

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

Filed: June 30, 2020

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MARISSA NICOLE COMO,	*	UNPUBLISHED
	*	
Petitioner,	*	No. 18-99V
	*	
v.	*	Special Master Gowen
	*	
SECRETARY OF HEALTH	*	Onset; Meningococcal B;
AND HUMAN SERVICES,	*	Trumenba; Small Fiber Neuropathy.
	*	
Respondent.	*	
* * * * *	*	

Ronald C. Homer & Joseph Pepper, Conway, Homer, P.C., Boston, MA, for petitioner.
Traci R. Patton, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT¹

On January 22, 2018, Marissa Nicole Como (“petitioner”) filed a timely petition in the National Vaccine Injury Compensation Program.² Petition (ECF No. 1). Petitioner alleges that as a result of receiving a meningococcal B vaccination (brand name Trumenba) on February 8, 2015, she suffers from small fiber neuropathy and related sequelae. *Id.*; Amended Petition (ECF No. 55). Both parties have requested a ruling on the onset of petitioner’s symptoms based on the existing record, without need for a hearing. As detailed below, I find that the onset of petitioner’s symptoms was shortly after the vaccination.³

¹ Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this opinion contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court’s website is at <http://www.uscfc.uscourts.gov/aggregator/sources/7>. This means the opinion will be available to anyone with access to the Internet. Before the opinion is posted on the court’s website, each party has 14 days to file a motion requesting 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). “An objecting party must provide the court with a proposed redacted version of the [opinion].” *Id.* If neither party files a motion for redaction within 14 days, the opinion will be posted on the court’s website without any changes. *Id.*

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-1 to 34 (2012) (“Vaccine Act” or “the Act”). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

³ Pursuant to Section 13(a)(1), in order to reach this determination, I have considered the entire record including all of the medical records, affidavits, and other evidence submitted by petitioner. This ruling discusses only the

I. Procedural History

On January 22, 2018, petitioner, acting *pro se*, filed a petition concerning her receipt of a meningococcal B vaccination (brand name Trumenba) on February 8, 2015, at the student health center at Providence College in Providence, Rhode Island. Petition (ECF No. 1) at ¶ 4. Petitioner alleged regarding onset: “Shortly after receipt of meningococcal vaccination, I developed severe headaches, nausea, tiny purple dots on my legs, fatigue, weakness, intense ringing in ears, tingling in toes and fingers, and nerve pain.” *Id.* at ¶ 5. Petitioner alleged that she developed injuries “including but not limited to the development of Inflammatory Neuropathy, Small Fiber Neuropathy and/or Chronic Fatigue Syndrome (CFS) and its related sequela”, which were caused-in-fact by the meningococcal B vaccination. *Id.* at Preamble, ¶ 14. Petitioner initially did not file any supporting documentation for her claim.

The case was assigned to my docket. ECF No. 4. On February 20, 2018, Ronald C. Homer of Conway Homer, PC filed a motion with petitioner’s consent to become her attorney of record. ECF No. 6. On February 22, 2018, I suspended the deadline for respondent to file the report pursuant to Vaccine Rule 4(c) and ordered petitioner to file all records required to support her claim. ECF No. 8. Over the next six months, petitioner filed her medical records and an affidavit of no prior civil action as Petitioner’s Exhibits (Pet. Exs.) 1-22. She filed a Statement of Completion on August 20, 2018. ECF No. 22.

On October 19, 2018, respondent filed a status report identifying three sets of records as being either missing or incomplete. ECF No. 24. On December 7, 2018, an attorney at Conway Homer, PC filed an affidavit averring that he had discussed the missing or incomplete records with petitioner and her mother, who confirmed that there were no such records. Pet. Ex. 25. Petitioner also filed transcribed records from her primary care provider which had been previously filed as Pet. Ex. 2, as Pet. Ex. 23. Petitioner also requested that Providence College, from which student health center records had been previously filed as Pet. Ex. 4, provide “a more clear copy of the 2/18/2015 telephone note (the bottom is cut off)”, which was supplied. However, the health center could not satisfy petitioner’s request for “a transcription of the handwritten note from 2/12/2015, which [Conway Homer, PC] clerk found to be illegible” because the nurse practitioner who wrote the note no longer worked at the college. Pet. Ex. 24. On December 7, 2018, petitioner filed a supplemental statement of completion.

On February 26, 2019, respondent filed his report pursuant to Vaccine Rule 4(c). Respondent recommended that compensation be denied, on the grounds that the medical records – particularly those from the college student health center and an emergency room visit – established that petitioner’s symptoms began *before* her vaccination and did not support a claim for significant aggravation. Resp. Report, ECF No. 33.

On April 1, 2019, I held a status conference to discuss the onset issue. *See* Scheduling Order at ECF No. 34. I noted that contemporaneous medical records are generally presumed to be accurate and complete. *Id.* If a petitioner believes that contemporaneous medical records are not accurate, it is her burden to show, by way of later evidence that is “consistent, clear, cogent,

elements of the record I found most relevant to resolving onset.

and compelling,” what is and is not accurate. *Id.* (quoting *Camery v. Sec’y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998)). Petitioner had the option of either disputing the accuracy of contemporaneous medical records or seeking to supplement them. *Id.* I noted that petitioner had a history of migraines. *Id.* Additionally, during the relevant time period, there was concern about the reported cases of meningitis at her college. *Id.* I directed petitioner and her counsel to determine how to proceed, including whether a fact hearing would be helpful. *Id.*

On May 16, 2019, petitioner filed a status report suggesting a fact hearing in which she and her mother would testify. Status Report at ECF No. 37. During a status conference on June 6, 2019, petitioner confirmed that she disputed the accuracy of certain medical records with regard to onset of her alleged vaccine injury. Scheduling Order at ECF No. 38. It was agreed that petitioner would file additional evidence regarding onset. *Id.* Respondent requested – and I agreed – that petitioner file that evidence, which would impact whether a fact hearing was necessary. *Id.*

On August 23, 2019, petitioner filed her additional evidence regarding onset. Pet. Ex. 26. This was organized into four volumes: (I) campus climate at Providence College during the meningitis outbreak in 2015; (II) petitioner’s contemporaneous coursework during the meningitis outbreak in 2015; (III) her social events from February 6 – 8, 2015; and (IV) personal statements.

During a status conference on September 9, 2019, respondent’s counsel requested additional detail. Scheduling Order at ECF No. 46. Per respondent’s request, on October 10, 2019, petitioner filed Pet. Ex. 27 - signed and dated personal statements; Pet. Ex. 28 – date-stamped photographs; Pet. Ex. 29 - her college transcript; and Pet. Ex. 30 – her social media posts from February 1 - 15, 2015.

On November 25, 2019, respondent advised that he had reviewed all of the evidence and intended to continue defending the case. ECF No. 50. Respondent first requested a ruling on onset, which could be done on the record without the need for an in-person fact hearing. *Id.* Second, respondent proposed that after I issue my factual findings, the parties should retain experts and file expert reports in support of their respective positions on entitlement. *Id.*

Following another status conference on December 19, 2019, I granted petitioner additional time to determine whether to request a fact hearing or a ruling on the record. Scheduling Order at ECF No. 51. On March 16, 2020, petitioner filed an amended petition which identified her alleged vaccine injury as “small fiber neuropathy and related sequelae” and providing additional detail and citations to the record. ECF No. 55. Petitioner also filed a supplemental affidavit regarding the onset of her symptoms. Pet. Ex. 31. Petitioner also filed a status report: “respectfully requesting the Court to make a ruling on the record with regard to onset of her injury.” *Id.* Neither party has requested to brief the issue and I do not find that to be necessary. Accordingly, the matter is ripe for adjudication.

II. Legal Standard Regarding Fact Finding

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition.

§11(c)(2). The Federal Circuit has made clear that medical records “warrant consideration as trustworthy evidence.” *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d at 1528. Medical records that are created contemporaneously with the events they describe are presumed to be accurate and “complete” (i.e., presenting all relevant information on a patient’s health problems). *Cucuras*, 993 F.2d at 1528.

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec’y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that “written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” *Lowrie*, at *19.

The Court of Federal Claims has recognized that “medical records may be incomplete or inaccurate.” *Camery*, 42 Fed. Cl. at 391. The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec’y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec’y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

III. The Factual Record

The parties have requested a ruling on the onset of petitioner’s symptoms in relation to the meningococcal vaccination received on February 8, 2015. Therefore, the following section is focused on the evidence directly relating to onset. This decision should not be interpreted to mean that the remainder of the medical records, affidavits, and other evidence submitted is not important or is not being considered.

A. Medical Records

1. Before Vaccination

Petitioner was born in 1994. Pet. Ex. 1. She was raised in New York. Her mother is recorded to have a history of Addison's disease, heart palpitations, syncope, migraines, and chronic fatigue syndrome. See Pet. Ex. 2 at 15, 79; Pet. Ex. 7 at 20.

Petitioner received regular medical care at Wolf Pediatrics in Mount Sinai, New York. Pet. Ex. 2 at 14-26. In November 2012, she reported one or two episodes of "heart racing" and dizziness. *Id.* at 26. Petitioner noted that at least one episode occurred after she had skipped breakfast. *Id.* Petitioner was referred to a cardiologist. An echocardiogram was normal: the impression was that petitioner had no structural heart disease but may be having an intermittent arrhythmia. Petitioner would receive an event monitor and further workup would depend on the results of that monitoring. Pet. Ex. 2 at 79-81. No further cardiology records have been filed.

The primary care provider did not record any further concerns relating to heart racing, palpitations, or arrhythmia. Pet. Ex. 2 at 18-25. A February 2013 record provides that petitioner was running cross country, was in twelfth grade, and planned to obtain further education relating to computer science. *Id.* at 26.

In fall 2013, petitioner started as an undergraduate student at Providence College in Providence, Rhode Island. In advance, she submitted a form which discloses the mother's autoimmune disease, but provides that her father and three siblings were all in "excellent" health. Pet. Ex. 4 at 2. Petitioner reported her own medical history was limited to exercise-induced asthma, fractured bones, and pneumonia. *Id.*

Over the next year, petitioner presented several times to her primary care provider for symptoms of upper respiratory infection or sinus infection. Pet. Ex. 2 at 16-21. She also presented with those symptoms to the student health center. Pet. Ex. 4 at 32-37.

On August 8, 2014, petitioner went to urgent care for a one-week history of headache at the back of her head. Pet. Ex. 11 at 6-7. Two days later, she followed up with her primary care provider, who recorded: "HA x 5 days – constant, +R eye pain, +photo/ phonophobia... +diarrhea, +nausea." Pet. Ex. 2 at 15. Motrin was associated with mild relief. *Id.* The primary care provider's diagnosis was "migraine" for which she recommended Excedrin for Migraine and gave a referral to a neurologist. *Id.* However, there are no further records suggesting that petitioner actually saw a neurologist.

The next medical appointment is from September 24, 2014, when petitioner presented to the student health center. She endorsed fever, nasal congestion, post-nasal drip, sore throat, cough, and shortness of breath. She did not endorse headache, neck pain, body aches, or joint aches. The assessment was upper respiratory infection and asthma flare. Pet. Ex. 4 at 30-31.

The next medical appointment was on January 5, 2015, at her primary care practice. Pet. Ex. 2 at 14. Petitioner complained of bilateral ear pain, congestion, and pressure. She was

diagnosed with an upper respiratory infection. *Id.* This record does not mention headache, muscle pain, or neck pain. The primary care provider has indeed submitted a letter confirming that petitioner was never examined for or treated for a neck injury. Pet. Ex. 26 Vol. IV at 6.

2. After Vaccination

On Sunday, February 8, 2015 at approximately 1:13 p.m., petitioner received a meningococcal B vaccination at Providence College. Pet. Ex. 1 at 1; Pet. Ex. 4 at 84-85.⁴

Three days after vaccination, on Wednesday, February 11, 2015, petitioner presented to the student health center, where she was seen by nurse practitioner Cynthia Buckley. Pet. Ex. 4 at 28-29. NP Buckley recorded:

Patient] [complains of] neck/shoulder/back pain since Fri[day] – hurts to move. Ibuprofen [does not] help. [Headache] behind eyes/occipital – began Sun[day]/Mon[day]. . . .behind eyes. . . .2 Tylenol [at] night 9[pm]/Excedrin migraine 9[am] helped In general – behind [right] – initially behind both[.] [C]hills Sat[urday]/hot [F]ri[day] night. [No] gym[.] [L]aundry Sat[urday] – worse [after] that[.] [Positive] nausea[,] [No] vomiting[.] [V]accine Sun[day] 12[:]45[.] When did your symptoms start? 5[days]/2 [days] – 3 [days] [headache]. . . . Do you have any of the following medical conditions? . . . [M]igraine during summer – 1st time lasted 1 [week] – behind [right] eye/general [history] [headache][,] [Not] worst [headache] ever[,] never saw neurologist. . . .Pain[:] [headache] 4-5/6 neck/shoulder[,] 8/10 last night. . . .Neck:. . . [Full] [range of motion][,] [positive] tenderness . . .trapezius. . . .Assessment: [Headache] Prob[ably] migraine/musculoskeletal neck pain. . . Excedrin migraine. . . [W]arm moist compresses. . .hot shower[.]

Id. at 28-29. Later that day at 5:45 p.m., NP Buckley called to follow up and recorded that petitioner's headaches were better with Excedrin for Migraine. *Id.* at 29.

Petitioner returned to the student health center later in the evening and then again at approximately 2:00 a.m. Pet. Ex. 4 at 26-27. The record for these encounters provides:

Since Fri[day] neck, shoulders pain – getting worse. Come in today. Nauseated since _____. Advil helped[,] Excedrin Migraine – today – [History] migraine ([headache] in [left] eye)[,] Constant neck pain – difficulty ____ ‘pressure.’ . . . [N]ausea[,] feels like going to have diarrhea[,] sweaty[,] [no] fever. [A]te [at] 6pm – grilled cheese[.] [No] URI[.] Meningitis [vaccine][.] Worse neck pain

⁴ As addressed below, in early February 2015, two individuals attending the college were confirmed to have the same strain of meningococcal B, but no link between the two individuals was identified. Accordingly, the school, in coordination with the state health department and the manufacturer, offered a mass vaccination clinic. Petitioner was among approximately 3,600 individuals who received the first dose of the meningococcal B vaccination on February 8, 2015. See Fiorito T.M. et al., *Rapid Response to a College Outbreak of Meningococcal Serogroup B Disease: Nation's First Widespread Use of Bivalent rLP2086 Vaccine*, *Journal of American College Health*, DOI: 10.1080/07448481.2017.1285772 [filed as Pet. Ex. 26 – Vol. I at 45-49].

ever had. . . . General Appearance: Appears anxious. . . . Assessment: musculoskeletal neck strain. . . . Returned [at] 2am – worried about rash around ankles and scattered on lower extremities[.]

Id. at 26-27.

Four days after vaccination, on Thursday, February 12, 2015, petitioner presented to her established primary care provider, Nataloni Pediatrics in Mount Sinai, New York, where she was seen by Dr. Suzanne Santos. Pet. Ex. 2 at 13. Dr. Santos recorded: “Chief Complaint[:]. . . stiff neck – getting worse [headache]. . . Got meningitis B vaccine. . . LMP [last medical presentation?]: 1 week ago.” *Id.* Dr. Santos recorded a normal physical examination, including “Neurologic: no meningeal signs.” Dr. Santos’s diagnosis was “headaches”. *Id.*

Six days after vaccination, on Saturday, February 14, 2015 at approximately 5:00 p.m., petitioner presented to the emergency room at St. Charles Hospital in Port Jefferson, New York. Pet. Ex. 6 at 1-44. The arrival complaint is recorded as “cervicalgia”. *Id.* at 3, 36. She was first seen by Maureen W. Sileo, R.N., who recorded a chief complaint: “Neck pain (stiff muscles in neck and back and pain behind right eye. No vision problems. X 1 week.” *Id.* at 3, 36.

Petitioner was then seen by Justin Fink, P.A., who recorded: “Marissa Como is a 20 y.o. female presenting today to the emergency department complaining of Neck Pain. Patient presents to the ER with mother for concerns of continued neck and upper back and shoulder stiffness the past two months and right-sided headache. Patient has been seen by Health Center at school as well as by pediatrician yesterday. . . .” *Id.* at 4. The physician assistant recorded under physical exam: “Constitutional: Patient presents to the ER with complaints of neck stiffness into upper back and headache without fever on and off for the past 1.5 months.” *Id.* at 6. Petitioner rated her pain as 7/10. *Id.* The physician assistant gave Valium 5 mg to petitioner. Afterwards, her symptoms were recorded to have “fully resolved.” *Id.* at 7. The physician assistant did not request any consultations. He diagnosed petitioner with “1 – muscle strain, 2 – neck strain, 3 -tension headache.” *Id.* Petitioner was discharged home on Sunday February 14, 2015 at approximately 11:00 p.m. *Id.* at 44.

From February 14 – 16, 2015, the primary care practice had multiple phone conversations with petitioner’s mother, who was concerned that petitioner had an adverse reaction to the meningococcal vaccination. Pet. Ex. 2 at 31, transcribed at Pet. Ex. 23 at 31A-B.

Eight days after vaccination, on Monday, February 16, 2015, petitioner returned to Nataloni Pediatrics, where she was seen by Dr. Kerry Moore, who recorded:

[Follow-up] [regarding]: neck stiffness[,] headaches[,] meningococcal B vaccine 2/8/15[.] Maximum symptoms 2/10 [and] 2/11[.] Seen here 2/12[,] again in ER 2/14[.] On muscle relaxer feels better but noted tenderness and stiffness at back of neck[.] Some retroorbital pain but less[.] [Positive] history migraine headaches[,] slight headache post vaccine[,] resolved[.] Tinnitus last night but better now[.] Did have chills[,] arm ache post vaccine. . . . Diagnosis[:] [Rule out] adverse reaction to meningococcal B vaccine[,] neck strain, tension

headaches, tinnitus, symptoms not progressing, improving[.] Plan[:] Continue Robaxin as directed... Caution 2nd dose of vaccine – discuss [with] school [and] CDC... to see neurology... Dr. Berdia...”

Pet. Ex. 2 at 12, transcribed at Pet. Ex. 23 at 12B.

On February 17, 2015, Dr. Moore had two conversations with petitioner’s mother over the telephone. Pet. Ex. 2 at 29-30, transcribed at Pet. Ex. 23 at 29B-30B. Dr. Moore also recommended further evaluation by an infectious disease specialist and noted that the mother had contacted Susan Levine, M.D. Pet. Ex. 23 at 29B.

Also on February 17, 2015, Dr. Suzanne Bornschein, M.D. at the student health center recorded:

Marissa is here after being seeing [sic – seen] by the nurse practitioner twice 2/11 and 2/12 for what appeared to be some neck discomfort which began prior to having the vaccine. She was diagnosed also in the ER with having some paraspinal cervical spasm and given a muscle relaxer. She reports that there was a rash on her lower extremities confirmed by nurse practitioner. She was seen by her pediatrician twice over the weekend. I have some of the labs that were drawn. Everything looking within normal limits except for minimally elevated sed rate at 23. . . .Marissa herself reports that she is feeling no headache, reports no visual changes that she is sleeping well, with normal appetite. . . .I spoke with Dr. Keegan, the Pfizer representative who reported that in the early as well as the more recent large scale safety studies there have been no associated cases of autoimmune disease. She will follow up tomorrow with the nurse practitioner and possibly have EBV drawn.

Pet. Ex. 4 at 23.

On February 18, 2015, student health center NP Karen Kowa submitted a report to the Vaccine Adverse Event Reporting System (a VAERS report), which provides:

Presented to [Student Health Services] on 2/11/15 with [complaints of] [headache]/nausea since 2/8/15. Also [complained of] neck/shoulder pain since 2/6/15. Prescribed NSAIDs, heat, rehab exercises, bland diet. Returned later 2/11/15 [and] 2/12/15 with same complaints[.] Went home before labs could be drawn. Meningeal signs [negative]. Date of vaccination[:] 02/08/15[.] Time[:] 12:45 PM[.] Adverse event onset[:] 02/08/15[.]

Pet. Ex. 4 at 83.

On February 19, 2015, Dr. Susan Levine (referenced in Dr. Moore’s record, above) conducted an initial consult. Pet. Ex. 7 at 20-23. Dr. Levine recorded:

HPI: The patient is a 20 year old college student at Providence College whose mother has Chronic Fatigue Syndrome (CFS) and autoimmune thyroid disease and adrenal insufficiency⁵ who presents with post-exertional fatigue, ringing in ears, stiff muscles and some mild cognitive disturbances following the receipt of Trumenba Meningitis B vaccine on February 7, 2015. She missed school from that date but tried some classes the day afterwards and then returned home from 2/12 through 2/16. She then got sick and returned home on 2/18 after a 2 day trial... She continues to experience daily fatigue; cognitive problems; no change in appetite; low grade fevers and chills. She received the first of a three dose series of this vaccine. She reports stiff neck; headaches; the appearance of tiny purple dots; a weak feeling; ringing in her ears and a sensation of 'cold'. She tried to contact the CDC regarding adverse reactions with this vaccine but did not retrieve much useful information. She was put on meth[o]carbamol and continues on Flonase spray for chronic rhinitis. . . .Imp[ression]: The patient is a 20 year old female who developed muscle stiffness, fatigue, headache, stiff neck and ringing in her ears within 2 days of receiving a Meningitis B vaccine.

Id. at 20. Dr. Levine continued to see petitioner for suspected chronic fatigue syndrome and/or aseptic meningitis following the meningococcal B vaccination. *See generally* Pet. Ex. 7.

On March 9, 2015, Ajay Berdia, M.D., a neurologist affiliated with St. Charles Hospital, conducted an initial consult. Pet. Ex. 6 at 44-47. Dr. Berdia recorded a chief complaint of “after meningitis B vaccine developed nerve pains, shock-like feeling in all extremities, dizziness episodes.” *Id.* The history of present illness provides: “Had a meningitis B vaccine at school February 7, 2015. She started in 24 hours with muscle neck pain, arm pain, also had purple dots in the legs...” *Id.* Dr. Berdia’s assessment provides: “In summary, Ms. Como is a 20 y.o. year old [sic] female presenting with meningitis B vaccine developed nerve pains, shocks like feeling in all extremity, dizziness episodes. Likely neuropathy autoimmune, vaccine related...” *Id.* at 51. Dr. Berdia ordered MRIs of the brain and cervical spine, as well as an EMG. The MRIs were unremarkable. Pet. Ex. 9 at 2-3. The EMG report reflects a history of “neck and muscle pain beginning within days after receiving a meningitis B vaccination at 2/7/2015 at college. This was accompanied by shock-like sensations in the upper and lower limbs which have continued since. She denies muscle weakness, but gets fatigued.” Pet. Ex. 9 at 13.

On March 11, 2015, petitioner’s mother completed a second VAERS form. She reported the symptoms described already above and that the onset date was February 8, 2015. She incorrectly wrote that the vaccination date was February 7, 2015. Pet. Ex. 15 at 1-5.

On May 7, 2015, Louis Weimer, M.D., a neurologist at Columbia University Medical Center, conducted an initial consult. Pet. Ex. 9 at 7-9. Dr. Weimer recorded under history of present illness: “She is a sophomore at Providence College and in February, she got the Trumemba vaccine for meningitis B. A day after the shot, she developed a headache and neck pain. Three days afterwards, she developed ‘purple dots’ in the dorsum of her feet and ankles as

⁵ It is not clear whether the mother’s history was only reported to Dr. Levine or whether the mother was an established patient of Dr. Levine.

well as on her back but these skin changes resolved after a few days. She denies having a fever. She also developed intermittent, electric shock-like pain throughout her body around this time period...” *Id.* at 7. Dr. Weimer thought that petitioner may have had a mild case of aseptic meningitis and limited immune reaction but he was very doubtful of an active or ongoing process. *Id.* He did not see “evidence of large fiber nerve involvement” but “a restricted small fiber neuropathy remain[ed] possible.” *Id.*

On or around March 1, 2016, petitioner was seen at the Providence College Student Health Center, where she was diagnosed with mononucleiosis and pharyngitis. Pet. Ex. 4 at 17-18. Lab work also showed low cortisol levels. Pet. Ex. 4 at 40. This eventually resulted in an evaluation by an endocrinologist, Dr. Deepa Aravind in November 2016. Pet. Ex. 12 at 11-12. Dr. Aravind recorded petitioner’s history of: “Fatigue since Feb 2015 when she got a vaccine for meningitis B”. *Id.* at 11.

The treaters listed above continued to suspect that petitioner developed aseptic meningitis and/or small fiber neuropathy following receipt of the meningococcal B vaccination. *See, e.g.*, Pet. Ex. 6 at 82-86 (May 25, 2017 record by neurologist Dr. Berdia).

On August 9, 2017, petitioner, accompanied by her mother, presented for an initial consultation with Russell Chin, M.D., a neurologist at Weill Cornell Peripheral Neuropathy Center. Pet. Ex. 13 at 1-5. Dr. Chin recorded:

Chief Complaint[:] 1. Fatigue, neuropathy[.] History of Present Illness[:] 22 [year old] right-handed woman who presents for evaluation of fatigue and paresthesias. . . .Received Trumenba vaccination on 2/7/15 [sic – 2/8/15] while a sophomore at Providence College due to meningitis B outbreak affecting two students. Within 24 [hours] recalls developing neck stiffness and severe headache, followed later by paresthesias throughout her body, chills, fatigue and dizziness. About 36 [hours] post-vaccination, she developed skin lesions (flat, punctate, purplish dots) to her extremities and back. These resolved after 1-2 weeks. Later saw Dr. Susan Levine; says some elevated inflammatory markers were noted in her blood. Steroids for one week (Medrol Dosepak?) were helpful, but her symptoms recurred off medication. Saw local neurologist (Dr. Ajay Berdia). EMG/NCS reportedly normal; small fiber neuropathy was suspected. She was referred to Dr. Louis Weimer (5/15); he diagnosed prior aseptic meningitis and current small fiber neuropathy. Skin biopsy was deferred. . . . Current symptoms: Chronic fatigue: requires 10+ [hours]/night; feels worse if [less than] 9 [hours]; Neck stiffness, worse if she doesn’t have enough sleep. Cyclobenzaprine with benefit; Sensory symptoms: allodynia (sensations are ‘off’, e.g. touching tulle can feel painful), paresthesias/dysesthesias (random stabbing, pins/needles, icepick-like pains, crawling sensations) to face, neck, extremities. Pain in face with heat, cold (AC blowing on face); Photosensitivity[.] Feels symptoms are stable; she’s adjusted her lifestyle. . . .Assessment and Plan[:] 22 [year old] right-handed woman who reports prophylactic Trumenba vaccination on 2/7/15 [sic – 2/8/15] followed within 24 [hours] by suspected aseptic meningitis (neck stiffness and severe headache) and later paresthesias/

dysesthesias throughout her body and later skin lesions (now resolved). Reports persistent fatigue, sensory symptoms, variable neck stiffnessSuspected small fiber neuropathy given sensory symptoms and diffuse distribution. Post-vaccination, inflammatory etiology? Will evaluate further with additional lab studies, skin biopsy. . .and lumbar puncture[.]

Pet. Ex. 13 at 1-5. On October 6, 2017, petitioner underwent a skin biopsy. Pet. Ex. 19 at 1-4. A sample from her right thigh was normal. *Id.* at 1-4. However, a sample from her right calf showed low normal epidermal nerve fiber density and significantly reduced sweat gland nerve fiber density, consistent with small fiber neuropathy. *Id.* at 1-5.

B. Other Contemporaneous Evidence

1. Contemporaneous Evidence About Providence College During Meningitis Outbreak

Petitioner filed several local news articles which report that by Sunday, February 1, 2015, one case of meningococcal meningitis had been confirmed in a student at Providence College. Pet. Ex. 26 Vol. I at 1-6. The Rhode Island Department of Health communicated that meningococcal meningitis is a bacterial infection of the lining that surrounds the brain and spinal cord; it can be treated with antibiotics but quick medical attention is extremely important. *Id.* Routine meningococcal conjugate vaccinations, with the first dose recommended for all children at 11 – 12 years old, protected against all strains except for serogroup B. *Id.*

On Thursday, February 5, 2015, the college’s vice president of student affairs sent an email to all students and staff notifying that there was a second possible case and that both students remained hospitalized. *Id.* at 7-8. One of the student was found to have meningococcal meningitis serogroup B, which was not addressed by routine childhood vaccinations. *Id.* at 7. The college was working with the Rhode Island Department of Health and the Centers for Disease Control and Prevention (CDC) to secure a supply of a new vaccination against serogroup B (brand name Trumenba). *Id.* It was noted: “Meningitis may present as sudden onset of fever, headache, and stiff neck. It will often have other symptoms, such as nausea, vomiting, increased sensitivity to light, and altered mental status and/or a skin rash.” *Id.* Symptoms can appear quickly or over several days. *Id.* The student health center would operate twenty-four (24) hours a day, seven days a week to respond to any students who presented with symptoms, continue interviews about contact tracing, and provide prophylactic treatment as necessary. *Id.*

On Friday, February 6, 2015, the administration sent several more collegewide emails about the meningitis outbreak and the response. *Id.* at 10-12. That same evening at 9:18 p.m., petitioner’s brother emailed her a link to the Providence College webpage providing additional information about meningitis. *Id.* at 9.

On Saturday, February 7, 2015 at 3:00 p.m., the director of the state health department held an informational session on campus. *Id.* at 10, 15. He strongly encouraged all students to receive the meningococcal B vaccination which involved three doses; the first dose would be available the following day. *Id.* at 15. The vaccinations would be provided at no cost. *Id.* It

was communicated that students with any symptoms consistent with meningitis should “immediately report to or call the student health center”. *Id.* Petitioner’s mother also sent her an email titled: “well said about why you should receive vaccinations”, linking to a local news article. *Id.* at 14.

On Sunday, February 8, 2015 at 1:14 p.m., petitioner received the first dose of the meningococcal B vaccination. Pet. Ex. 1 at 1. She was one of 3,060 students who received the vaccination that day. *Id.* at 25-27, 47-49.

On Tuesday, February 10, 2015, the administration sent a collegewide email providing: “Some students, who received the vaccine on Sunday, have reported experiencing some of the common adverse reactions like pain at the injection site, fatigue, headache, muscle pain, nausea, and chills. While these are common, if you are concerned or if you experience more severe or unusual symptoms you can call or go to the Student Health Center... We’ve decided to keep the Student Health Center open 24/7 through Monday, Feb. 16th at 5p.m.” *Id.* at 29.

On Wednesday, February 11, 2015, from 10:00 a.m. to 4:00 p.m., a second vaccination clinic was offered to the approximately one hundred students who had not been available or willing on Sunday. *Id.* at 28. *See also* Fiorito T.M. et al., *Rapid Response to a College Outbreak of Meningococcal Serogroup B Disease: Nation’s First Widespread Use of Bivalent rLP2086 Vaccine*, *Journal of American College Health*, DOI: 10.1080/07448481.2017.1285772 [filed as Pet. Ex. 26 – Vol. I at 45-49].

2. Contemporaneous Records of Petitioner’s Coursework

Petitioner filed her class schedule and planner pages for the week of Monday, February 2 – Sunday, February 8, 2015, as well as related class notes and emails. *See generally* Pet. Ex. 26 Vol. II. On Monday, February 2, 2015, she had computer science class. Pet. Ex. 26 Vol. II at 8-9. On Tuesday, February 3, 2015, she had philosophy, math, an honors seminar on the development of Western Civilizations, and computer science. *Id.* at 8-9. On Wednesday, February 4, 2015, she had philosophy, math, computer science, tutoring, choir practice, and interviews of new members for the college radio station. *Id.* at 8-9.

On Thursday, February 5, 2015, she had the honors seminar and computer science. *Id.* at 8-9. At 10:15 p.m., she turned in an assignment for computer science more than 24 hours before the deadline. *Id.* at 3.

On Friday, February 6, 2015 at 8:29 a.m., she emailed a poem for publication in a student literary journal. *Id.* at 6. She had scheduled classes in philosophy, math, computer science (both a laboratory session and class) and the honors seminar. *Id.* at 8-9. She took handwritten notes during math. *Id.* at 7. She took notes and emailed herself the in-class assignment during computer science lab. *Id.* at 4-5.

Throughout the week, she also had various homework assignments to complete. She wrote down the time of the college town hall regarding the meningitis outbreak on Saturday at 3:00 p.m. *Id.* at 8-9.

Petitioner did not file the class schedule or planner pages for the following weeks in Spring 2015. Her anticipated schedule would likely have been the same or similar to what is reflected above. However, petitioner began missing classes and other college activities on February 9, 2015, in association with the symptoms reflected in the contemporaneous medical records. Additionally, petitioner has filed her college transcript and emails reflecting that she fell behind in her coursework. Pet. Ex. 29. This includes an email thread beginning April 22, 2015, with Dr. Gary Culpepper, the professor in her Development of Western Civilizations honors seminar. *Id.* at 5-7.

3. Contemporaneous Records of Petitioner's Social Interactions

Contemporaneous phone records reflect that on Friday, February 6, 2015 at 6:51 p.m., Gabrielle (Gabby) Shkreli, a classmate who lived in the same dormitory, texted petitioner about plans for that night. Pet. Ex. 26 Vol. III at 6. Petitioner responded and sent a picture of what she was planning to wear. *Id.* at 2; *also at* Pet. Ex. 28 at 1-2. At about 10:00 p.m., petitioner texted about coming up to Gabby's room. Pet. Ex. 26 Vol. III at 6. At 11:23 p.m. petitioner is pictured alongside another classmate. *Id.* at 23; *also at* Pet. Ex. 28 at 3-4. At 1:51 a.m., Gabby Shkreli emailed petitioner a photo of them together, commenting: "definitely my favorite one". Pet. Ex. 26 Vol. III at 8. Petitioner replied quickly: "HA". *Id.*

On Saturday, February 7, 2015 at 4:17 p.m., petitioner sent a text and a photo to her roommate, Meagan Nolan, which establishes that they were together in the college dining hall. Pet. Ex. 26 Vol. III at 7.

On Monday, February 9, 2015, petitioner texted: "HAPPY BIRTHDAY!", to Gabby Shkreli, who responded to say thank you. *Id.*

On Thursday, February 12, 2015 at 1:02 p.m., Gabby Shkreli texted to check on petitioner, who had not been in class, and to offer her notes. *Id.* at 9. Petitioner responded:

Yea my neck like muscles/head have been hurting and I went to the health center and they kept me there for four last night and then I got like blood spots on my legs and the PAs almost freaked but they said if it was mening it would be everywhere. But they wanted a blood test because it might be Lyme or something. So my dad just picked me up and I went home early

Id.; *see also* Pet. Ex. 30 (petitioner's social media posts from February 1 – 15, 2015, which I have reviewed and do not find to include information helpful to resolving onset).

C. Later Statements

1. Petitioner

In the petition filed *pro se* on January 22, 2018, petitioner alleges: "Shortly after receipt of meningococcal vaccination, I developed severe headaches, nausea, tiny purple dots on my

legs, fatigue, weakness, intense ringing in ears, tingling in toes and fingers, and nerve pain.” Petition at ¶ 5.

Petitioner submitted two subsequent statements. Pet. Ex. 26 Vol. IV at 1-2; Pet. Ex. 31. She avers that she was in perfect health without any history of neck or back injury before receiving the meningococcal B vaccine on Sunday, February 8, 2015. Pet. Ex. 26 Vol. IV at 1.

Petitioner provides considerable detail about her class schedule, homework, in-class activities, extracurricular activities, and social interactions leading up to when she received the vaccination. Her recollection is that she had (typical for her) good health, energy, and attention which allowed her to keep up with a busy schedule. See generally Pet. Ex. 31 at 1-7.

Petitioner recalls that on Friday, February 6, 2015, after waking at 8:00 a.m. and attending five classes, she and her friend Gabby Shkreli had a late lunch in the dining hall. *Id.* at 5. They planned to go out that night. *Id.* Petitioner went back to her room for a few hours, but was “feeling energetic and excited” for their plans. *Id.* She, Gabby, and other friends went to a pre-party and stayed out until later that night. *Id.* She and Gabby walked back to their dorm together at 1:30 a.m. and they texted at 1:51 a.m. *Id.* at 5-6. Petitioner avers: “It was a fun night out. I would not have stayed out that late at night unless I felt well. I was feeling healthy, active, and social that night.” *Id.* at 6.

Petitioner recalls that on Saturday, February 7, 2015, she did homework for three classes, went to the informational session with the director of the state health department, went to the dining hall with her roommate Meagan Nolan, and stayed in to watch a movie with some friends that evening (noting that it was lightly snowing). She felt “productive”, “social and engaged”, “joking and happy”. Pet. Ex. 31 at 6-7.

Petitioner recalls that on Sunday, February 8, 2015, she sang in the choir at the 11:00 a.m. mass, ate bagels at an after-mass social, attended a dormitory meeting about the meningitis outbreak, then walked over with her floormates to the clinic where she received the vaccination at 1:47 p.m. Pet. Ex. 31 at 7. Petitioner avers that she had received all routine vaccinations while growing up and she knew that “to receive a vaccine you should not be sick.” *Id.* “Since [she] felt completely healthy and well, [she] opted to receive the vaccine that Sunday afternoon.” *Id.* Afterwards, petitioner worked on homework for two classes. *Id.* at 8. She had received the meningococcal B vaccination in her left arm, which was hurting more than she had experienced with previous vaccines. *Id.* She had pain not just at the injection site, but throughout the arm. It hurt to move or lift. *Id.* Petitioner recalls that many other students were posting on social media that their arms were hurting after the meningococcal B vaccinations. *Id.* Petitioner agreed but was “beginning to have a feeling that [her] symptoms might be worse than everyone else’s.” *Id.* “By that evening, [she] was also beginning to experience fatigue, chills and had a slight headache. [She] was exhausted. [She] went to bed early thinking [she] would sleep it off and feel better in the morning.” *Id.* at 8-9.

Petitioner recalls that Monday, February 9, 2015, was a snow day on which classes were cancelled. Pet. Ex. 31 at 9. She “had never been so happy that classes were cancelled” because she continued to experience considerable arm pain, extreme fatigue, a light headache, pain in her

eyes, and body aches. *Id.* Petitioner and her roommate Meagan Nolan went to the student health center to report her symptoms. *Id.* They spoke briefly to a nurse, but the student health center was so busy with other students that she was told to go back to her dorm. *Id.* Petitioner stayed in her room for the rest of the day and went to bed early again. *Id.*

Petitioner recalls that on Tuesday, February 10, 2015, she continued to experience the symptoms described above, but her neck began to feel extremely tense and her headache was “starting to crescendo into a full-blown, crushing headache with a lot of pressure.” Pet. Ex. 31 at 10-11. She skipped all four classes scheduled that day. *Id.* at 10. She recalls thinking that if she didn’t feel better the next morning, she might go back to the student health center. *Id.* at 11.

Petitioner recalls that on Wednesday, February 11, 2015, she woke up feeling “absolutely awful”. Pet. Ex. 31 at 11. “Class wasn’t even a thought.” *Id.* Her headache was even worse and her neck and shoulders were tight. *Id.* When she stood up, her head felt really heavy, she felt dizzy and nauseous, the room seemed to spin a little, and her lower back was hurting a little too. *Id.* She realized that something was seriously wrong and she needed to go to the student health center when she was sitting on the toilet and she experienced “an extreme wave of head pain... the greatest amount of pressure [she had] ever felt... new levels of pain [she] previously did not know existed...” *Id.* Petitioner was confused and struggled to describe what was happening when she called her mother, who booked an appointment at the student health center. *Id.* When petitioner reached the student health center at approximately 3:00 p.m., she still had a terrible headache, neck and shoulder pain, body aches, fatigue, confusion, and heart racing. *Id.* at 12-13. She struggled to communicate her history and current symptoms. *Id.*

Petitioner avers that the student health center record of this encounter, which provides that her symptoms began before the vaccination on Sunday, February 8, 2015, is incorrect. Pet. Ex. 31 at 13. Petitioner may have given an inaccurate history because at the time, she inaccurately recalled receiving the vaccination on Saturday and telling that to her mother. *Id.* She also could not think backwards to accurately report when her symptoms started or how many days they had been present. *Id.* All she could think about were the severe symptoms she was experiencing in real time. *Id.*; *see also* Pet. Ex. 36 Vol. IV at 1.

Petitioner recalls that she went back to her dorm at approximately 4:00 p.m. Pet. Ex. 31 at 14. At 5:45 p.m., the student health center called to follow up and it was decided that petitioner would come back. *Id.* She went to the dining hall to get food for the first time that day, then returned to the student health center at 6:30 p.m. *Id.* At this time, petitioner had worsened symptoms and a low-grade fever even though she had taken acetaminophen. *Id.* at 14-15. She continued to feel “blurry”, “dependent on others figuring out what was happening to [her] because [she] could not figure it out for [her]self”, “completely wiped out and just could not think straight.” *Id.* at 14-15. Petitioner recalls staying at the student health center until about 10:30 p.m., when the nurses had campus security drive her back to her room. *Id.* at 15.

Petitioner recalls that later that night, she noticed new “small and large light purple dots on [her] feet and lower extremities.” *Id.* at 16. She called the student health center, where she was taken back by campus security immediately, at 2:00 a.m. *Id.* Petitioner recalls that the nurse and a CDC worker looked worried upon observing the petechia and purpura on her lower

extremities. *Id.* At their instruction, petitioner called her father in New York to pick her up from the college in Rhode Island. *Id.* Petitioner emphasizes that her symptoms remained very severe: she could not fully express how horrible her headache was and she never would have asked her father to drive several hours to pick her up in the middle of the night, impacting his demanding job, unless she felt that something was seriously wrong. *Id.* at 16-17.

Petitioner recalls that on Thursday, February 12, 2015, in the morning, her father picked her up and drove back to New York. Pet. Ex. 31 at 17. Petitioner continued to have severe symptoms during the car ride and during an appointment with her primary care provider. She also avers that her text message to Gabby Shkreli was out of character, “extremely confusing, long, and wordy” and further evidence of the severity of her symptoms and difficulty communicating at this time. *Id.* at 17-19.

Petitioner recalls that on Friday, February 13, 2015, she continued to have “the same unbearable symptoms”. Pet. Ex. 31 at 19. By this point, the rash was on her legs, arms, and back. *Id.* She stayed in bed all day “shaking with chills”. *Id.*

Petitioner recalls that on Saturday, February 14, 2015, her symptoms were even worse and she developed the new onset of severe ringing in her ears, which prompted her presentation to the emergency room that evening. Pet. Ex. 31 at 19-20. Petitioner recalls that the emergency room was packed and the staff was busy. *Id.* at 20. Petitioner recalls trying to describe her history and current symptoms to a male doctor who looked “young” and “like he wasn’t listening to me”. *Id.* She recalls that the male doctor gave her a Valium and said that she was fine. *Id.* at 21. She recalls feeling frustrated that she could not communicate effectively, wasn’t being heard, and wasn’t being treated adequately. *Id.* at 20-21. She avers that the male doctor incorrectly wrote down that she had been experiencing symptoms for two months: “I am not sure if the doctor was mixing me up with someone else because [the emergency room] was packed, or if he just was not listening, but this is incorrect. I had only been experiencing these symptoms since after I received the Trumenba vaccine. The symptoms slowly built into an unbearable pain and that was why I was at the ER.” *Id.* at 21; *see also* Pet. Ex. 26 Vol. IV at 1-2.

Finally, petitioner avers that Dr. Bornschein’s note dated February 17, 2015 within the student health center chart (at Pet. Ex. 4 at 23) is inaccurate in two respects. Pet. Ex. 26 Vol. IV at 2. First, Dr. Bornschein only repeats the nurse practitioner’s earlier history that petitioner’s symptoms began before the vaccination, which petitioner says is incorrect. *Id.* Second, Dr. Bornschein records that “Marissa herself reports that she is feeling no headache, reports no visual changes, that she is sleeping well, with normal appetite.” Petitioner avers that she is “confused where this is coming from.” *Id.* Petitioner avers that she went into the student health center only to authorize release of her medical records; she was not there for a medical appointment. *Id.* Petitioner avers that Dr. Bornschein’s notation conflicts with everything else going on in petitioner’s life at that time – including her various symptoms, emails to her professor, her mother’s phone calls to the student health center, her travel between college and her family home, and the number of doctors’ visits they were scheduling. *Id.*⁶

⁶ Dr. Bornschein’s note appears to be cursorily written. It provides: “I have some of the labs that were drawn [at the primary care practice]. Everything looking within normal limits except for... H&H [presumably hemoglobin and hematocrit] of 3 & 11...” Pet. Ex. 4 at 23 (emphasis added). This note seems to be cursorily written. The primary

1. Meagan Nolan

Ms. Nolan, petitioner's roommate during the 2014 – 2015 school year, recalls that before receiving the meningococcal B vaccination, petitioner was healthy and slept six hours a night on average. Pet. Ex. 26 Vol. IV at 7. Petitioner was able to attend classes and social events and study without needing to rest midday. *Id.* She did not complain about any aches and pain. *Id.*

Ms. Nolan recalls that petitioner complained that she had a sore neck and was concerned that she may be reacting to the vaccine. Pet. Ex. 26 Vol. IV at 7. Ms. Nolan avers: "Taking no chances, I traveled with Marissa (in a snow storm) to the health center to speak to the health center staff, who reassured Marissa and I that Marissa did not have meningitis because Marissa could put her chin to her chest without experiencing excruciating pain." *Id.* Ms. Nolan goes on to describe petitioner's continuing symptoms throughout the spring 2015 semester and to the present day. *Id.* Ms. Nolan avers that these all began after the vaccination and she "did not notice any other significant lifestyle changes that explain the symptoms that Marissa came to experience". *Id.*

2. Gabrielle Shkreli

Ms. Shkreli recalls meeting petitioner and having classes together during their first year of college (2013 - 2014), and becoming "close friends" during their sophomore year (2014 - 2015). Pet. Ex. 26 Vol. IV at 3. She recalls that because her birthday is February 9, her "birthday weekend" was from Friday, February 6 to Sunday, February 8 in 2015. *Id.* She recalls celebrating that Friday night with petitioner, who was "socializing and chatting with everyone in the dorm room, telling funny stories and singing along to the songs being played, and just having a good time with friends." *Id.* Ms. Shkreli recalls that petitioner's "spirits and energy were high all night and when we arrived back to our dorms in Meagher Hall in the early morning hours, she was just the same." *Id.* "We took pictures together that night, joked about class, and talked about some of our favorite music. It was a great night for everyone." *Id.* Ms. Shkreli goes on to recall how petitioner's condition changed after the vaccination, that they were roommates together the following year, and that they have remained friends. *Id.*

3. Dr. Jim Tattersall

Dr. Tattersall first taught petitioner in a Calculus II class in fall 2013 and again in a Foundations of Mathematics Class in spring 2015. Pet. Ex. 26 Vol. IV at 5. He recalls that petitioner was an excellent student who attended class on Tuesday, February 3, 2015 and an extra credit colloquium on Wednesday, February 4, 2015. *Id.* On Friday, February 6, 2015, she attended class and turned in a homework assignment. *Id.* She was doing "excellent work" up until that point. *Id.* Afterwards, she did not turn in any further homework assignments and did worse on the second exam. *Id.* Dr. Tattersall avers: "There is no doubt in my mind that Marissa took a turn for the worse after receiving the vaccine in February 2015." *Id.*

care practice labwork actually provides that *red blood cells* were at 3.98 M/uL (within the reference range), *hemoglobin* was at 11.6 g/dL (slightly under the reference range of 11.7 – 15.1 g/dL), and *hematocrit* was at 35.3 (within the reference range). Pet. Ex. 23 at 63.

4. Ann Como

Ann Como, petitioner's mother, avers and provides supporting documentation that petitioner was accomplished in academics and extracurricular activities prior to receiving the meningococcal B vaccination. Pet. Ex. 26 Vol. IV at 9, 10-23. She does not specifically address onset or the medical records suggesting that petitioner's symptoms began before the vaccination.

5. Dr. Erika Lorig-Wolf

Dr. Wolf, petitioner's primary care provider, submitted a list of exam dates and diagnoses for petitioner. Pet. Ex. 26 Vol. IV at 6. She avers that petitioner has never been examined or treated for a neck injury. She reviews and essentially confirms the accuracy of the primary care appointment records from immediately before and after the vaccination, which are already addressed above. *Id.*

IV. Discussion and Findings of Fact

Respondent contends that the medical records – particularly those from the college student health center beginning three days post-vaccination and an emergency room visit – establish that petitioner's symptoms began *before* the meningococcal B vaccination on Sunday, February 8, 2015. Resp. Report filed February 26, 2019 (ECF No. 33). After reviewing petitioner's additional contemporaneous evidence and later statements, respondent continues to defend the claim and requests a finding of fact regarding onset, based on the record and without need for a hearing. Resp. Status Report filed November 25, 2019 (ECF No. 50). Petitioner agrees with respondent's request. Pet. Status Report filed March 16, 2020 (ECF No. 58).

Upon review, petitioner was in good health before receiving the vaccination. She had one or two episodes of "heart racing" prompting consultation with a cardiologist in November 2012, but there was no clear diagnosis or suggestion that this issue continued. The subsequent primary care records record only complaints of upper respiratory infections and sinus infections, which are quite common. These were sometimes associated with headache, which was not thought to be severe. Petitioner had one episode of headache that was characterized as a migraine by urgent care and her primary care provider in August 2014. However, headache, even when characterized as migraine, is fairly common and non-specific. The term migraine is often used just to mean a bad headache rather than a specific diagnosis. And in petitioner's case, this appears to have been a one-time episode. There are no further contemporaneous records of headache, even though petitioner went to her primary care provider and the student health center for routine complaints of upper respiratory infection or sinus infection two more times before receiving the vaccination. I do not see this isolated episode of migraine to be related to petitioner's post-vaccination symptoms. Additionally, the primary care provider and the student health center's records do not mention any pain or injury involving her neck or shoulders. The record also reflects that petitioner was a full-time college student who was engaged in her classes, extracurricular activities, and social life prior to the vaccination.

The student health center's handwritten records on February 11 - 12, 2015, contain a history that petitioner began to have neck/ shoulder/ back pain and felt hot on Friday, February 6,

2015; had chills on Saturday, February 7, 2015; and developed headache behind her eyes on February 8, 2015. Pet. Ex. 4 at 26-27, 28-29. This history is carried forward in the nurse practitioner's VAERS report, at Pet. Ex. 4 at 83, and a note by Dr. Bornschein, who records having a conversation with petitioner although there is no formal appointment record, *id.* at 23. While contemporaneous medical records are generally presumed to be accurate and complete, here, petitioner has offered substantial additional evidence – both contemporaneous and later in time – to rebut that presumption.

First, petitioner's additional evidence establishes that Providence College, including its student health center, was not operating under normal conditions at the time in question. Instead, the college was responding to confirmation that two students had a serious illness, which was possibly continuing to spread throughout campus. This was specifically a serogroup which was not addressed by routine childhood vaccinations. The student health center was open twenty-four hours per day, seven days per week to address possible cases. Additionally, the college mounted a vaccination clinic first on Sunday, February 8 and again on Wednesday, February 11. After the majority of students – over 3,000 - received the vaccination on February 8, significant numbers of students were either presenting or calling to complain of sore arms and other routine post-vaccination symptoms. The student health center had a heavier-than-usual burden at the time of petitioner's presentation.

Petitioner has also submitted both contemporaneous records (news articles, emails, text messages, and coursework) and later statements which decrease the likelihood that the student health center records are accurate. This evidence instead shows that on Thursday, February 5, she attended her classes and completed her homework. On Friday, February 6, 2015, she woke at 8:00 a.m., attended five classes, and went out with friends for several hours, had a pleasant time, and went to bed at approximately 2:00 a.m. Petitioner has also submitted statements and contemporaneous evidence that she was also healthy on Saturday, February 7, 2015 and Sunday, February 8, 2015, before receiving the meningococcal B vaccination. This includes the statement from her roommate Meagan Nolan, who did not notice any change in petitioner's usual state of health until Monday, February 9, 2015, when they walked together to the student health center during a snowstorm to report that petitioner was having a sore neck.

It is also noted that by at least February 1, 2015, the college, the state health department, and local news media was disseminating information about the outbreak and the meningococcal meningitis outbreak. And again, the student health center was open around the clock. I find it reasonable to find that if petitioner was having symptoms prior to receiving the vaccination, she would have recognized them as possibly representing meningitis and would have recognized the importance of seeking prompt medical attention. Additionally, petitioner avers that she received routine vaccinations, understood that they should not be received while you are ill, but she proceeded to get the meningococcal B vaccination on Sunday, February 8, 2015.

Finally, petitioner avers that her overwhelming symptoms prevented her from providing an accurate history during the encounters at the student health center. Based on her statements and corroborating facts including that she had to be transported by campus security, was present at the student health center until 2:00 a.m., and her father drove in the middle of the night from New York to Rhode Island to pick her up, I find petitioner's explanation to be credible.

For the foregoing reasons, I find that petitioner has provided additional evidence that is “consistent, clear, cogent, and compelling” enough to rebut the presumption that these student health center records are accurate. *Camery*, 42 Fed. Cl. at 391.

Respondent also notes, correctly, that the February 14, 2015 emergency room visit contains a history that petitioner had been experiencing neck, shoulder, and back stiffness and headache for approximately 1.5 – 2 months. Pet. Ex. 6 at 4, 6. These notations were by a male physician assistant. However, the emergency room records are internally inconsistent: they also contain a registered nurse’s notation of these symptoms had been present “x 1 week.” *Id.* at 3, 36. There are also reasons to suspect that the physician assistant’s history is not accurate. First, approximately five weeks beforehand on January 5, 2015, petitioner had an appointment with her primary care provider for what was diagnosed as an upper respiratory infection; this record does not mention symptoms involving the neck, shoulder, back, or headache. Pet. Ex. 2 at 14. I tend to assign more weight to a contemporaneous medical record from a regular treating physician at a scheduled appointment, than an emergency room record. Additionally, petitioner has offered a compelling explanation that she was still experiencing significant pain and confusion preventing her from communicating effectively. She also avers that the physician assistant (described in her affidavit as being a young male doctor) did not record everything that she and her mother reported, including the receipt of the meningococcal B vaccination eight days beforehand. Accordingly, I find that petitioner has also provided additional evidence that is “consistent, clear, cogent, and compelling” enough to rebut the presumption that the emergency room record is accurate. *Camery*, 42 Fed. Cl. at 391.

The other medical records are consistent with petitioner’s allegations. For example, eight days after vaccination, on Monday, February 16, 2015, Dr. Kerry Moore at the primary care practice recorded: “[Follow-up] [regarding]: neck stiffness[,] headaches[,] meningococcal B vaccine 2/8/15[.] Maximum symptoms 2/10 [and] 2/11[.] Seen here 2/12[.] again in ER 2/14[.] On muscle relaxer feels better but noted tenderness and stiffness at back of neck[.] Some retroorbital pain but less[.] [Positive] history migraine headaches[,] slight headache post vaccine[,] resolved[.] Tinnitus last night but better now[.] Did have chills[,] arm ache post vaccine. . . .” Pet. Ex. 2 at 12, transcribed at Pet. Ex. 23 at 12B. While being slightly later than the student health center and emergency room records, this record was still close in time to onset and made by an established treater during a scheduled appointment. I do not see reason to suspect that this record is not accurate and complete.

I hereby make the following findings of fact regarding onset of the alleged vaccine injury: Petitioner was in good health upon receiving the meningococcal B vaccination on Sunday, February 8, 2015 at 1:13 p.m. That evening, she developed pain and difficulty moving her left arm, in which the vaccine was administered; fatigue; chills; and a slight headache. Throughout February 9, 2015 and February 10, 2015, these symptoms increased and she also developed neck and shoulder pain and general body aches. On February 11, 2015, these symptoms increased further and she also developed nausea and dizziness, prompting petitioner’s presentation to the student health center at about approximately 3:00 p.m. By February 12, 2015 at 2:00 a.m., petitioner developed a rash, described as tiny purple dots, on her lower extremities and back, which resolved within a few days. By February 14, 2015, she developed a ringing in her ears which was diagnosed as tinnitus. There is not clear evidence of fever. These symptoms

continued for at least six months (satisfying the threshold severity requirement for eligibility to pursue a claim in the Vaccine Program).

V. Conclusion

The parties are ordered to provide this ruling to any expert they retain. If the expert's opinion is not consistent with the above findings of fact, the opinion is likely to not be persuasive. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (1993) (holding that a special master did not abuse his discretion upon declining to hear the live testimony of an expert who "based his opinion on facts not substantiated by the record.").

Beyond the above findings of fact, it is noted that multiple treating physicians recorded that there may be a causal association between the meningococcal B vaccination and petitioner's subsequent symptoms. *See, e.g.*, Pet. Ex. 12 at 12, transcribed at Pet. Ex. 23 at 12B (primary care provider Dr. Moore: "Caution 2nd dose of vaccine"); Pet. Ex. 6 at 51 (neurologist Dr. Berdia: "likely neuropathy autoimmune, vaccine related"); Pet. Ex. 13 at 5 (neurologist Dr. Chin: "Post-vaccination, inflammatory etiology?").

With regard to the nature of petitioner's injury, certain medical records suggest that after receiving the vaccination, petitioner developed aseptic meningitis. Chronic fatigue syndrome was also suspected. Regardless, petitioner's allegation is that the meningococcal B vaccination caused her to suffer a small fiber neuropathy and related sequelae. Amended Petition (ECF No. 55) at Preamble. A neurologist first raised suspicion of small fiber neuropathy in May 2015, *see* Pet. Ex. 9 at 7. A confirmatory skin biopsy was deferred until October 2017, at which point petitioner was found to have low normal epidermal nerve fiber density and significantly reduced sweat gland nerve fiber density, consistent with small fiber neuropathy. Pet. Ex. 19 at 1-4.

The following is **ORDERED**:

- 1) The parties shall file a joint status report proposing further proceedings **within 30 days, by Thursday, July 30, 2020.**

IT IS SO ORDERED.

s/ Thomas L. Gowen
Thomas L. Gowen
Special Master