In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-706V
Filed: December 17, 2018

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KATHLEEN WYATT,	*	
	*	
Petitioner,	*	
v.	*	Dismissal; Influenza ("Flu") Vaccine;
	*	Guillain-Barré Syndrome; Insufficient
SECRETARY OF HEALTH	*	Proof of Causation
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
* * * * * * * * * * * * * * *	*	

Braden A. Blumenstiel, Esq., Blumenstiel Falvo, LLC, Dublin, OH, for petitioner.
Jennifer L. Reynaud, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

Roth, Special Master:

On August 5, 2014, Kathleen Wyatt ("Ms. Wyatt" or "petitioner") filed a timely petition pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] ("Vaccine Act" or "the Program"). Petitioner alleged that she received a Fluarix vaccine on October 1, 2012, and within a few days, began to feel "joint pain in lower and upper extremities, radiating to upper torso affecting ADL caused by the Fluarix, the flu vaccine." *See* Petition ("Pet.")

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[1] Although this Decision has been formally designated "unpublished," it will nevertheless be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Decision will be available to anyone with access to the internet.** 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. *Id*.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

at 1. Petitioner claims she has continuing symptoms related to the flu vaccine including weakness, numbness, and tingling in her upper and lower extremities. *Id.*

Petitioner has failed to prove by preponderant evidence that she suffers from a definitive vaccine-related injury or that any alleged vaccine-related injury lasted longer than the requisite six months. Moreover, petitioner has failed to satisfy the three prongs set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). Accordingly, for the reasons detailed below, I find that petitioner is **not** entitled to compensation.

I. Procedural History

On August 5, 2014, petitioner filed her petition along with a compact disc containing Petitioner's Exhibits 1-15.[3] ECF No. 1. A Statement of Completion was filed on August 25, 2014. ECF No. 7.

This case was initially assigned to Chief Special Master Dorsey.[4] An initial status conference was held on October 14, 2014, after which petitioner was ordered to file additional medical records requested by respondent. Order, ECF No. 8. The filings by petitioner thereafter are confusing at best, but ultimately petitioner filed a Statement of Completion on January 22, 2015. ECF No. 17.[5]

On February 23, 2015, though the docket states that petitioner filed a status report, it was respondent who filed the status report seeking sixty days to file his Rule 4(c) Report. Respondent's Status Report ("Resp. S.R.") at 1, ECF No. 19. On the same day, Chief Special Master Dorsey ordered respondent to file a Rule 4(c) Report by April 24, 2015. Order at 1, ECF No. 20.

On April 16, 2015, petitioner filed a status report stating that she had submitted a settlement demand to respondent. Pet. S.R. at 1, ECF No. 23. Respondent immediately filed a status report in response advising that he had informed petitioner prior to preparing a settlement demand, that engaging in settlement discussions was not appropriate at this time. Resp. S. R. at 1, ECF No. 25.

On April 24, 2015, respondent filed his Rule 4(c) Report which stated "[P]etitioner has failed to proffer any medical opinion or theory supporting her allegations or establishing a logical cause and effect relationship between the flu vaccine and her alleged injuries." Resp. Rule 4(c) Report at 14, ECF No. 26. Respondent asked that the case be dismissed. *Id.*

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[3] In addition to her medical records, the CD contained a Wage Loss Computation (Petitioner's Exhibit ("Pet. Ex.") 11), Payroll Records (Pet. Ex. 12), a Life Expectancy Chart (Pet. Ex. 13); a PDR Brochure on flu vaccines and an article by CDC on Guillain-Barré ("GBS") (collectively as Pet. Ex. 14).

[4] This case was reassigned to me on October 22, 2015. ECF No. 41.

[5] Counsel repetitively failed to follow the Vaccine Guidelines for filing documents. *See, e.g.*, ECF Nos. 60-65, 79-85.

A Rule 5 status conference was held on May 28, 2015. The Chief Special Master discussed her preliminary views of the case advising that an expert report would be required in order to establish petitioner's claims. *See* Order at 1, ECF No. 27. She noted that petitioner's medical records showed that petitioner's injuries resolved in January 2013—three months after she received the flu vaccination—and that petitioner returned to work at that time. *Id.* The Chief Special Master questioned petitioner's ability to satisfy the six month statutory requirement. *Id.* The Chief Special Master noted that petitioner's case included a claim that petitioner fell down the stairs and fractured her left leg as a result of weakness associated with the October 1, 2012 flu vaccine. *Id.* She noted petitioner could probably provide expert testimony that a leg fracture of this kind takes at least six months to heal, thus enabling petitioner to meet the statutory duration requirement. *Id.* Petitioner was ordered to file additional medical records by June 29, 2015. Respondent was ordered to file a status report thirty days thereafter. *Id.* at 2.

Petitioner filed additional medical records in June and August 2015. Pet. Exs. 23-28, ECF Nos. 28, 34.

On September 21, 2015, respondent filed a status report requesting twenty-one days to decide how to proceed, which was granted. Resp. S.R. at 1, ECF No. 36. On October 13, 2015, Respondent filed a status report stating that he was not interested in entertaining settlement discussions without an expert report in support of petitioner's claim. Resp. S.R. at 1, ECF No. 38. Petitioner was ordered to file an expert report by December 14, 2015 and respondent was to file an expert report sixty days thereafter. Order at 1, ECF No. 39.

On February 10, 2016, after two motions for extensions of time (ECF Nos. 42-43), which were granted, petitioner filed an expert report from Dr. Phillip DeMio and an "opinion letter" from Dr. Charles MacCallum, petitioner's treating physician. Pet. Exs. 29, 31, ECF No. 44. A Statement of Completion was filed on February 16, 2016. ECF No. 46.

On February 23, 2016, petitioner filed updated medical records and an Amended Statement of Completion. Pet. Exs. 32-34, ECF Nos. 47, 49. On April 11, 2016, respondent requested an extension of time to file a responsive expert report, which was granted. *See* ECF No. 50.

On May 11, 2016, respondent filed a status report advising that he transmitted a counteroffer to petitioner's April 2015 settlement demand on May 4, 2016. Resp. S.R. at 1, ECF No. 51. In response thereto, on May 31, 2016, petitioner filed a status report stating that respondent's initial counteroffer "of insignificant figures made it clear that settlement is not a realistic potential in this case." Thus, in order to "help clarify the evidence," petitioner requested that respondent depose petitioner, her primary care physician, and her other treating physicians. Pet. S.R. at 1, ECF No. 52.

A status conference was scheduled for June 29, 2016 by Order of the Court on June 9, 2016. Order at 1, ECF No. 53.

On June 29, 2016, in anticipation of the status conference, respondent filed a status report highlighting the weaknesses in petitioner's case as set forth in his Rule 4(c) Report and noting he concurred with petitioner that it is "clear that settlement is not a realistic potential in this case." Resp. S. R. at 1, ECF No. 54. He also pointed out that petitioner's expert, Dr. DeMio's "practice focuses on the medical testing and treatment for you and/or loved one with Autism Spectrum Disorder." *Id.* Further, respondent noted that petitioner's primary care physician, Dr. McCallum, did not offer any specific diagnosis or theory of causation as to how the flu vaccine could have caused petitioner's condition. *Id.* Respondent added that efforts to resolve this matter were in good faith, but informal resolution did not appear possible. *Id.* A date for respondent's expert report was requested. *Id.*

A status conference was held on June 29, 2016, at which time a lengthy discussion took place regarding petitioner's claims. The discussion included petitioner's claim that her symptoms began within 24 hours of vaccination; the lack of any definitive diagnosis or injury by any treating physician associated with the flu vaccine in the medical records; and a lack of any treatment for the alleged injuries after January 2013, three months post-vaccination, contained in the medical records. Order at 1-2, ECF No. 55. Further discussed were the opinions and conclusions contained in Dr. DeMio's report which stated that as a result of her flu vaccine, petitioner suffered from autoimmunity, Guillain-Barré syndrome ("GBS"), and inflammatory arthritis. *Id.* I ordered petitioner to file a supplemental report from Dr. DeMio that "include[d] specific references to the exact medical records, test results, and literature upon which [he] has relied in concluding that petitioner suffer[ed] from a vaccine-related injury." *Id.* at 2. Dr. DeMio was also ordered to address each of the three prongs established in *Althen*, 418 F.3d at 1278. *Id.* Petitioner's counsel advised that petitioner had been recently re-evaluated by Dr. MacCallum; I noted that Dr. MacCallum had already submitted a written statement that "there is no way to prove cause and effect" between petitioner's symptoms and the flu vaccine, and "evaluations by rheumatology had failed to unearth any significant autoimmune disease." *Id.* (citing Pet. Ex. 31).

On July 14, 2016, petitioner filed additional records. Pet. Ex. 35, ECF No. 56.[6] On September 20, 2016, petitioner filed a supplemental report from Dr. DeMio along with medical literature. Pet. Exs. 36-41, ECF No. 63. Dr. DeMio's supplemental report failed to address the *Althen* prongs and simply repeated the statements contained in his first report. There were no references to the medical records or what he relied upon in reaching his conclusions. *See generally* Pet. Ex 36; *cf.* Pet. Ex. 29.[7]

[6] On July 21, 2017, petitioner filed a notice advising that Dr. MacCallum's notes in Pet. Ex. 35 were his intended written report. *See* ECF No. 58.

[7] Petitioner's counsel continued to ignore the Vaccine Guidelines when filing documents throughout the next year, despite numerous reminders to consult the Guidelines. Consequently, the docket in this matter contains several erroneously filed documents and filings that were struck from the record. *See e.g.* ECF Nos. 60, 80, 93.

On October 13, 2016, petitioner filed a status report advising that on August 1, 2015, petitioner had fallen in a parking lot, fracturing her hip, and had filed a civil action in the State Court of Ohio against the property owner for personal injuries. Pet. S.R. at 1, ECF No. 66.[8] Attached to the status report was the Complaint and Demand Letter filed by petitioner's counsel as her attorney in the State Court civil suit for personal injuries. *See id.* at 3-11.

A status conference was held on October 25, 2016, during which the merits of Petitioner's case were once again discussed. Respondent advised of his intention to file a Motion to Dismiss. Order at 1, ECF No. 67.

On January 6, 2017, respondent filed a Motion to Dismiss, arguing that Petitioner failed to demonstrate by preponderant evidence (1) that she suffered a medically-recognized injury; (2) that any symptoms persisted for more than six months as required by the Vaccine Act; and (3) that she had satisfied the causation requirements under *Althen*. Motion to Dismiss at 4-5, ECF No. 68. On January 23, 2017, Petitioner filed a copy of Dr. DeMio's Curriculum Vitae (Pet. Ex. 42), and a response to the motion to dismiss, arguing that Petitioner's affidavits and medical records provided "an overwhelming amount of evidence" to satisfy the six-month requirement and *Althen*. Response to Motion to Dismiss at 13, ECF No. 70.

On April 21, 2017, an Order was issued, advising that a comprehensive review of all of the evidence filed in this matter revealed that petitioner's complete medical history for the three years prior to her vaccine had not been filed, due to references in the record of a history of arthritis (Pet. Ex. 4) and fibromyalgia (Pet. Ex. 5 at 9) prior to the October 1, 2012 vaccination. Order at 1, ECF No. 72. It was pointed out that petitioner had previously been ordered to file these records, but failed to do so. *See* Order, ECF No. 8. Petitioner was again ordered to file complete medical records by June 20, 2017. Order at 1, ECF No. 72. Respondent's Motion to Dismiss, along with petitioner's response, was not ruled upon because additional evidence was required.

Petitioner missed the June 20, 2017 filing deadline. After two reminders from Chambers, a "Response to the 4/21/17 Order" was filed by petitioner's counsel, detailing the closing of his law firm, the exit of his secretary, and the disabling of his PACER account. Response at 1, ECF No. 74. Petitioner's counsel then provided a detailed analysis of petitioner's medical records, *his* opinions regarding her health prior to the alleged vaccinations, and *his* explanations for the contents of her medical records, including references to arthritis and fibromyalgia. *Id.* at 2-3.

On June 26, 2017, a Non-PDF Order was issued requiring petitioner, not her counsel, to affirm that the records filed in this matter were complete, accurate, and contained all of her medical care for the five years prior to and since her vaccination. Non-PDF Order, dated June 26, 2017. She was also ordered to affirm that, despite the references in the record, she was never diagnosed

[8] The Court was notified of petitioner's fall and related injuries only after petitioner's counsel filed a lawsuit in State Court against the owner of the parking lot – nearly 10 months later. Pet. S.R. at 1, ECF No. 66.

with arthritis or fibromyalgia. *Id.* Petitioner filed her affidavit on July 20, 2017. Pet. Ex. 43; ECF No. 76.

On July 21, 2017, petitioner filed "Petitioner's Motion for a Hearing on Entitlement." In it, petitioner stated that Pet. Exs. 1-43 support a ruling in her favor. ECF No. 80 (improperly designated on the docket as "Stricken see Order filed 12/22/17). She "…believes the record is complete and the case is ready for a decision on entitlement… Thus, I file this Motion for Hearing on Entitlement during which we could depose Dr. MacCallum and I would ask the Court's permission to have Petitioner Kathleen Wyatt and her 2 adult daughters be allowed to offer their testimony, as well, and undergo cross examination by Respondent's Attorney and questions by Special Master Roth, as well. After said depositions, Petitioner would then ask this Court for a Ruling on Entitlement based on the Record and to allow briefs, if the parties so desire." *Id.* at 1-2.

On August 4, 2017, respondent filed his response to petitioner's Motion for a Hearing on Entitlement, pointing out that respondent had previously filed a Motion to Dismiss on January 6, 2017, and petitioner had filed a response arguing that her case should not be dismissed. Resp. Response at 1, ECF No. 81 (citing ECF Nos. 68, 70). Respondent further noted that on April 21, 2017, the Court ordered petitioner to file additional medical records for at least three years prior to October 1, 2012. *Id.* (citing ECF No. 72). Respondent noted that subsequently, petitioner filed a supplemental affidavit addressing the medical records as petitioners' Exhibit 43. *Id.* (citing ECF No. 76). Respondent referenced an email from Chambers in which the parties were advised that testimony from Dr. MacCallum would be helpful to clarify some issues in petitioner's medical records.[9] *Id.* Respondent pointed out that in response to that inquiry, petitioner filed a Motion for a Hearing on Entitlement. *Id*. Respondent proposed that testimony of Dr. MacCallum be taken by telephone in order to conserve resources. *Id.* Respondent pointed out that affidavits of petitioner and her daughters were already part of the record, therefore additional testimony would not assist in the special master's factual findings. *Id.* Respondent added that it was his position that "any hearing at this juncture would be for the limited purpose of ruling on respondent's pending Motion to Dismiss." *Id.* at 2. Respondent added that should his Motion be denied, then he would submit rebuttal evidence regarding causation and entitlement, but based on the current record, petitioner's claim should be dismissed as it "lacks the factual and legal basis to establish petitioner's entitlement to compensation." *Id.*

On August 7, 2017, petitioner filed additional literature along with an Amended Exhibit List. Pet. Exs. 44-46, ECF Nos. 82-83. On that date, petitioner also filed "Petitioner's Supplemental Motion for a Hearing on Entitlement." ECF No. 84. (The docket reads "Stricken, see Order filed 8/8/17"). A Non-PDF Order was issued, striking document No. 84 as already filed. Non-PDF Order, dated Aug. 8, 2017.

On August 9, 2017, petitioner filed a status report stating that she filed a "Supplemental Motion for a Hearing on Entitlement" on August 7, 2017, but the Court struck it, believing it was

[9] An informal entry regarding this communication was inadvertently not entered on the docket.

a duplicate of the Motion filed earlier. ECF No. 85. Petitioner submitted that it was titled 'Supplement' because she filed all of the text contained in the earlier Motion, and "added material at the end of the Motion for Hearing." *Id.*[10]

A fact hearing was ultimately scheduled for November 16, 2017. Prehearing Order, ECF No. 89. A prehearing conference was held on November 14, 2017, at which time it was confirmed that Dr. Charles MacCallum would be the only witness testifying. Order at 1, ECF No. 90. He and petitioner's counsel would appear by videoconference from Ohio. *Id.* Counsel was reminded that the hearing was limited to petitioner's alleged injuries and not damages. *Id.*

The hearing was conducted on November 16, 2017. *See* Scheduling Order at 1, ECF No. 90. On November 20, 2017, petitioner's counsel filed a status report advising that Braden Blumenstiel, his son, would be substituting in as counsel of record. Pet. S.R. at 1, ECF No. 91. A Consented Motion to Substitute Attorney was filed on November 22, 2017. ECF No. 92. Prior counsel then filed an Application for Fees and Costs. ECF No. 93. Current counsel was advised that his father's Application for Fees and Costs was premature. Informal Communication, dated Dec. 19, 2017. A Motion to Strike was filed and granted. ECF Nos. 93, 96.

On December 21, 2017, petitioner's counsel contacted Chambers to advise that he would be filing a Motion to Strike the Motion for an Entitlement Hearing (ECF No. 80) and would discuss with Respondent's counsel how to proceed with respondent's pending Motion to Dismiss. Non-PDF Order, dated Dec. 21, 2017. Petitioner filed her Motion to Strike the First Motion for Hearing on Entitlement on Dec. 22, 2017. ECF No. 97. An Order granting the Motion to Strike was entered that day. Non-PDF Order, dated Dec. 22, 2017.

A status conference was held on January 18, 2018. Since medical records, affidavits, and testimony were provided after respondent's Motion to Dismiss was filed, I suggested that respondent move to strike his Motion to Dismiss and that Petitioner file a Motion for Ruling on the Record. Scheduling Order at 1, ECF No. 98. Respondent's counsel suggested that petitioner file her Motion for Ruling on the Record and the Court render the Motion to Dismiss moot in the decision. *Id.* Petitioner's current counsel asked for an opportunity to review and analyze the file in order to determine whether there were any holes in the record he needed to address before he filed the Motion for Ruling on the Record. *Id.* I discussed the same issues in this case that I previously discussed with predecessor counsel, including, but not limited to there being: (1) no diagnosis of any injury or illness causally related to the vaccine, and (2) no medical records filed supporting any illness or injury lasting longer than six months after vaccination. *Id.* Petitioner's counsel was specifically ordered to review the entire docket in this matter, all prior orders issued, as well as all of the medical records, reports and testimony of Dr. MacCallum. *Id.* Counsel was ordered to file a status report in sixty days advising that he had in fact conducted a thorough review of the file. He was to update the Court on how petitioner intended to proceed. *Id.* Petitioner's counsel was

[10] Petitioner's counsel's continued refusal to follow the Vaccine Rules and Guidelines caused the docket to be unnecessarily confusing and messy.

reminded that contemporaneous medical records carry more weight than the facts provided by petitioner in affidavits prepared years after the events took place. *Id.*

Instead of complying with the Court's Order, on March 15, 2018, petitioner filed a status report stating that his review of respondent's Motion to Dismiss "demonstrates it is focused on the singular issue of whether petitioner's symptoms lasted the requisite six months after vaccination. Pet. S.R. at 1, ECF No. 99. As symptoms lasting six months or longer after vaccination is a prerequisite for compensation under the National Vaccine Act, petitioner believes a ruling on the currently-pending motion to dismiss would provide guidance and assistance to the parties, and help narrow the disputed issues, as we work to bring this claim to a resolution." *Id.* Petitioner further offered that predecessor counsel responded to the Motion to Dismiss by arguing that petitioner's daughters' affidavits, treating physician, physical therapist, medical records, and reports from retained experts demonstrated that her symptoms lasted the required six months to warrant compensation. *Id.* at 2. Petitioner asked that the Court rule on the pending Motion to Dismiss. *Id.*

In response thereto, I issued an order on March 20, 2018, pointing out that petitioner's submission ignored several aspects of respondent's Motion to Dismiss. Order at 1, ECF No. 100. First, respondent's motion to dismiss was filed in January 2017, following which additional evidence was filed and had not been addressed. *Id.* Second, in the Motion to Dismiss, respondent argued that, in addition to the failure to meet the six-month requirement, petitioner failed to satisfy any of the *Althen* causation prongs. *Id.* (citing ECF No. 68). Third, a fact hearing was held in which petitioner's primary care physician, Dr. MacCallum, testified. Dr. MacCallum's testimony had not been—and certainly needed to be—addressed by petitioner. *Id.* Finally, the Court's ruling on the Motion to Dismiss was not an option offered to petitioner nor contemplated at the recent status conference. *Id.* To the contrary, counsel was ordered to review the record and all of the Orders previously entered in this matter with the contemplation that petitioner would either "file a Motion for Ruling on the Record" addressing all of the evidence now in the record or move for dismissal of the case. *See id.*[11]

On May 21, 2018, petitioner filed two exhibit lists, the second attaching the transcript of Dr. MacCallum's testimony at hearing as an exhibit. ECF Nos. 101-02. Also on May 21, 2018, petitioner filed a Motion for Judgment on the Administrative Record. ECF No. 103. On June 4, 2018, respondent filed his Response. ECF No. 104. Petitioner filed a Reply on June 11, 2018. ECF No. 105.

Respondent's Motion to Dismiss was rendered moot by the additional evidence filed into the record along with the testimony of Dr. MacCallum. Petitioner's Motion for Ruling on the Record is now ripe for determination.

[11] Petitioner's counsel never filed a status report confirming that he reviewed the entire record as ordered, and his filling confirms that he failed to do so.

II. Petitioner's Medical and Personal History

A. Petitioner's History Prior to the Allegedly Causal Flu Vaccine

Petitioner was born on September 15, 1952. Petition at 1. Her past medical history includes stage III melanoma, benign right temporal clinoidal meningioma,[12] and osteopenia.[13] Petitioner also has a history of dyspnea[14], hyperhomocystinemia,[15] fatigue and chronic low white blood count. Pet. Ex. 20 at 5; Pet. Ex. 23 at 6. Despite these health issues, petitioner described her overall health and physical activities in the years prior to the allegedly causal flu vaccine on October 1, 2012, as "more active than most individuals at [her] age." Pet. Ex. 1 at 2. Her daughter, Amanda Grace, stated petitioner walked several miles a day, lifted weights, and tackled a variety of personal projects at home. Pet. Ex. 3 at 2; Pet. Ex. 18 at 1. Petitioner was also an active grandmother, helping change her grandchildren's diapers, frequently carrying them up and down stairs, and playing with them on the floor. Pet. Ex. 3 at 2.

Petitioner spent the majority of her career working as a physical therapist after receiving her Bachelor of Arts degree in Psychology and a Bachelor of Science degree in Physical Therapy. Pet. Ex. 1 at 2. She worked as a Senior Physical Therapist at University Hospitals Ahuja Medical Center ("UHAMC") in Beachwood, Ohio from 2011 to 2014. This was a physically demanding position that required petitioner to frequently use her hands when working with clients and completing day-to-day tasks.

The only remarkable medical records filed from the three years prior to the allegedly causal flu vaccine came from visits on January 1, 2012, and August 22, 2012, the year of her vaccine. Petitioner presented to her primary care physician, Dr. Charles MacCallum, on January 1, 2012, for a routine physical. Petitioner returned to Dr. MacCallum on August 22, 2012, "with multiple complaints" – although the records from this visit did not indicate what petitioner's complaints were. At both visits, Dr. MacCallum noted petitioner had failed to follow up with oncology regarding her meningioma for several years. Pet. Ex. 7 at 197. Thus, she was referred to a

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[12] Clinoidal meningioma is defined as "a benign, slow-growing tumor of the meninges usually next to the dura mater, probably arising from cells associated with arachnoid villi. . ." in the clinoid process of the sphenoid bone. *Meningioma*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1132 (32d ed. 2012) [hereinafter DORLAND'S]; *processus clinoideus anterior*, DORLAND'S at 1519.

[13] Osteopenia is defined as "any decrease in bone mass below normal." *Osteopenia*, DORLAND'S at 1347.

[14] Dyspnea is defined as "breathlessness or shortness of breath." *Dyspnea*, DORLAND'S at 582.

[15] Hyperhomocystinemia is defined as "the presence of excessive homocysteine in the blood, a condition closely related to homocystinuria." *Hyperhomocysteinemia*, DORLAND'S at 889. Homocysteine is defined as "a type of amino acid, a chemical [the] body uses to make proteins. . . . There should be very little homocysteine left in the bloodstream. If [there is] high levels of homocysteine in [the] blood, it may be a sign of a vitamin deficiency, heart disease, or a rare inherited disorder." *Homocysteine Test*, MEDLINE PLUS, https://medlineplus.gov/lab-tests/homocysteine-test/ (last visited Dec. 4, 2018).

dermatologist, Dr. Gerstenblith, and a neurosurgeon, Dr. Selman, for examination. *Id.* Additional tests were ordered including a diagnostic mammogram and thyroid function labs. *Id.*

B. Petitioner's History Following the Allegedly Causal Flu Vaccine

Petitioner received the allegedly causal flu vaccine on October 1, 2012, as required by her employer, UHAMC. Pet. Ex. 17 at 1. Petitioner has provided conflicting accounts regarding the onset of her symptoms. In her initial affidavit, petitioner said she completed her normal workout routine the night she received the flu vaccine and began experiencing left hand and wrist discomfort the next day, October 2, 2012.[16] Pet. Ex. 1 at 4. In a supplemental affidavit, petitioner stated she began experiencing symptoms in her hands, arms, feet, and legs within a "few days" of receiving the flu vaccine. Pet. Ex. 17 at 1. These symptoms included "sharp shooting pain in [her] hands and forearms, initially beginning first in [her] left hand and arm then progressing to include [her] right hand and arm. . . It felt like [an] electric 'zap' that traveled from [her] hand . . . to [her] elbow." In the worker's compensation claim form she filed, petitioner stated she "began to experience pain and weakness in both hands and feet with shooting pain distal to proximal within twenty-four hours of receiving the vaccine." Pet. Ex. 5 at 4. Petitioner also stated that within 7-10 days following the vaccine, she began experiencing the pain and weakness she had initially felt in her upper extremities, in her legs and feet. Pet. Ex. 17 at 1. Petitioner's co-worker, Cordell Jones, affirmed that petitioner complained of pain and weakness in her hands and forearms initially" after receiving the vaccine, and then indicated pain and unsteadiness in her feet and legs. Pet. Ex. 24 at 1. Ms. Wyatt's younger daughter who lived with her, Lindsay Wyatt ("Lindsay"), stated that petitioner complained several times a day of severe hand and wrist pain following the flu vaccine and required additional help around the house. Pet. Ex. 2 at 2.

The week petitioner received the flu vaccine, her older daughter, Amanda Grace ("Ms. Grace"), was scheduled to visit petitioner with her family. Pet. Ex. 17 at 1, 4. According to petitioner and her daughters, this visit was a struggle, as petitioner was experiencing pain that "engulfed both hands with shooting pain radiating distal to proximal with . . . increasing foot and lower leg pain spastically shooting frequent pain from great toes throughout the feet up through the lower legs into the knees." Pet. Ex. 1 at 7. Ms. Grace and Lindsay both stated they could tell something was wrong with Ms. Wyatt during this October 2012 visit. Ms. Grace noted her mother taking Aleve, observed swelling in her hands, and heard several complaints of fatigue and weakness. Pet. Ex. 3 at 2; *see also* Pet. Ex. 18 at 1. Ms. Grace's visit in October 2012 was much different from the one she had with her mother in July and August 2012, when petitioner came to help Ms. Grace while she was on maternity leave with her newborn daughter and two year old son. Pet. Ex. 3 at 2; Pet Ex. 18 at 1.

[16] Petitioner submitted three affidavits in this matter. Her first affidavit was submitted on October 1, 2013 with her petition. Pet. Ex. 1. She submitted her second affidavit on November 20, 2014. Pet. Ex. 17. The third affidavit, entitled "Supplemental Affidavit," was filed on July 19, 2017. Pet. Ex. 43. These "affidavits," along with the affidavits of petitioner's daughters, are comprised of a series of questions posed by petitioner's counsel and petitioner's answers to those questions. These affidavits are more akin to interrogatories than traditional affidavits filed in the Vaccine Program

Petitioner stated that when she returned to work on October 15, 2012, she could no longer tolerate the pain in her hands and "pleaded" with coworkers to assess the symptoms she "developed since receiving the flu shot on October 1, 2012." Pet. Ex. 1 at 7; *see also* Pet. Ex. 17 at 2. One of petitioner's coworkers suggested petitioner's recent flu vaccine could be the cause of her symptoms and suggested petitioner speak to their supervisor. Pet Ex. 17 at 2. Petitioner's supervisor directed her to Donna Gigliotti, R.N., a nurse at the corporate health department. Nurse Gigliotti filed a Vaccine Adverse Event Reporting System ("VAERS") Report with the Center for Disease Control on October 16, 2012. In this report, Nurse Gigliotti stated petitioner suffered from "[j]oint pain in lower and upper extremities radiating to upper torso affecting ADL." Pet. Ex. 4 at 1. She wrote that petitioner told her these symptoms began on October 10, 2012. *Id.* On the VAERS Report, arthritis was listed as a pre-existing condition. *Id.* Nurse Gigliotti advised petitioner to follow up with her primary care physician for further treatment. Pet. Ex. 1 at 7.

On October 16, 2012, petitioner presented to Dr. MacCallum with complaints of soreness from her hands up to her elbows and in her feet, as well as mobility issues and fatigue in her fingers. Dr. MacCallum wrote that petitioner's symptoms started after a flu shot received two weeks prior to this visit but noted as well that she had previously been diagnosed with fibromyalgia. Pet. Ex. 7 at 196.[17] Bloodwork was performed at this visit and showed a positive ANA and a parvovirus antibody.[18] Dr. MacCallum prescribed prednisone and referred petitioner to a rheumatologist, Dr. Aminda Lumapas, for myalgias and joint symptoms. Pet. Ex. 5 at 9.

According to petitioner, by October 24, 2012, she realized that she needed further medical intervention and was planning on calling Dr. MacCallum to discuss her symptoms. However, on October 28, 2012, she fell down the stairs in her home, injuring both of her ankles. Lindsay heard her mother fall down the stairs. Pet. Ex. 2 at 3-4. Petitioner presented to Ahuja Medical Center Emergency Department and stated that she was "walking down the stairs when she evidently missed 2 steps" and then heard "a pop on the left side and [has since] had pain in her left malleolar area" as well as her right ankle. Pet. Ex. 7 at 201. Petitioner affirmed that she later tried to tell the ER staff that the symptoms following her flu vaccine caused her fall, but the "busy staff member had gathered the minimal information needed to complete each line on the their forms and nothing further was entered regardless of [her] continued explanation of the symptoms." Pet. Ex. 1 at 8. X-rays confirmed a fracture of her left ankle. Pet. Ex. 7 at 202. Petitioner was discharged that day with a splint, crutches, and pain medication. She was directed to follow up with an orthopedist. *Id.*

[17] Dr. MacCallum's note that petitioner had fibromyalgia was crossed out on the record at some point, but there is no indication as to when that happened. Tr. 11.

[18] The ANA test is "used to diagnose systemic lupus erythematosus (SLE) and other autoimmune diseases. The antibodies are primarily used to screen for SLE. Because almost all patients with SLE develop autoantibodies, a negative ANA test excludes the diagnosis. If the ANA test is positive, other antibody studies must be done to corroborate the diagnosis." *Mosby's Manual of Diagnostic and Laboratory Tests* 80 (Pagana eds., 6th ed. 2018).

After the fall, according to Lindsay, she became her mother's "24/7 live-in caregiver," as petitioner "needed help with nearly every aspect of daily life." Pet. Ex. 3 at 4.

On November 1, 2012, petitioner presented to an orthopedist, Dr. Robert Corn. Pet. Ex. 9 at 139. According to Dr. Corn's record, petitioner informed him she "misjudged the bottom two steps [at her home] and fell injuring both ankles," which resulted in a comminuted, but essentially nondisplaced left distal fibular fracture. *Id.* After examining petitioner, Dr. Corn opined that petitioner was in "minimal distress other than with her left ankle and due to the fact that she is going to be out of work for a period of time." He concluded petitioner's fracture "should heal without surgical intervention." *Id.* He fitted her with a CAM walker boot and completed FMLA and short-term disability forms. *Id.* There is no mention of any complaints of pain and or weakness in petitioner's hands, arms, legs, or feet at this visit. *See id.*

Petitioner returned to Dr. Corn's office on November 13, 2012. Dr. Corn noted there was no significant change in her fracture pattern since the previous visit. Pet. Ex. 9 at 136. Dr. Corn referred petitioner to Dr. Anouchi for her next scheduled visit, while he was away. He further noted that by the next visit, petitioner could consider going back to work. *Id.* There was no mention of any complaints and/or weakness in petitioner's hands, arms, legs, or feet. *See id.*

On December 5, 2012, petitioner presented to Dr. Anouchi for follow-up regarding her left ankle fracture and right ankle sprain. Pet. Ex. 9 at 133. X-rays revealed a healing nondisplaced fracture of the right distal fibula. *Id.* Dr. Anouchi noted residual swelling in petitioner's left lateral ankle with tenderness to palpation along the fracture line. *Id.* He also noted some right ankle tenderness along the medial deltoid ligament. *Id.* Petitioner advised she had been transitioning out of the CAM walker boot, but was still not putting significant weight on her left ankle. *Id.* She was instructed to continue wearing the boot when she was out of the house. She was informed it was unlikely she could return to work, given the strenuous nature of her job, until the ankle was fully healed. *Id.* Dr. Anouchi ordered petitioner to follow up with Dr. Corn in four weeks. *Id.* There is no mention of any complaints of pain and/or weakness in petitioner's hands, arms, legs, or feet. *See id.*

On December 18, 2012, petitioner contacted Dr. Corn by letter requesting that he complete a travel insurance form, so she could extend her trip to her daughter. Pet. Ex. 9 at 163. In the letter, petitioner stated she "continue[d] to experience joint pain in both [her] upper extremities as well as my lower extremities as [she] had been since [she] received her flu vaccine on October 1, 2012." *Id.* Dr. Corn completed the form based on petitioner's November 1, 2012 examination and submitted the form to petitioner's insurance company on December 21, 2012. *Id.*

On January 3, 2013, petitioner presented to the rheumatologist, Dr. Lumapas, complaining of painful joints, especially in her wrists. Pet. Ex. 10 at 308. Petitioner informed Dr. Lumapas that she had shooting pain in her thumbs from her wrists to her elbows. *Id.* She also mentioned pain in her feet and lower legs, with shooting pain from her big toes to her heels. *Id.* Petitioner told Dr. Lumapas that the prednisone prescribed by Dr. MacCallum "didn't really do anything for her

symptoms." *Id.* Dr. Lumapas ordered a series of blood tests which showed a decreased white blood cell count, which was possibly caused by the medication petitioner took related to her cancer diagnosis, and a positive ANA. *Id.* at 314. Dr. Lumapas opined that petitioner may have previously had a positive ANA along with some autoimmune disorder that could have been exacerbated by her October 2012 flu vaccine, but she was unsure if the vaccine was related to petitioner's current symptoms. *Id.* Dr. Lumapas ordered x-rays of petitioner's hands and right foot. *Id.* She instructed petitioner to follow up in two weeks. *Id.*

On January 4, 2013, petitioner had blood work performed that revealed normal or negative results for all tests performed except for a low white blood cell count and a positive ANA. Pet. Ex. 7 at 216-23.

On January 7, 2013, petitioner had appointments with a dietitian, Kimberly Ortega, and oncologists, Drs. Christian Okoye and Simon Lo, for issues unrelated to her injuries claimed to be from the flu vaccine. Nothing significant was noted at either visit.

On January 8, 2013, petitioner returned to Dr. Corn for follow up. X-rays taken revealed "almost complete healing of the fracture." Pet. Ex. 9 at 132. Dr. Corn advised petitioner to begin weaning out of wearing the walking boot. He released her back to work on the following Monday for four hours a day for two weeks, and then back to full time "when she can tolerate it." *Id.* He ordered follow up in one month. *Id.*

Petitioner returned to work on January 11, 2013 as directed by Dr. Corn, with minor restrictions. Pet. Ex. 8 at 286. Once she was back at work, she wore the walking boot, with a surgical shoe cover over it to comply with her employer's footwear policy. Petitioner noted that once she returned to work, she noticed her hands and forearms hurt more than her legs. She stated it was difficult for her to work with patients and carry charts throughout her workday and required assistance from coworkers and aides. Petitioner claimed the pain and weakness in her hands and feet, and the anxiety that accompanied her injuries, had put her "in great risk of being fired." Petitioner had several warnings placed in her record, including a final warning, allegedly as a result of her injury.[19] Pet. Ex. 17 at 4-5.

On January 14, 2013, petitioner returned to Dr. MacCallum complaining of pain in her hands and metacarpophalangeal joints and shooting pain in her foot that began the day after the flu vaccine. Pet. Ex. 7 at 195. Dr. MacCallum noted petitioner's complaints of fatigue and increased pain in her hands since returning to work. *Id.* X-rays of petitioner's right hand revealed

[19] Petitioner claims that after she explained to her co-workers that she was having heightened anxiety with sudden unexpected position changes, they targeted her with a prank so that when she sat down in her chair for lunch, the chair tilted back suddenly, eliciting anxiety. Pet. Ex. 1 at 13. She claims that she repeated multiple times that "it wasn't funny" and when she turned around one of them was laughing. *Id.* She then used expletives, for which she was advised she may be reprimanded, further heightening her anxiety about losing her job. *Id.* There is no record of any reprimand as a result of job performance. Petitioner did not lose her job until November 2014, over two years after her vaccine. Pet. Ex. 24.

mild marginal osteophytosis at the first digit interphalangeal joint as well as the second through fifth digits distal interphalangeal joints. Pet. Ex. 21 at 19. There were no periarticular erosive changes and no radiographic evidence of inflammatory arthritis. However, in a letter to petitioner's employer exempting her from future required flu vaccines, Dr. MacCallum opined petitioner had "developed polyarthritis in her hands and feet after receiving a flu shot on 10/01/12." Pet. Ex. 8 at 289.

Petitioner returned to Dr. Lumapas on January 17, 2013. The record states she reported she had begun to feel better. Pet. Ex. 10 at 299. Petitioner complained of some joint swelling but was having less difficulty manipulating her hands. Dr. Lumapas opined that petitioner may have developed a reactive arthritis process after receiving the flu vaccine on October 1, 2012, but that "has now resolved." *Id.* at 307. Dr. Lumapas also noted that she was unsure as to the significance of petitioner's positive ANA, since petitioner did not have results consistent with SLE, she just had mild inflammation. *Id.*

On January 30, 2013, petitioner presented to Dr. Meg Gerstenblith, a dermatologist, for follow up regarding her melanoma. Pet. Ex. 23 at 28; Pet. Ex. 7 at 231-33. A skin biopsy of petitioner's left forearm taken that day revealed basal cell carcinoma and superficial growth pattern present on the peripheral margin. Pet. Ex. 23 at 28.

On February 1, 2013, Dr. Corn issued a Return to Work Authorization stating that petitioner could return to work on February 4, 2013, with no restrictions. Pet. Ex. 9 at 168. He noted she should "continue to wear her walking boot at her discretion for comfort and support." *Id.* Petitioner had no further appointments with Dr. Corn or any other orthopedic specialist regarding her injuries related to the October 28, 2012 fall.

Once she returned to work, two co-workers noted her continued mention of pain, particularly in her wrists and fingers, which made it more difficult for her to do her job. *See* Pet. Ex. 25 at 1; Pet. Ex. 24 at 1.

On February 7, 2013, an Employee Incident Report was issued by Ahuja Workers Compensation summarizing the events surrounding petitioner's allegedly causal flu vaccine. Pet. Ex. 8 at 295-96. The report stated petitioner "began experiencing [pain] and weakness [in] bilateral wrists and bilateral feet and toes with pain and weakness increasing requiring [petitioner] to seek adaptive ways to perform [her] job requirements." *Id.* at 296.

On February 11, 2013, petitioner submitted an application for workers compensation benefits because she was "subjected to a mandatory flu vaccine"[20] as required by her employer. Pet. Ex. 5 at 4. In her application, petitioner described the pain and weakness she experienced in

[20] Despite medical records and testimony that petitioner received the flu vaccine in her left arm, her application for workers compensation indicates she received the flu vaccine in her right arm. Pet. Ex. 5 at 4.

both her hands and feet within twenty-four hours of receiving the flu vaccine. She also noted the adaptations she had to make in her personal and professional lives to accommodate her ongoing symptoms. *Id*. Petitioner indicated that her workers compensation claim was approved as being work-related; however, she received no financial award. The reason for the denial was never provided. Pet. at 3.

Thereafter, a nine-month gap exists between petitioner's last medical visit on January 30, 2013 with Dr. Gerstenblith (unrelated to her alleged vaccine injury) and her next medical visit on September 14, 2013, when she presented to Dr. MacCallum. On that date, she complained of strep throat and left eye, jaw, ear, and facial pain. Pet. Ex. 7 at 194. Petitioner affirmed that all of her medical records have been filed. *See* Pet. Ex. 43 at 3.

On September 30, 2013, petitioner returned to Dr. MacCallum's office complaining of anxiety, anger, stress, and a cold sore. Pet. Ex. 7 at 192. She was prescribed anxiety, depression, and antiviral medications. *Id.*

Petitioner presented to Dr. MacCallum's office three times in December 2013, with complaints of fatigue and gastrointestinal issues. *See* Pet. Ex. 26 at 5-9; Pet. Ex. 21 at 20-25. There were no complaints of myalgias, joint pain, joint swelling, or other rheumatological issues at any of these visits.

On February 12, 2014, petitioner presented for and passed her annual employer-mandated tuberculosis screening. *See* Pet. Ex. 21. Petitioner filled out the requisite form that accompanied the testing documenting that she did not suffer from any illness, extreme fatigue, weakness or other infirmity, and had no musculoskeletal problems such as weakness in her arms, hands, legs, or feet, or back pain, stiffness, or difficulty with activity. *Id.* at 6-7; 9.

After presenting to Dr. MacCallum's office in December 2013 and the February 2014 employer examination, petitioner did not see any medical provider again until February 2015.[21]

According to a co-worker, Petitioner was discharged from employment with UHAMC in November 2014. Pet. Ex. 24 at 1. This co-worker affirmed that petitioner then worked as a travel home care therapist, which required less physical labor and more time to rest while commuting between patients' homes. *Id.*

On February 21, 2015, petitioner presented to Dr. MacCallum's office with complaints of possible allergies, tender right sinus, runny nose, sluggishness, a rash on her back, and joint pain. Pet. Ex. 26 at 4. She also noted a head cold that had persisted since January and pain in the gland in front of her ear. Petitioner was diagnosed with sinusitis and prescribed doxycycline. *Id.*

[21] Petitioner confirmed that there are no medical visits for this time period in her affidavit. Pet. Ex. 43 at 3.

Petitioner's next medical visit was to Crystal Clinical Orthopedic ("Crystal" or "Orthopedic" or "CCO") on October 16, 2015, at which time she complained of left hip pain following a fall in a parking lot that occurred on August 1, 2015.[22] *See* Pet. Ex. 34. Petitioner's counsel conceded that the medical records in Pet. Ex. 34 are unrelated to petitioner's vaccine claim. *Id.* at 1. Petitioner denied numbness, tingling, or any other neurological issues at this visit. *Id.* at 3-4. X-rays of the left hip revealed well-preserved cartilage space with no other obvious bony pathology. *Id.* at 5.

On December 7, 2015, petitioner retuned to CCO for follow up regarding her August 2015 fall. She complained of left hip pain and difficulty ambulating, but denied numbness, tingling, fever, chills, neurological symptoms, or vomiting and did not mention an upper extremity pain or weakness. Pet. Ex 34 at 4, 11. Her symptoms were aggravated by walking, stairs, hills, standing, and changes in position. *Id.* Despite the pain, petitioner continued to work as a physical therapist. *Id.* at 3. Anti-inflammatories had helped with some of the pain and discomfort. *Id.* An MRI was performed the next day, December 8, 2015, and revealed a relatively large high grade partial tear of the distal gluteus medius tendon and trochanteric bursitis. *Id.* at 13-14.

The following day, December 8, 2015, petitioner presented to Dr. Saltis, a neurologist at Western Reserve Health System, complaining of pain in her hands and feet. Pet. Ex. 32 at 1-2. She stated the pain began after a flu vaccine in 2012. *Id.* Petitioner told Dr. Saltis that she had previously seen a rheumatologist, but they "did not hit it off" so she did not return. *Id.* According to petitioner, she had a "workman's comp case as it was determined she had a reaction to the flu vaccine, which precipitated the fall" on October 28, 2012. *Id.* at 1. Petitioner also stated she was fired from her job, and as a result, took a "travel job." Dr. Saltis documented that petitioner was very emotional at this visit. *Id.* Upon examination, there was no swelling of the extremities, a normal range of motion, and normal development and muscle bulk. *Id.* at 1-2. Petitioner's neurological exam was normal, except for decreased sensation of the lower left extremity with poorly downgoing plantars on the left. *Id.* at 2. Dr. Saltis wrote that petitioner had a positive ANA and elevated CRP[23] although no bloodwork results were filed. *Id.* at 1.

On January 13, 2016, an MRI of the cervical spine was performed, revealing small, broad-based disc protrusions at C2-3, C3-4, C5-6, and C6-7, without significant spinal stenosis, and bilateral foraminal narrowing at C5-6. *Id.* at 4. EMGs of petitioner's bilateral upper extremities

[22] On October 13, 2016, petitioner filed a status report advising that she had filed a civil action in the State Court of Ohio against the property owner for injuries sustained in a fall in a parking lot in August 2015. Pet. S.R., ECF No. 66. Attached to the status report was the complaint and demand letter filed by petitioner's counsel as her attorney in the Ohio state civil suit for her personal injuries resulting from the fall. *Id.* No medical records immediately following the fall were filed.

[23] C-reactive protein ("CRP") is a protein used to indicate an inflammatory illness. It is elevated in patients with a bacterial infectious disease, tissue necrosis, or an inflammatory disorder. A positive test result indicates the presence, but not the cause, of the disease. *See Mosby's Manual of Diagnostic and Laboratory Tests* 165-66 (Pagana eds., 6th ed. 2018).

performed on January 18, 2016 revealed mild axonal peripheral neuropathy with mild right carpal tunnel syndrome. *Id.* at 5.

On February 3, 2016, Dr. MacCallum wrote a letter to petitioner's counsel about petitioner's recent medical history, even though he had not personally examined her since January 14, 2013, two years prior. Pet. Ex. 31 at 1. In this letter, Dr. MacCallum stated petitioner "started to develop extremity weakness, arthralgias, and difficult walking up and down stairs," approximately one week after receiving a flu vaccine on October 1, 2012. *Id.* "[T]he most plausible explanation of [petitioner's] bizarre symptoms and persistent weakness would be an autoimmune reaction to the vaccine. Guillain [Barré] syndrome only occurs in one out of every million vaccines[,] but she certainly could be one that developed a variant." *Id.* However, Dr. MacCallum wrote "[e]valuation by rheumatology failed to unearth any significant autoimmune disease." *Id.*

Petitioner returned to Dr. Saltis on February 4, 2016. Pet Ex. 32 at 10-12. She was scheduled for hip surgery due to her August 1, 2015 fall. *Id.* Dr. Saltis' assessment was polyneuropathy associated with underlying disease, monoclonal gammopathy,[24] sensory disturbance, elevated C-reactive protein, and positive ANA. *See id.* No treatment or medication was ordered. Petitioner was directed to return in six months. *Id.* at 11. Dr. Saltis did not relate any of these findings to the allegedly causal flu vaccine. *See id.* Routine blood work performed after this visit showed no abnormalities other than a positive ANA. Pet. Ex. 33 at 5.[25]

Petitioner received extensive orthopedic care during the first half of 2016 as a result of the August 2015 fall, including hip surgery. *See generally* Pet. Ex. 32.

On June 24, 2016, petitioner presented to Dr. MacCallum to "discuss vaccines and paperwork." Pet. Ex. 35 at 2. She complained of joint pain at this visit. *Id.* Dr. MacCallum was asked by petitioner's counsel to summarize the "sequence of events that led to her terrible disability." *Id.* Dr. MacCallum wrote, petitioner received the flu vaccine per corporate policy on October 1, 2012, and began developing pain in her left hand that progressed to her right hand and then lower extremities seven days later. *Id.* Petitioner continued to experience this pain and numbness in her extremities and has since developed atrophy in her hands. *Id.* She was referred to a rheumatologist and that rheumatology workup "was completely negative." *Id.* Dr. MacCallum then opined that "the fact that there were no other precipitating facts [prior to the flu vaccine] seems to logically incriminate the vaccine as being the cause" of petitioner's symptoms. *Id.* Dr. MacCallum also stated, "We can see rare cases of Guillian-Barré (sic) Syndrome and other neurologic problems as a result of vaccination." *Id.* "Unfortunately there can be no tests that can prove this, only the temporal relationship." *Id.* Finally, Dr. MacCallum diagnosed petitioner with

[24] Monoclonal gammopathy is defined as "a condition in which an abnormal protein – known as monoclonal protein or M protein – is in [the] blood. The protein is produced in a type of white blood cell (plasma cells) in [the] bone marrow. [Monoclonal gammopathy] usually causes no problems. But sometimes it can progress over years to other disorders . . .". *Monoclonal Gammopathy of Undetermined Significance (MGUS)*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/mgus/symptoms-causes/syc-20352362 (last updated July 29, 2017).

[25] No blood work showing any elevated CRP was ever filed.

depression, inflammatory polyarthropathy, muscle spasticity, myalgia, polyneuropathy, and tingling in the extremities. *Id.* at 4. No testing was ordered nor documentation provided to support any of these findings.

According to petitioner's daughters, the residual effects of the allegedly causal vaccine and subsequent fall have been "devastating" for their mother. Pet. Ex. 2 at 5; *see also* Pet. Ex. 18 at 3. Petitioner continues to complain of pain and soreness in her hands and feet and is not active the way she used to be. Pet. Ex. 18 at 3; *see also* Pet. Ex. 19 at 3. Petitioner's daughters attribute Ms. Wyatt's ongoing symptoms to the October 1, 2012 flu vaccine and subsequent fall on October 28, 2012. Pet. Ex. 18 at 3-4; *see also* Pet. Ex. 19 at 4.

III. Dr. MacCallum's Testimony

Dr. MacCallum testified at the fact hearing held on November 16, 2017. He has been a family physician for thirty-eight years and works full-time on an outpatient basis at the University Hospitals of Cleveland. Transcript ("Tr.") 5, 7. He has been petitioner's primary care physician for approximately thirty years. Tr. 7. In his practice, he sees neurologic or immunologic issues on a daily basis. *Id.*

A. Dr. MacCallum's testimony regarding specific office visits

Dr. MacCallum was asked about his August 22, 2012 office record that documents that petitioner presented with "multiple complaints." Pet. Ex. 7. Dr. MacCallum stated that he did not see petitioner on that date, a nurse practitioner did, so he did not know what petitioner's complaints were. Tr. 12-13; Pet. Ex. 7 at 197.

Dr. MacCallum was also asked about his office record for October 16, 2012. He recalled that petitioner "developed an upper extremity pain and also tingling in her upper extremities within a day of the immunization. It subsequently progressed to more generalized weakness and symptoms also involving her lower extremities." Tr. 9. Dr. MacCallum clarified that he did not see petitioner after her vaccine on October 1, 2012 until October 16, so he documented her symptoms as developing approximately a week after the vaccine. He later stated he was probably incorrect, and her symptoms may have started earlier than a week after the vaccine. Tr. 69. Dr. MacCallum also stated that the history petitioner gave was that her symptoms started the night of the vaccine. She worked out and initially thought it was soreness from working out but the symptoms persisted and got worse. Tr. 10, 52. "The initial soreness may have actually just been the soreness of the vaccine, you know, in her upper arm. Then subsequent to that, what developed over the subsequent days, I think, was an adverse reaction to the vaccine." Tr. 54. He acknowledged that in her worker's compensation report, she reported onset within 24 hours of the vaccine. Tr. 67.

When pressed by respondent's counsel regarding the onset of petitioner's symptoms, Dr. MacCallum stated "it's real subjective, but over a period of – over that following week after the vaccine it became clear that something was affecting her…maybe coincidentally she had had a virus or it was going to subside…it occurred probably over a month to six weeks after the vaccine…just soreness and some early weakness in her upper extremities during the first week or

so as I recall." Tr. 54-55. Dr. MacCallum noted that the parvovirus B-19 in her blood work was not an acute illness. Tr. 56-57; Pet. Ex. 7 at 225.

Dr. MacCallum admitted that he was unfamiliar with VAERS, but the symptoms contained in the VAERS report coincided with petitioner's complaints after the vaccine, as did the "Employee Incident Report," which documented pain and weakness in bilateral wrists, feet and toes with pain and weakness increasing after the flu vaccine. Tr. 14; 17-18; *see also* Pet. Ex. 4, Pet. Ex. 8 at 296. Dr. MacCallum stated that petitioner did not suffer from arthritis prior to October 1, 2012, and that when Nurse Gigliotti completed the VAERS report, she may have misinterpreted his note of October 16, 2012 of polyarthritis as a preexisting condition. Tr. 15.[26] He explained that polyarthritis just meant involvement of more than one joint. It occurs in reaction type circumstances. Tr. 15-17; Pet. Ex. 8 at 289.

Dr. MacCallum discussed petitioner's recent medical history at the January 14, 2013 office visit. He stated that the examination was a follow up of her complaints after the flu shot of pain in both first metacarpal phalangeal joints and fingers, shooting pain in the right foot, and fatigue. She had to work with painful hands and "fell going down steps couldn't grasp the rail." Pet. Ex. 7 at 195. In his opinion, it was all an adverse reaction to the flu vaccine. Tr. 20-21. With regard to petitioner's fall down the stairs, "we made the assumption that it was due to the weakness in her hand and that she lost control of herself going down the stairs." Given her history of good health, it surprised him that she would lose her balance in that way. Tr. 21. He confirmed that he documented her symptoms as beginning the day after the vaccine based on the history she provided of when she started having symptoms. Tr. 75.

Dr. MacCallum was presented with Dr. Corn's emergency room record, which stated that petitioner reported having missed the last two steps as the reason for her fall down the stairs on October 28, 2012. Tr. 22. Dr. MacCallum responded that he did not know what petitioner reported to Dr. Corn, but Dr. Corn probably did not pursue the neurologic aspect of the fall. Tr. 22.

Dr. MacCallum stated that he disagreed with Dr. Lumapas' record of January 17, 2013 in which she concluded that "[Petitioner's] symptoms have resolved." Tr. 23-25; Pet. Ex. 7 at 242.

Dr. MacCallum confirmed that petitioner was not seen in his office between January 14, 2013 and September 14, 2013. Tr. 59; 63. He further confirmed that he did not see petitioner but rather, his staff member examined her on September 13, 2013, October 30, 2013, and December 9, 2013 for strep throat, anxiety, depression, anger and diverticulitis with lower abdominal pain. Tr. 59-61. There were no complaints of joint pain or weakness documented during any of these visits. Tr. 59-61; Pet. Ex. 7 at 190; 192; 194; Pet. Ex. 21 at 24; 25.

Dr. MacCallum noted that on December 16, 2013, petitioner was seen by a nurse practitioner for abdominal pain and complaints of fatigue. He admitted having trouble reading the handwriting but believed that bloodwork and an arthritis panel were ordered. He added maybe the

[26] Dr. MacCallum stated "[T]he nurse may have misinterpreted my note of polyarthritis, which I was theorizing was the reaction she was having as prior arthritis. That was an error." Tr. 15.

record said positive redness and swelling joint in the hand, but he was not good at reading the note. Tr. 62. Pet. Ex. 21 at 23.

Dr. MacCallum suggested that petitioner did not see him or any medical provider between January 2013 and September 2013 because she lost her insurance. Tr. 62-63. When it was pointed out to Dr. MacCallum that petitioner was still working at that time and had reported to his staff in September 2013 that she believed that her co-workers were playing jokes on her and harassing her, he stated she was afraid of losing her job and went back to work in pain. Tr. 63-64. He then added that "maybe she felt she just had exhausted all options. It's just conjecture on my part . . . nobody came up with an answer for her, so I think she just said, well, I have to live with this." Tr. 64.

Petitioner's counsel tried to redirect Dr. MacCallum by suggesting that petitioner's complaints of anxiety and depression in September 2013 were the result of her "adverse reaction to the vaccine…pain, tingling, weakness in her hands, arms and legs and difficulty walking and it cost her her job…". Dr. MacCallum responded that he could not speak to that "but it was certainly possible, but I can't say that that was the cause of her depression. It likely was." Tr. 75.[27]

Dr. MacCallum attempted to reason away the gaps in the medical records by suggesting that there was no treatment for her. Prednisone worked a little, but the rheumatologist saw her and thought she was improved. Tr. 64. He then admitted that he did not see her again between December 16, 2013 and June 24, 2016. Dr. MacCallum noted that his records show a visit on February 21, 2015 for strep throat, for which she saw one of his partners. Tr. 64-65; Pet. Ex. 26 at 4; 35. He further confirmed that he did not receive any medical records from any other providers for her during this time. Tr. 65.[28]

Dr. MacCallum was then asked about petitioner's visit in June 2016, in which he documented that petitioner presented "to discuss vaccines and paperwork. Pt. c/o joint pain today." Dr. MacCallum was asked by petitioner's counsel to read the "History of Present Illness" into the record, which he did. Tr. 76-77 Pet. Ex. 35 at 3. He was asked again by petitioner's counsel if it was his opinion that the vaccine caused petitioner's problems. He stated that a lot of petitioner's complaints came from the vaccine, but other things could have occurred during the time period when he had not seen her. Tr. 71. "She brought me up-to-date on her symptoms." He believed she didn't have insurance and was trying to minimize visits, so it made him think that her complaints in June 2016 were attributable to the vaccine and permanent, since she was still complaining five years after her vaccine. Tr. 78.

B. Dr. MacCallum's testimony regarding petitioner's "GBS diagnosis"

Dr. MacCallum was presented with the insert for Fluarix by petitioner's counsel. Tr. 28. He agreed with petitioner's counsel that the insert stated that if one suffered from GBS within six

[27] However, Dr. MacCallum had already testified that he never saw petitioner in the fall of 2013, only his staff did; there were no complaints regarding her arms, hands, legs, or feet at that time, and she was still working full time. Tr. 59-61.

[28] The only records that were filed during this time frame were the orthopedic records for Crystal Clinic Orthopedic associated with the fall in August 2015 in a parking lot. Pet. Ex. 34.

weeks of the vaccine, another vaccine should not be given. Tr. 28-29; Pet. Ex. 14. He described GBS as ascending weakness that starts in the lower extremities and ascends to the upper extremities, ultimately moving to the chest and leading to paralysis of the diaphragm. Tr. 29. The paralysis reverses and gradually disappears, leaving symptoms such as muscle weakness. Tr. 29. He agreed that the insert discussed fatigue and arthralgias, two complaints made by petitioner. Tr. 28-29; Pet. Ex. 14 at 4.[29] Initially, Dr. MacCallum stated that petitioner had neuropathy, meaning that the nerve was malfunctioning, and brachial neuropathy, which is in the upper chest, affecting the upper extremity and neck. Tr. 30-31. When asked why his records only document complaints in her hands and feet, he responded that when she first came to see him, she complained of soreness in her upper extremities which she thought was soreness at the site of the flu shot but he did not mark it down. Tr. 31. However, he later retracted his statement that petitioner had brachial neuropathy stating "No, I don't think that because it really wasn't documented by nerve conduction studies. And I'm not sure, frankly, if she ever had a nerve conduction study done by the neurologist. I'm not aware of that in the record." Tr. 55. Dr. MacCallum admitted that he was unaware that petitioner had undergone nerve conduction studies in 2015 that showed carpal tunnel syndrome but no other neurological deficits. Tr. 56

Dr. MacCallum was presented with the Vaccine Injury Table by petitioner's counsel and asked to confirm that the Table covers GBS, if the onset of the injury is within three to 42 days of flu vaccine. Tr. 35. Dr. MacCallum agreed that GBS is on the Table but stated that petitioner did not have GBS. *Id.* "[I]t was not Guillain-Barré that she had, but the onset of an adverse reaction occurred within that time frame." "I don't believe she had Guillain-Barré syndrome. I think that's the only identified adverse reaction in a neurological sense that they list in this table and then they talk about it having an onset within 3 to 42 days. That's all that's there." Tr. 35-36.

Despite Dr. MacCallum's testimony that petitioner did not have GBS, petitioner's counsel insisted on presenting him with articles discussing GBS and influenza vaccine and asking that Dr. MacCallum explain autoimmune disease and damage to the myelin sheath caused by GBS. Tr. 36-37; Pet. Ex. 45. Dr. MacCallum responded to the questions asked of him and then stated "I can't testify that her myelin sheaths have been damaged. All I can go by are her symptoms." Tr. 38. GBS has a "more clinical presentation and then I believe there are tests that can be done on the spinal fluid to help document it." Tr. 38. Dr. MacCallum then repeated, "I do not believe this was Guillain-Barré. Guillain-Barré is just a good example of a neurologic disorder as an adverse reaction to a vaccination." Tr. at 39.

Petitioner's counsel insisted that Dr. MacCallum agree that petitioner's adverse reaction to the flu vaccine caused damage to her myelin sheath. Tr. 46. However, Dr. MacCallum maintained his position that he could not say in this case whether the myelin sheath was attacked because no investigation into that was done. "We relied on rheumatologic opinion and neurology opinion that looked for other causes. But to my knowledge, nobody has any other ideas." Tr. 47.

[29] Petitioner's counsel then read the information for the 1976 swine flu vaccine and associated increased frequency of GBS into the record. Tr. 30.

C. Dr. MacCallum's letters and evaluation of the evidence in this case

Dr. MacCallum was questioned about his "opinion letter" authored on February 3, 2016. Tr. 43; Pet. Ex. 31. He stated that at the time he wrote the letter, he felt that it was extremely unlikely that petitioner's symptoms after the flu vaccine were due to some transient viral infection, he was trying to come up with some possible cause for her symptoms at that time. Tr. 45. He stated that he still holds the opinion that "the most plausible explanation of the bizarre symptoms and persistent weakness would be an autoimmune reaction to the vaccine." Tr. 45. He stated that his reference to GBS was "just a different presentation." Tr. 45.

Dr. MacCallum was then presented with Dr. Saltis' record of December 8, 2015 and asked what a positive ANA was.[30] Dr. MacCallum explained that ANA stands for anti-nuclear antibody and is a marker for over-reactivity or autoimmune disease, most known for being present in lupus, though it can be present in other autoimmune disease. Tr. 39-40; Pet. Ex. 32. Dr. MacCallum stated that Dr. Saltis' assessment was sensory disturbance. Tr. 41. Dr. MacCallum also agreed that all of the information provided in the "History of Present Illness" portion of Dr. Saltis' record was information provided by the patient." Tr. 41-42.

Petitioner's counsel asked Dr. MacCallum whether Dr. Saltis gave "another" cause for petitioner's symptoms other than the vaccine. I corrected counsel's question stating that Dr. Saltis did not give "any" cause for petitioner's symptoms. Dr. MacCallum agreed, stating, "That's correct." Tr. 42. Petitioner's counsel again asked whether any doctor provided "any other" explanation for petitioner's injury which was more likely to be the causative factor than an adverse reaction to the vaccine. Dr. MacCallum responded, "No". Tr. 32-33, 42.

I asked Dr. MacCallum whether "any of the doctors that you have sent [petitioner] to ever diagnosed her with any injuries causally related to the vaccine?" Tr. 48.[31] Dr. MacCallum responded that petitioner's treating physicians noted her history and her symptom development following the flu vaccine and nothing further. *Id.* He then added "It's as if they just assumed that –I read it as they just assumed these things have happened after having had a flu vaccine, but we can't explain what exactly is going on." *Id.* Dr. MacCallum agreed that there has been no definitive diagnosis provided for petitioner's complaints. He confirmed that neither the rheumatologist nor the neurologist diagnosed petitioner with a disease or condition causally related to the vaccine. Tr. 47-48.

Petitioner's counsel posed the following hypothetical to Dr. MacCallum: if following an automobile accident, the car fills with gas and the driver gets sick, isn't that how a correlation between history and diagnosis of a problem is typically reached?[32] Dr. MacCallum responded

[30] Petitioner's counsel read the entire History of Present Illness into the record. Tr. 76-77.

[31] Petitioner's counsel objected to my question. Tr. 48.

[32] This is an incorrect analogy of petitioner's burden in Vaccine Program cases. Applying this hypothetical, petitioners must, in fact, demonstrate (1) how the hypothetical gas could cause the person to be ill, (2) if the hypothetical gas actually caused the person to be ill, and (3) whether the timing supports that the hypothetical gas caused the person to be ill. *See Althen v. Sec'y of Health & Human Servs*. 418 F.3d 1274, 1278 (Fed. Cir. 2005).

"yes". Tr. 49. Counsel then asked if anyone has come up with any history to suggest another cause for petitioner's injuries. Dr. MacCallum responded, "No". Tr. 49.

Dr. MacCallum was questioned about his statements in the opinion letter he wrote on February 3, 2016, regarding petitioner's fall down stairs due to weakness and the fact that she never fully recovered after that. Tr. 26-27, 66; Pet. Ex. 31. He admitted that his statement that her fall down the stairs due to "weakness" was based on what petitioner told him. Tr. 68. He was asked how he would know that she never recovered when he had not seen her in over two years. Tr. 68. It was also pointed out that his office record contained copies of the orthopedic records from petitioner's fall in a parking lot in August 2015 which show that as of October 16, 2015, "[S]ensation is normal in all dermatomes of both lower extremities, lower extremity reflexes, both legs are normal, lower extremity pulses equal and symmetric throughout both legs." Tr. 70; Pet. Ex. 34 at 4-6. Dr. MacCallum stated "I—so that letter that I wrote in February (sic) was based on just what we had known had gone on a few years before. I just assumed that she had not improved." Tr. 70-71.

I asked if his opinion in this case was based solely on temporal relationship to the vaccine and he responded "yes". Tr. 73.[33] Dr. MacCallum stated if a patient breaks out in a rash a day or two after being given an antibiotic, it is "put down as an allergic reaction to that drug. It's a temporal relationship." Tr. 73. I asked him to confirm that his opinion in this case was based solely on temporal relationship and he responded "that's correct." Tr. 74.

IV. Petitioner's Expert: Dr. Phillip DeMio, M.D.

Petitioner's expert, Dr. Phillip DeMio, M.D., obtained his Bachelor of Science degree from Creighton University in 1980 and his M.D. from Case Western Reserve University in 1984. *Id.* He completed a residency in pathology at the University Hospitals of Cleveland, and Medicine and Emergency Medicine residencies at Mt. Sinai Medical Center. *Id.* Dr. DeMio's current practice primarily consists of the treatment of chronic tick-borne and other infections and Autism Spectrum Disorder. *Id.* at 2. He also treats adults for "chronic pain and disease," as well as injuries. *Id.* Dr. DeMio's curriculum vitae lists several medical faculty positions he has held, including positions at the Cleveland Clinic Foundation, Case Western Reserve University School of Medicine, Mt. Sinai Medical Center, American College of Surgeons, and the American Heart Association, as well as certifications he holds from the American College of Emergency Physicians, and in Advanced Pediatric Life Support and Advanced Trauma Life Support for Physicians. *Id.* However, his CV does not indicate when he held these positions, when he received the certifications, or whether any of them are current. Additionally, Dr. DeMio has written publications regarding arthritis, gout, inflammation, gastrointestinal issues, and nutrition and has spoken at conferences covering topics such as chronic spine injuries and Lyme disease. *Id.* at 3.

On February 10, 2016, petitioner filed an expert report authored by Dr. DeMio. Pet. Ex. 29. Dr. DeMio began this report by outlining his current practice. *Id.* at 1. Despite what is listed under "Current Practice" on Dr. DeMio's CV, he stated in his report that he sees "many patients with chronic illnesses including neurodegenerative disease, neuropathy, illness associated with

[33] Petitioner's counsel again objected to my question. Tr. 73.

vaccination, and autoimmunity." He then outlined the facts that he relied upon in forming his opinion in this case. According to Dr. DeMio, petitioner was "in her usual state of excellent health," and led a very active lifestyle before receiving the flu vaccine on October 1, 2012. He then stated that the day after receiving the flu vaccine, petitioner "noted pain which was uncharacteristic in the left upper extremity including the hand." *Id.* Dr. DeMio further noted that at two weeks post-vaccine, Ms. Wyatt "rapidly was in a state where she was unable to do her work functions as noted by her colleagues, due to pain, weakness, and dysesthesias in four extremities." *Id.* at 1-2. Over the months following the vaccine, petitioner received "full medical work-ups, leading to findings of pathology on tests [and] exams, and she was diagnosed with autoimmunity and inflammatory arthritis." *Id.* at 2. Dr. DeMio's report neglected to include citations to any of petitioner's medical records in support of any of his statements. *See id.*

Dr. DeMio diagnosed petitioner as suffering from "autoimmunity with a minimally improved Guillian-Barré (sic) Syndrome, with severe persisting sequelae." *Id.* He opined that petitioner's symptoms and the results of medical testing "clearly make the diagnosis of autoimmunity and Guillian-Barré (sic) Syndrome, and they exclude other diagnoses." *Id.* Dr. DeMio described GBS in general terms, stating that the "pathology is thought to arise from mechanisms including molecular mimicry by microbial antigens including those that are present in the influenza vaccine that Ms. Wyatt received." *Id.* Dr. DeMio failed to provide any support for his statements or for his assertion that "the aforementioned microbial antigens are thought to cause the molecular mimicry and to cross react immunologically with human peripheral nerve antigens leading to autoimmune attack on peripheral nerves, with resultant weakness, pain, and dysesthesias." *Id.* at 3. Rather, Dr. DeMio relied solely on the timing of Ms. Wyatt's symptoms and "the lack of another temporally associated reasonable trigger" or causation, concluding that the flu vaccine was the sole cause of petitioner's current symptoms. *Id.*

I ordered petitioner's counsel to file a supplemental report from Dr. DeMio containing specific references to petitioner's medical records, testing, and medical literature to support his opinions. Order at 2, ECF No. 55. Additionally, I ordered that Dr. DeMio specifically address how petitioner's case satisfies each *Althen* prong or the report would be insufficient. *Id.*

On September 22, 2016, petitioner filed Dr. DeMio's supplemental report in which he opined that "autoimmunity, inflammation, polyneuropathy, and arthritis" are petitioner's diagnoses. Pet. Ex. 36 at 1. He further reiterated that the flu vaccine can cause GBS, inflammation and arthritis. He included a list of five articles in support of this proposition but failed to explain the relevance of these articles to this case. *Id.* at 2; *see also* Pet. Ex. 37.[34] The supplemental report referred generally to petitioner's medical records, without reference to objective test results or

[34] Adi Hersalis Eldar & Joab Chapman, *Guillain Barré Syndrome and Other Immune Mediated Neuropathies: Diagnosis and Classification*, 13 AUTOIMMUNITY REV. 4-5, 525-30 (2014); Mazen M. Dimachkie & Richard J. Barohn, *Guillain-Barré Syndrome and Variants*, 2 NEUROLOGY CLINICS 31, 491-510 (2013); *Guillain-Barré Syndrome Fact Sheet*, NAT'L INST. OF NEUROLOGICAL DISORDERS & STROKE (June 1, 2016), https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Guillain-Barr%C3%A9-Syndrome-Fact-Sheet; Fred F. Ferri, FERR'S CLINICAL ADVISOR 2017: 5 BOOKS IN 1 529 (Elsevier Health Sciences 2017); Nortina Shahrizaila & Nobuhiro Yuki, *Bickerstaff's Brainstem Encephalitis and Fisher Syndrome: Anti-Gq1b Antibody Syndrome*, 85 J. NEUROLOGY, NEUROSURGERY & PSYCHIATRY 5, 576-583 (2013).

specific medical records in support of his conclusion that petitioner suffered GBS, autoimmunity, inflammation, polyneuropathy, and arthritis caused by the flu vaccine received on October 1, 2012. Pet. Ex. 36 at 2. Furthermore, Dr. DeMio neglected to discuss *Althen* or how this case satisfied the *Althen* prongs, despite my explicit order to do so. *See id.*; Order at 2, ECF No. 55.

V. Legal Framework

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that he or she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the timeframe provided within the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* 42 U.S.C. § 300aa-13(a)(1)(B). Alternatively, where the claimed injury is not listed in the Vaccine Table or does not fit squarely within the Table parameters, a petitioner may bring an "off-Table" claim. 42 U.S.C. § 300aa-11(c)(1)(C)(ii). An "off-Table" claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(II). Initially, a petitioner must provide evidence that he or she suffered, or continues to suffer, from a definitive injury. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury are sufficient for recovery. *See Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Additionally, the Vaccine Act requires petitioners to show by preponderant evidence that the "residual effects or complications" of the alleged vaccine-related injury lasted longer than six months. 42 U.S.C. § 300aa-11(c)(1)(D)(i).

VI. Discussion

Because petitioner does not allege an injury listed on the Vaccine Injury Table, her claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, petitioner must show by preponderant evidence that she suffered an injury and that this injury was caused by the vaccination at issue. *Capizzano*, 440 F.3d at 1320. There are three key areas of weakness in this case that ultimately preclude a finding of entitlement: (1) the lack of a definitive diagnosis, (2) her inability to demonstrate her injuries and/or related sequalae lasted the requisite six months, and (3) her failure to satisfy the *Althen* requirements.

A. Defined and Recognized Injury

An initial step in an off-Table claim is to "determine what injury, if any, was supported by the evidence presented in the record." *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). The Vaccine Act "places the burden on the petitioner to make a showing of at least one defined and recognized injury," and "[i]n the absence of a showing of the very existence of any specific injury[,] . . . the question of causation is not reached." *Id.*; *Broekelschen*, 618 F.3d at 1346 (explaining that a vaccine-related injury "has to be more than just a symptom or manifestation of an unknown injury."); *Stillwell v. Sec'y of Health & Human Servs.*,

118 Fed. Cl. 47, 56 (2014) ("[I]f the special master finds, as a preliminary matter, that petitioner has failed to substantiate the alleged injury, the special master need not apply the *Althen* test for causality."). Thus, petitioner has the burden to demonstrate what medically-recognized injury from which she suffers. *Broekelschen*, 618 F.3d at 1348; *see also Lasnetski v. Sec'y of Health and Human Servs.*, 128 Fed. Cl. 242 (2016).

When determining whether petitioner has adequately proven a demonstrable injury, special masters analyze petitioner's complete medical records filed into the record. 42 U.S.C. § 300aa-11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and complete such that they present all relevant information on a petitioner's health problems. *Cucuras v. Sec'y of Health and Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Subsequent statements made by third parties that contradict contemporaneous medical records are less persuasive to special masters than the medical records. *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006).

Respondent submitted, and I agree, that petitioner has failed to meet her burden of showing at least one defined and recognized injury. Throughout her medical records, it is clear that petitioner suffered from a host of symptoms within the first three months following her October 1, 2012 flu vaccine, including hand and wrist discomfort and pain, weakness in both of her upper and lower extremities, painful joints in her upper extremities, and fatigue. *See* Pet. Ex. 1 at 3-4; Pet. Ex. 5 at 4; Pet. Ex. 7 at 195; Pet. Ex. 10 at 308. She also fractured her left ankle when she fell down the stairs on October 28, 2012, which is likely attributable to the pain and weakness she was experiencing following her flu vaccine. *See* Pet. Ex. 7 at 201; Pet. Ex. 1 at 8. However, after her visit with her rheumatologist, Dr. Lumapas, on January 17, 2013, petitioner did not complain of these symptoms again until December 8, 2015, when she presented to a neurologist, Dr. Saltis, complaining of pain in her hands and feet that allegedly began after she received a flu vaccine in 2012. Pet. Ex. 32 at 1-2. It is noted that the day before, she denied any such problems when she presented to the orthopedic specialist regarding her parking lot fall. Pet. Ex. 10 at 314.

Moreover, despite visits with her primary care physician, rheumatologist, and even Dr. Saltis three years after her vaccination, no treating physician diagnosed her with GBS or any other definable injury or illness causally related to the flu vaccine. The only possible diagnoses found in petitioner's medical records are in a letters from Dr. MacCallum in which he diagnosed petitioner with polyarthritis in his January 14, 2013 note (Pet. Ex. 8 at 289) and then diagnosed her with inflammatory polyarthropathy, muscle spasticity, and polyneuropathy in his June 24, 2016 letter, a letter written after not seeing petitioner for over three years, based on the facts told to him by her, and at the request of her attorney. Pet. Ex. 35 at 4. The only remarkable test result in petitioner's medical records was a positive ANA test on January 4, 2013, approximately two months after her influenza vaccine. Pet. Ex. 7 at 216-23. However, as pointed out by Dr. Lumapas, it was unclear as to whether petitioner's ANA levels were recently elevated or had been previously elevated, as there was no prior testing done and no symptoms consistent with ~~it~~ a positive ANA. Pet. Ex. 10 at 314. Petitioner provided nothing more than "symptomology," as contained in the medical records. Motion for Judgment on the Administrative Record 1-4, ECF No. 103. Petitioner has failed to provide any definitive diagnosis and thus, her claim is insufficient for a finding of entitlement.

i. Dr. MacCallum's Testimony

Dr. MacCallum's testimony during the November 16, 2017 fact hearing further supports respondent's argument that there has been no definitive diagnosis of GBS or any other vaccine related illness or injury in this case. In *R.K. v. Sec'y of Health & Human Servs.*, the Court affirmed a special master's determination that petitioner failed to establish a definitive diagnosis after the special master heard contradictory testimony from petitioner's expert. 125 Fed. Cl. 57 (2016), *aff'd,* 671 Fed. Appx. 792 (Fed. Cir. 2016). The expert initially testified that petitioner suffered from a mitochondrial disorder based on her review of petitioner's medical records and examination of petitioner. However, on cross examination, the expert contradicted her earlier report by "conceding that she could not conclude that [petitioner] definitively had mitochondrial disorder." *Id.* at 72. In conjunction with this testimony, the special master examined petitioner's objective test results and medical literature proffered by the expert in question. Based on this review, the special master found that petitioner failed to meet her burden of establishing petitioner suffered from a definitive diagnosis. The Court upheld the special master's decision because the special master "considered the relevant evidence or record, [drew] plausible inferences, and articulated a rational basis for the decision." *Id.* (citing *Lampe v. Sec'y of Health and Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000).

Here, Dr. MacCallum concluded that petitioner suffered from some form of reaction following her receipt of the influenza vaccine in his opinion letters filed on February 2, 2016 and June 24, 2016, but his testimony at hearing could only support a temporary reaction. *See* Pet. Exs. 31, 35. When questioned by respondent's counsel and myself, Dr. MacCallum stated several times that he had never actually diagnosed petitioner with GBS nor did he believe she suffered from GBS. Tr. 35-36 ("I don't believe she had Guillain-Barré syndrome."); Tr. 39 ("I do not believe this was Guillain-Barré. Guillain-Barré is just a good example of a neurological disorder as an adverse reaction to a vaccination."); Tr. 47 ("[W]e can't explain exactly what is going on." "So there's been no definitive diagnosis, correct?" "No."). He further stated that no one diagnosed petitioner with any injury or disease associated with the flu vaccine other than a temporal one that resolved shortly thereafter. *See* Pet. Ex. 10 at 307, 314; Pet. Ex. 32 at 1-2; Tr. 35-36. Therefore, when I considered Dr. MacCallum's opinion letters in conjunction with the entirety of the record, as well as his testimony during hearing as the Court did in *R.K. v. Sec'y of Health & Human Servs.*, it was clear that petitioner has failed to provide preponderant evidence that she suffered from GBS.

ii. Dr. DeMio's Report

In his initial report, Dr. DeMio diagnosed petitioner with GBS, but that diagnosis is insufficiently supported by record evidence to support petitioner's claim. Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his or her claim. *Lampe*, 219 F.3d at 1361. The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id.* at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly ex rel. Moberly v.*

Sec'y of Health and Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010). The *Daubert* 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) ("[U]niquely 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"). Special masters are not required to accept 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 ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). Moreover, petitioner must establish the reliability of an expert's opinion to support her claim. *See La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 201 (2013).

A special master may reject an expert's theory if the special master determines the expert lacks the requisite expertise in a certain medical specialty to authoritatively opine on the subject. *Veryzer v. Sec'y of Health and Human Servs.*, 98 Fed. Cl. 214, 224-25 (2011) (determining the special master's rejection of petitioner's expert was proper on the ground that she lacked the requisite expertise in in the subject on which she was asked to opine); *see also Gardner-Cook v. Sec'y of Health and Human Servs.*, 59 Fed. Cl. 38, 48 (2003) (affirming a special master's finding that petitioner's expert was not "capable of offering an expert opinion on an alleged neuroimmunological disorder" when the expert had never practiced neurology).

Petitioner's expert, Dr. DeMio, has been criticized by this Court in the past for testifying in cases regarding medical theories which he is not qualified to render. *See Dia v. Sec'y of Health & Human Servs.*, No. 14-954, 2016 WL 6835549, at *1 (Fed. Cl. Spec. Mstr. Oct. 24, 2016) ("[A]lthough Dr. DeMio's background is in autism, he did not explain his qualifications to opine about peripheral neuropathy."); *Holt v. Sec'y of Dep't of Health & Human Servs.*, No. 05-0136V, 2015 WL 4381588, at *16 (Fed. Cl. Spec. Mstr. June 24, 2015) ("[Dr. DeMio] is board certified in emergency medicine. He has no formal specialized training in . . . any of the several areas [pediatrics, immunology, neurology, or gastroenterology], in which he proffered opinions. His only publications involved chapters on arthritis, gout, inflammation, and nutrition in an integrative medicine textbook."). Once again, Dr. DeMio has rendered an opinion in a case in which he lacks the underlying requisite medical expertise. Dr. DeMio has neither specialized training in either autoimmune or neurological disorders nor has he ever conducted research or written papers in either of these fields.

Moreover, I find Dr. DeMio's opinions as offered in this case insufficient to support petitioner's claim. Dr. DeMio opined that petitioner suffered from autoimmunity and GBS, concluding that "[petitioner's] symptoms and their course of onset, plateauing, and some improvement, along with the results of her medical tests [and] treatment clearly make the diagnosis of autoimmunity and Guillian-Barré[] (sic) Syndrome, and they exclude all other diagnoses." Pet. Ex. 29 at 2. But Dr. DeMio provided no references to any objective testing, contemporaneous medical records, medical opinion of treating physicians, or medical literature to support this conclusion, even after being ordered to do so. *See* Order at 2, ECF No. 55. Dr. DeMio's conclusory opinion that petitioner suffered from GBS and/or autoimmunity causally related to the influenza vaccine is insufficient to outweigh the clear lack of evidence in the record, or the testimony of

petitioner's treating physician that she was never diagnosed with GBS or any other demyelinating condition following the flu vaccine administered on October 1, 2012.

Petitioner has failed to prove a medically recognized injury or diagnosis causally related to the vaccine received on October 1, 2012, either supported by contemporaneously made medical records or qualified expert testimony.

B. Six Month Requirement

The Vaccine Act requires petitioners to show by preponderant evidence that the "residual effects or complications" of the alleged vaccine-related injury lasted for more than six months. 42 U.S.C. § 300aa-11(c)(1)(D)(i). In *Cloer v. Sec'y of Health and Human Servs.*, the Federal Circuit explained that the six month requirement is "a condition precedent for filing a petition for compensation" in the vaccine program, and serves as a restriction on eligibility for compensation in the Program. 654 F.3d 1322, 1335 (Fed. Cir. 2011). Congress intended this duration requirement "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." *Id.* (quoting H.R. Rep. No.100-391(I), at 699 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, -373.

In this case, petitioner's medical records confirm that any symptoms she suffered following the flu vaccination on October 1, 2012 were resolved by January 17, 2013—three months post-vaccination. *See* Pet. Ex. 7 at 46. There are no records of medical care filed between January 2013 and September 2013. Petitioner's medical treatment in September 2013 through December 2013 involved upper respiratory and gastrointestinal infections with no mention of any lower or upper extremity pain or weakness. There are then no records for any medical treatment for the year 2014. The only record that mentioned extremity pain associated with the flu vaccine after 2013 was in December 2015, when petitioner presented to Dr. Saltis, a neurologist. Pet. Ex. 32 at 1-2. This visit was one day after her visit to an orthopedic for complaints of hip pain following a fall in a parking lot the previous August. *See* Pet. Ex. 34 at 13-14. Petitioner did not complain of nor did the orthopedic examination find any joint pain, swelling or limitation. *Id.* Dr. Saltis made no association between petitioner's complaints and the flu vaccine. *See* Pet. Ex. 32 at 1-2. The remainder of petitioner's medical records are associated with a slip-and-fall that occurred in the summer 2015—which Petitioner admitted was completely unrelated to her vaccine. *See generally* Pet. Exs. 32-34. Only Dr. MacCallum's letters from February and June 2016 mention complaints associated with the flu vaccine. *See* Pet. Exs. 31, 35. Dr. MacCallum admitted that he had not seen petitioner in three years, wrote the history he was told by her and issued the reports at the insistence of her counsel. Tr. 68, 70-71. Furthermore, his opinions were based on temporal relationship alone, nothing more. Tr. 73 ("So is it your opinion that simply because her symptoms started 7 days or 24 hours or whatever it is that she may say following the flu vaccine that it had to be the flu vaccine." "Yes."); Tr. 74 ("So it's based on temporal relationship?" "Correct.").

There is little doubt that petitioner suffered from pain in her fingers, hands and arms, and potentially her feet, for a time following the influenza vaccine in October 2012. She may very well have been suffering from those complaints since August 2012, though the record is unclear as to what her "multiple complaints" were at that visit. These symptoms may have been responsible for her fall down the last three steps in her home on October 28, 2012, or she may have missed those

steps as she reported to the emergency room physician and then Dr. Corn, several days later. In any event, Chief Special Master Dorsey provided petitioner with the opportunity to secure a report from her orthopedist regarding the time it would take to fully heal from her ankle injuries, but she failed to do so. *See* Order, ECF No. 27. She was also released back to work by Dr. Corn in February 2013 without restriction. Pet. Ex. 9 at 168. She had no further orthopedic care until her fall in a parking lot several years later. Petitioner failed to provide any support that she continued to suffer any ongoing sequela after February 2013 when she was released back to work full time.

Based on the records in their entirety, including the affidavits of the witnesses herein, I find that petitioner has failed to establish that the residual effects of her alleged vaccine-related injury lasted for more than six months as required under the Vaccine Act and in fact, resolved within three months.

C. *Althen* Criteria

Petitioner has failed to provide evidence of a definitive diagnosis that lasted longer than the requisite six months and has therefore failed to establish her claim. Typically, "[i]n the absence of a showing of the very existence of any specific injury of which petitioner complains, the question of causation is not reached." *Lombardi*, 656 F.3d at 1353. However, even if Ms. Wyatt had shown some definable injury that lasted at least six months, she would be unable to sustain her burden of proving causation under the three-pronged test established in *Althen*, 418 F.3d at 1278. *Althen* requires that petitioner establish by preponderant evidence that the vaccination she received caused her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Petitioner in this case fails on all three prongs.

i. Reputable Medical Theory

The first *Althen* prong requires petitioner to provide a "reputable medical theory" demonstrating that the vaccines received *can* cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id.* at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde*, 746 F.3d at 1341.

While it is unclear what injury or condition petitioner was claiming she suffered as a result of the flu vaccination, it appears, based on petitioner's counsel's insistence in his arguments on

paper and questions at hearing, that GBS was the claim. In this case, petitioner has not offered a reputable medical theory of causation that the flu vaccine can cause her symptoms.

To that end, GBS is an established injury following flu vaccine and as such, is an injury listed on the Vaccine Table. Following a review of the 2012 Institute of Medicine ("IOM") report, which was developed after the IOM conducted a comprehensive review of the scientific literature on vaccines and adverse events, the committee charged with this review (the Advisory Commission on Childhood Vaccines, or "ACCV") agreed to proposed changes to the Vaccine Table. In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, Title III of Public Law 99-660, 100 Stat. 3779 (42 U.S.C. § 300aa-1 note) and section 2114(c) of the Public Health Service Act as amended (PHS Act) (42 U.S.C. § 300aa-14(c)), the following change, *inter alia,* to the Vaccine Table became effective on March 21, 2017: "XIV. Seasonal influenza vaccine…(D) Guillain-Barré Syndrome 3-42 days (not less than 3 days and not more than 42 days)." National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6,294 (Jan. 19, 2017) (to be codified at 42 C.F.R. pt. 100).

Thus, prong I would be satisfied with regard to influenza vaccine causing GBS. However, petitioner failed to provide any evidence that influenza vaccine can cause an undefined autoimmune disease or injury. Therefore, with regard to any other injuries alleged in this case, petitioner failed to satisfy prong I.

ii. Logical Sequence of Cause and Effect

The second *Althen* prong requires proof of "[a] logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). In other words, even if the vaccination can cause the injury alleged, petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id.* at 961 (citation omitted), and "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," *Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375).

Petitioner fails on this prong as well. As the medical records establish, petitioner's treating physician, Dr. MacCallum, never diagnosed petitioner with GBS or any other autoimmune or polyneuropathic injury. In his opinion letters authored on February 2, 2016 and June 24, 2016, Dr. MacCallum mentioned the possibility that petitioner may have suffered from a GBS like illness, but then emphatically rejected the notion stating that there is testing for GBS that was never ordered by either petitioner's rheumatologist or neurologist, because they did not consider GBS an option and he only used GBS as an example of a kind of neurological disorder associated with the flu vaccine. Tr. 35-36 ("I don't believe she had Guillain-Barré syndrome."); Tr. 39 ("I do not believe this was Guillain-Barré. Guillain-Barré is just a good example of a neurological disorder as an adverse reaction to a vaccination."); Tr. 47 ("[W]e can't explain exactly what is going on." "So there's been no definitive diagnosis, correct?" "No."). As petitioner's treating physician, Dr.

MacCallum was clearly in the best position to determine whether the flu vaccine in question did cause GBS and he definitively stated that petitioner did not suffer from GBS.

Additionally, petitioner's other treating physicians, Dr. Lumapas and Dr. Saltis, did not associate petitioner's symptoms with the October 2012 flu vaccine. At petitioner's January 3, 2013 visit, Dr. Lumapas opined, petitioner did have a positive ANA result which could indicate inflammation or a possible autoimmune disorder that could have been exacerbated by the October 1, 2012 flu vaccine, but she could not definitively connect the results and the vaccine. Pet. Ex. 10 at 314. On January 17, 2013, Dr. Lumapas stated that while petitioner may have developed a reactive arthritis process after receiving the flu vaccine on October 1, 2012, petitioner's possible arthritis "has now resolved." *Id.* at 307. Moreover, at petitioner's December 8, 2015 visit, Dr. Saltis was presented with petitioner's history regarding her symptoms following the October 1, 2012 flu vaccine and disregarded the flu vaccine as noncontributory to her complaints. *See* Pet. Ex. 32 at 1-2.

Dr. DeMio concluded petitioner suffered from GBS and autoimmunity in his expert reports but failed to provide any basis in petitioner's medical records, lab testing, or medical literature to support his diagnoses. *See* Pet. Ex. 29, 36. He further failed to consider or chose to disregard the medical records from Dr. Lumapas, Dr. Saltis and Dr. MacCallum which concluded that "evaluations by rheumatology failed to unearth any significant autoimmune disease." Pet. Ex. 31; Pet. Ex. 35 at 2. Additionally, Dr. DeMio is not qualified to opine on autoimmune or demyelinating diseases such as GBS. Therefore, without any support from any of her treating physicians, that her symptoms were causally related to the influenza vaccine, petitioner failed to satisfy prong II.

iii. Proximate Temporal Relationship

To satisfy the third *Althen* prong, petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen,* 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan,* 539 F.3d at 1352. Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

In terms of influenza vaccines leading to GBS, it is well established that the proximate temporal relationship between the vaccine and the onset of GBS-like symptoms is no less than three days and no more than 42 days. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6,294 (Jan. 19, 2017) (to be codified at 42 C.F.R. pt. 100).

There is no clear date of onset in this case. Petitioner initially reported pain and weakness as early as the night she received the flu vaccine. Pet. Ex. 1 at 4. She also reported she began to feel symptoms within seven to ten days, and up to two weeks following the vaccine administration. *See* Pet. Ex. 17 at 1. In the report from her supervisor, she advised onset as October 10, 2012. Pet. Ex. 4 at 1. Dr. MacCallum was also unclear of when petitioner's symptoms began, admitting that he did not see her until two weeks after the vaccine, so he relied upon what she told him. *See* Pet. Ex. 7 at 196. Whether it was the same day, the next day, October 10, 2012, or as Dr. MacCallum stated, in the weeks that followed, having no definable diagnosis renders timing impossible to determine. Pet. Ex. 5 at 3-4; Pet. Ex. 4 at 1; Pet. at 2; Pet. Ex. 1 at 5; Pet. Ex. 17 at 1.

In forming his "expert" opinion, Dr. DeMio concluded that petitioner's alleged injuries began the day after her flu vaccine when she "noted pain which was uncharacteristic in the left upper extremity including the hand" and "the lack of another temporally associated reasonable trigger makes the vaccine the sole cause of [Petitioner's] current state of medical symptoms." Pet. Ex. 29 at 1.[35] However, Dr. DeMio provides no evidence or explanation as to how that timeframe is consistent with an influenza vaccine causing the onset of symptoms of GBS or any other autoimmune disease. Rather, Dr. DeMio's opinion on temporal relationship is premised on a random date of onset, with no support for his opinion on timing. Having no definitive diagnosis, no consistent date of onset or medical literature to support the onset of an undefined injury associated with influenza vaccine, petitioner fails to satisfy prong III.

VII. Conclusion

There is no doubt that petitioner suffered from pain and weakness in her fingers, arms, and hands, and potentially in her feet and to a lesser extent her legs, for a time following receipt of the influenza vaccine, and potentially in the months prior thereto. However, despite sympathy for petitioner, my decision must reflect a thorough analysis of the evidence presented and the application of the law based upon probative weight and persuasiveness. In the instant case, after review of all of the medical records and reports, medical literature and documentation, testimony and submissions of counsel, it is clear that petitioner has failed to provide sufficient evidence to demonstrate: (1) that she suffered any definable injury following the influenza vaccination; (2) that the injuries alleged to have occurred lasted in excess of the requisite six months; and/or (3) that the influenza vaccine can cause and did cause her to suffer an injury within an appropriate timeframe in order to satisfy the *Althen* criteria.

For these reasons, I find that petitioner has not established entitlement to compensation and her petition must be **dismissed.**[36] In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk is directed to enter judgment consistent with this decision.[37]

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[35] There were multiple references to onset in this matter: within twenty-four hours (Pet. Ex. 5 at 3); one day (Pet. Ex. 1 at 3); ten days (Pet. Ex. 4); and anywhere from a few days up to ten days (Pet. at 1; Pet. Ex. 17 at 1-2). Dr. DeMio decided to choose one day as the date of onset of petitioner's symptoms.

[36] Respondent's Motion to Dismiss filed on January 6, 2017 is hereby rendered moot. *See* ECF No. 68.

[37] Pursuant to Vaccine Rule 11 (a), if a motion for review is not filed within 30 days after the filing of the special master's decision, the clerk will enter judgment immediately.

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master