsequent period, he completed a course of anticoagulant medication treatment by June 6, 2013, more than six months after his symptoms allegedly began. *Id.* at 6. The Petition also states that Petitioner continued to suffer other sequelae—namely, arm pain and soreness—even as recently as the time of filing, although neither the medical records nor Petitioner's sworn statement corroborate such claims. *See generally* Ex. 1; Ex. 2; Ex. 18.[11]

Past decisions in the Vaccine Program indicate that taking medication over a period of time, without evidence of other noticeable effects of an alleged vaccine-caused injury, only satisfies the six-month severity requirement when the medication treats symptomology that would otherwise be present over that time period. Thus, in *Toebe v. Secretary of Health & Human Services*, No. 91-1623V, 1992 WL 101638 (Cl. Ct. Spec. Mstr. Apr. 23, 1992), a special master found that taking anti-seizure medication for several months following vaccine-related seizures did *not* constitute a residual effect or complication of the petitioner's injury. In that case, the petitioner suffered multiple seizures in the day immediately following a vaccination, was placed on phenobarbital, and did not suffer any subsequent seizures even after cessation of phenobarbital. *Id.* at *3. From this, the special master inferred that, while the medication "may have blocked seizures which would have otherwise occurred, a finding that it did could only be

[11] Petitioner also asserted at one point in this course of this case that he experienced related dizziness two years after his vaccination, Pet. at 4, but he seems to have abandoned this position following Dr. Gershwin's assessment that his documented October 2014 vertigo could not be linked to either the flu shot or DVT. *See* Gershwin First Rep. at 2; *see generally* Pet. Resp. (no mention of vertigo).

based on speculation." *Id.* But had the petitioner's seizures resumed after stopping phenobarbital, then the special master would have found that "residual effects continued for more than six months and were [only] masked by the medication." *Id.* It is thus not enough that there is a perceived increase risk of a recurrence of a particular condition to establish severity. *See, e.g.*, *Parsley v. Sec'y of Health & Human Servs.*, No. 08–781V, 2011 WL 2463539, at *5 (Fed. Cl. Spec. Mstr. May 27, 2011) (concluding that "an increased risk of recurrence without an actual recurrence of a condition is not medically recognized as a 'residual effect' and is not a residual effect within the meaning of § 300aa-11(c)(1)(D)(i) of the Vaccine Act").

By contrast, in *Faup v. Secretary of Health & Human Services*, No. 12-78V, 2015 WL 443802 (Fed. Cl. Spec. Mstr. Jan. 13, 2015), another special master found that "the ongoing need for medication to prevent symptoms and/or relapse of the alleged vaccine-caused illness constitutes a residual effect or complication of that illness." *Faup*, 2015 WL 443802, at *4. *Faup* involved a petitioner with juvenile idiopathic arthritis ("JIA") who was prescribed methotrexate in order to help control her symptoms. *Id.* But the *Faup* special master highlighted that "neither expert opined that A.F.'s [arthritis] had been 'cured' at six months post-vaccination"—thereby suggesting that (consistent with *Toebe*) Petitioner's JIA-related symptoms would otherwise have manifested absent medication. *Id.* Accordingly, a course of medicine that is actively treating an ongoing condition, as opposed to being administered prophylactically, *can* be evidence of the condition's underlying severity.

The circumstances of this case are more like *Toebe* or *Parsley* than *Faup.* Mr. Prepejchal's DVT seems to have resolved by early 2013. Neither party filed detailed literature on the course and resolution of DVT, but it appears that anticoagulants of the kind he received (such as Coumadin and Lovenox) are administered to prevent further possible clotting—not to treat an existing DVT, since clots will dissolve on their own.[12] The fact that Dr. Meeker did not recommend further treatment after June 6, 2013, when the initial course of anticoagulants was completed (Ex. 1 at 8) confirms that the DVT had resolved before this time. No other record evidence indicates that Petitioner's DVT or related sequelae continued into 2013 (given the absence of medical records for a lengthy period of time post-vaccination).[13] Thus, although Petitioner's failure to offer a plausible causation theory is a more fundamental failure in his evidentiary showing, his insufficient showing on the severity requirement is another basis for the claim's dismissal.

[12] "Deep Vein Thrombosis (DVT) Diagnosis & Treatment," *Mayo Clinic*, https://www.mayoclinic.org/diseases-conditions/deep-vein-thrombosis/diagnosis-treatment/drc-20352563. Petitioner filed the "Symptoms & causes" subsection from the Mayo Clinic's DVT overview as Ex. 21, but did not include the following "Diagnosis & treatment" subsection.

[13] Had Petitioner been able to point to medical records in the January–June 2013 period in which he sought treatment for ongoing swelling or pain associated with the DVT discovered in November 2013, this finding would be different.

D. *The Case Was Properly Resolved Without a Hearing*

In ruling on the record, I am declining to follow Petitioner's suggestion to hold a hearing.[14] The choice of how best to resolve this case is a matter that lies generally within my discretion, but I will briefly explain my reasoning here.

A hearing provides a petitioner with the opportunity to put on live testimony, which aids the special master most in cases where witness credibility is at issue or where there is a need to pose questions to a witness in order to obtain information not contained in, or not self-evident from, the existing filings. *See, e.g.*, *Hooker*, 2016 WL 3456435, at *21 (discussing a special master's discretion in holding a hearing and the factors that weighed against holding a hearing in the matter); *Murphy*, 1991 WL 71500, at *2 (no justification for a hearing where the claim is fully developed in the written records and the special master does not need to observe the fact witnesses for the purpose of assessing credibility). It may also permit a claimant to expand upon or illuminate points already set forth in paper filings, or respond to unanticipated questions raised in the matter—but again, only where necessary to reach a decision.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes *without* a hearing.

In this case, live witness testimony was not required in order for me to reach a reasoned decision. The flaws in Petitioner's theory of causation were self-evident from my review of the medical records and the three succinct expert reports submitted by Dr. Gershwin. Such deficiencies did not require oral testimony to be understood for purposes of deciding the case. Dr. Gershwin's expertise in the field of immunology gives credibility to his concession that there is no immunological link between the flu vaccine and DVT. At the same time, his inability to meaningfully expound on his "mechanical injury" theory—which relies largely on (1) the faulty assumption that all cases of DVT have a known origin, and (2) an analogy to NS of very little utility—is sufficiently clear from his three written reports. The case turns wholly on whether I accept this theory, and hearing live testimony from Dr. Gershwin would not increase the likeliness of such acceptance.

[14] As noted above, Petitioner did not expressly request a hearing, but in opposing Respondent's motion seemed to suggest that he would desire one if I were not inclined to rule in his favor. Opp. at 17.

I similarly had no need to hear from Petitioner directly. While there is some ambiguity with regard to when he began to experience the swelling in his left arm, the outcome of this case does not turn on onset. Compelling testimony that Mr. Prepejchal experienced swelling and soreness related to his DVT earlier than his medical records indicate would, at most, serve to increase the temporal nexus between the flu vaccination and the onset of his DVT—not bulwark the overall causation theory. As noted above, temporal correlation alone does not suffice to show causation when a petitioner attempts to show causation in fact. A plausible theory of causation must also be proffered, and Petitioner has failed to offer such a theory here.

At bottom, the most significant issue in deciding whether to hold a hearing is determining if the refusal to do so will deprive the claimant of the fair opportunity to prosecute his case. Petitioner here has received such an opportunity. His chances of winning would not have increased merely because his claim was litigated in court.

CONCLUSION

Having reviewed the medical records, expert reports, medical literature, and arguments put forth by the parties, I do not find that Petitioner has established with sufficient preponderant evidence that the flu vaccine he received on November 7, 2012, could have caused, or did cause, his DVT. Accordingly, he has not established entitlement to a damages award and I must **DISMISS** his 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.