In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-1212V
Filed: August 15, 2022
PUBLISHED

ALICIA SKINNER-SMITH, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Tetanus Diphtheria and acellular Pertussis ("Tdap") vaccine; cause in fact; cellulitis; chronic fatigue syndrome (CFS)

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Terrence Kevin Mangan, Jr., U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On December 17, 2014, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that the tetanus, diphtheria, acellular pertussis ("Tdap") vaccine that petitioner received on February 6, 2012, caused her to suffer an abscess, pain, and related injuries that became chronic. (ECF No. 1.) By the time of the hearing held in this case in May of 2021, petitioner had clarified that the chronic injury she alleges is Chronic Fatigue Syndrome ("CFS"). (ECF No. 132.) For the reasons set forth below, I conclude that petitioner is entitled to compensation for her more limited cellulitis injury but is not entitled to compensation for her broader CFS.

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In many cases, however, the vaccine recipient may have suffered an injury not of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner may not receive a Vaccine Program award based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In what has become the predominant framing of this burden of proof, the *Althen* court described the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about 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 proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting their claim, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. The court also indicated that, in finding causation, a Program fact finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id*. at 1280.

In this case, none of the injuries alleged by petitioner are injuries identified by the Vaccine Injury Table. Accordingly, petitioner must satisfy the above-described *Althen* test for establishing causation in fact.

II. Procedural History

As noted above, petitioner filed her petition on December 17, 2014. (ECF No. 1.) Since the filing of that petition, this case has had a long history under four different special masters as two threshold issues were successively litigated before expert presentations and an entitlement hearing were eventually reached.

Based on the allegations in the petition (abscess and related pain), this case was initially assigned to the Special Processing Unit ("SPU") under then Chief Special Master Vowell. (ECF No. 5.) "The Special Processing Unit is designed to expedite the processing of claims that have historically been resolved without extensive litigation." (*Id*. at 1.) Petitioner's initial Statement of Completion was filed soon thereafter on December 24, 2014. (ECF No. 7.) However, the parties engaged in litigation regarding a threshold question of the administration site of petitioner's vaccine, a point made significant by petitioner's allegation of an (abscess) injury local to the area of injection.[3]

[3] More accurately, the medical records indicate petitioner suffered "cellulitis," which is "an acute, diffuse, spreading, edematous, suppurative inflammation of the deep subcutaneous tissues and sometimes muscle, sometimes with abscess formation. It is usually caused by infection of a wound, burn, or other cutaneous lesion by bacteria . . . ." *Cellulitis,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=8514 (last accessed July 28, 2022). An "abscess" is "a localized collection of pus within tissues, organs, or confined spaces." *Abscess,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=185 (last accessed July 28,

During this period, the case was reassigned to Special Master Dorsey when she became Chief Special Master. (ECF No. 31.)

After a year and a half of litigation, Chief Special Master Dorsey issued a "Ruling on Facts" on April 26, 2016, that addressed the parties' dispute regarding the injection site of petitioner's February 6, 2012, Tdap vaccination. She concluded that petitioner received her vaccination in her left dorsal gluteal muscle.[4] (ECF No. 45; *see also Skinner-Smith v. Sec'y of Health & Human Servs.,* No. 14-1212V, 2016 WL 3180635 (Fed. Cl. Spec. Mstr. Apr. 27, 2016).) This is consistent with the fact finding urged by petitioner. (ECF No. 13-2.) Respondent was ordered to file his Rule 4(c) Report, which he did on July 5, 2016. (ECF No. 45, p. 4; ECF No. 48.) Respondent recommended against compensation on a number of grounds. (ECF No. 48.)

Following the filing of respondent's report, the case was reassigned out of the SPU and to Special Master Millman. (ECF No. 50.) She initially ordered petitioner to file an expert report. Petitioner continued to develop the record for over a year, from August of 2016 through October of 2017, but did not file an expert report during this period.[5] However, during a status conference held October 19, 2017, Special Master Millman specifically ordered petitioner to file materials relating to the medical review panel referenced in the petition.[6] (ECF No. 73.) Petitioner filed such materials marked as Exhibit 14 and 15. (ECF No. 74.) The fact of petitioner's prior medical review panel filing then constituted the focus of the case for the next year.

Special Master Millman issued an Order to Show Cause why the case should not be dismissed on the basis that Exhibit 14 showed petitioner to have had a medical malpractice suit pending at the time she filed this petition. (ECF No. 75.) Following motion practice on the issue, Special Master Millman issued a decision dismissing this case on June 25, 2018. (ECF No. 89; *see also Skinner-Smith v. Sec'y of Health & Human Servs.*, No. 14-1212V, 2018 WL 3991343 (Fed. Cl. Spec. Mstr. June 25, 2018*), review granted, decision rev'd*, 141 Fed. Cl. 348 (2018).) She concluded that

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2022). Petitioner's initial diagnosis was "cellulitis/left gluteal abscess." (Ex. 1, p. 441.) However, subsequent records suggested no evidence of an abscess underlying petitioner's cellulitis. (*Id*. at 680, 705.)

[4] This finding of fact is not binding on me; however, I agree with the outcome and analysis in this fact finding and will not address the issue further. *Godfrey v. Sec'y of Health & Human Servs.*, 2015 WL 10710961, at *9 (Fed. Cl. Spec. Mstr. Oct. 27, 2015) (noting that "[g]enerally, special masters may change or revisit any ruling until judgment enters, even if the case has been transferred."); *see also Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998), *aff'd*, 191 F.3d 1344 (Fed. Cir. 1999) (special masters are not bound by their own or other special masters' decisions).

[5] Petitioner did file a letter by one of petitioner's treating physicians, Dr. Ferrier (ECF No. 55; Ex. 8). However, the special master required petitioner to file a further, more detailed, report explaining the basis for the opinion stated in the letter. (ECF No. 56.) Petitioner never filed a further report from Dr. Ferrier and ultimately argued that such a report was unnecessary. (ECF No. 63.)

[6] In her petition, petitioner acknowledged the prior filing of a "medical review panel proceeding," but represented that no civil action had been filed. (*Id*. at 1-2.)

petitioner's filing of a complaint with the Louisiana medical review panel constituted initiation of a civil action under Section 11 of the Vaccine Act. (*Id*. at 5.)

Petitioner then pursued a successful motion for review of that dismissal decision. On December 18, 2018, the Court of Federal Claims issued an Opinion and Order granting petitioner's motion for review and remanding the case for further proceedings before the special master with instructions to reinstate the petition. (ECF No. 103; *see also Skinner-Smith v. Sec'y of Health & Human Servs.,* 141 Fed. Cl. 348 (2018).) Once the case was remanded, petitioner returned to pursuing an expert to support her claim. (ECF No. 106.)

Due to Special Master Millman's subsequent retirement, the case was reassigned to the undersigned's docket on June 7, 2019. (ECF No. 110.) After several motions for extension of time, petitioner filed her initial expert report by Dr. Charles Lapp on August 16, 2019. (ECF No. 113; Ex. 16.) Petitioner filed a further report by Dr. Lapp, inclusive of a physical examination, on November 15, 2019. (ECF No. 115; Ex. 21.) Respondent filed expert reports by Drs. Oddis and He on January 3, 2020. (ECF Nos. 115-19; Exs. C-D.) Petitioner filed a responsive supplemental report by Dr. Lapp on April 6, 2020. (ECF No. 121; Ex. 22.)

Thereafter, on May 11, 2020, a two-day entitlement hearing was scheduled to commence May 20, 2021. (ECF No. 124.) The pre-hearing record closed on April 26, 2021 (ECF No. 126); however, petitioner filed for leave to file medical literature out of time (ECF No. 136). Respondent filed a competing motion to strike the proposed filings. (ECF No. 137.) On May 13, 2021, petitioner's motion for leave to file out of time was granted and respondent's motion to strike denied. (ECF No. 140.) Respondent was permitted an opportunity to address any issues that might arise during the hearing relative to the late-filed literature with post-hearing filings. (*Id*.)

The hearing was held as scheduled on May 20-21, 2021 and was held via Webex video conference due to the ongoing Covid-19 pandemic. (*See* Transcript of Proceedings ("Tr."), May 20-21, 2021, at ECF Nos. 148-49.) During the hearing, petitioner, Dr. Lapp, Dr. Oddis, and Dr. He testified. Following the hearing, petitioner was ordered to file two articles (by Rook and Mu respectively) referenced by Dr. Lapp during the hearing, a graphic used during his testimony, and updated medical records. (ECF No. 143.) Respondent was instructed to file a status report 30 days thereafter indicating whether he would request an opportunity for further filings or otherwise confirming the record to be complete. (*Id*.) On July 6, 2021, respondent confirmed the record is complete. (ECF No. 150.)

Accordingly, this case is now ripe for resolution. In total, petitioner has filed medical records marked as Exhibits 1-6, 11-13, 31-32, and 37-38, affidavits marked as Exhibits 7 and 10, medical review panel Exhibits 14-15, a treating physician letter marked as Exhibit 8, expert reports by Dr. Lapp marked as Exhibits 16, 21-22 (his curriculum vitae as Exhibit 20), and medical literature marked as Exhibits 17-29, 23-30.

Respondent has filed reports, curricula vitae, and supporting medical literature by Drs. Oddis and He marked as Exhibits C (with tabs 1-3) and D (with tabs 1-2).[7]

III. Factual History

a. As Reflected by the Medical Records

i. Pre-Vaccination Records

Prior to the vaccination at issue, petitioner had a history of rosacea, vitamin D deficiency, degenerative cervical disc disease with radiculopathy, anemia, and recurrent throat infections. (Ex. 1, p. 109, 418, 451, 574.) Additionally, petitioner had a right rotator cuff repair on October 22, 2009, and a right shoulder arthroscopic lysis of adhesions, arthroscopic revision, subacromial decompression, and bursectomy on January 15, 2010. (Ex. 1, p. 430.)

On March 8, 2010, petitioner presented to Dr. Deryk Jones, the orthopedist who performed petitioner's rotator cuff repair surgery. (Ex. 1, p. 577.) On examination, petitioner demonstrated a slight decrease in internal rotation on the involved side with excellent strength and good range of motion overall. Patient appeared to be doing "quite well overall." (*Id.*)

On September 30, 2010, petitioner presented to Dr. Herbert Van Horn complaining of "a 6-month history of recurrent throat infections, but also [] nasal congestion symptoms and sinusitis." (Ex. 1, p. 574.) She also complained of an "ear ringing sensation." (*Id.*) Dr. Van Horn noted in the HPI that petitioner "occasionally takes Vicodin for her right shoulder pain as she is recovering from rotator cuff and torn labrum surgery performed in January of this year." (*Id.*) He noted that petitioner's family members had a history of throat and tonsillar problems. (*Id.*) No evidence for recent strep cultures were found in the computer database. (*Id.*) Dr. Van Horn concluded that petitioner was "not acutely ill and [did] not require antibiotics[.]" (*Id.* at 575.) He discussed concerns with petitioner about concomitant use of Vicodin and Zyrtec because of sedation possibilities and encouraged petitioner to use the Vicodin sparingly. (*Id.*)

On October 20, 2010, petitioner presented to Dr. Jones for a follow-up on her right shoulder pain and pathology. (Ex. 1, p. 572.) Petitioner was "currently reporting no significant limitations at this time." (*Id.*) On examination petitioner demonstrated mild weakness with stress of the rotator cuff musculature at the right side. (*Id.*)

On March 29, 2011, petitioner presented with pain and numbness in her legs that had worsened within the past two weeks. (Ex. 1, p. 465.) Spinal MRI on April 20, 2011, showed bulging at L3-L4 and L4-L5 and straightening of the lumbar lordosis. (Ex. 1, pp.

[7] Respondent's Exhibits A-B relate to a subpoena issued by respondent relative to litigating the site of injection. (ECF Nos. 41, 43.)

477-79.) On March 31, 2011, results from petitioner's ultrasound showed no evidence of a lower extremity deep venous thrombosis. (Ex. 1, p. 581.)

On April 20, 2011, petitioner underwent erect weight-bearing ("stand up") MRI of the lumbar spine without contrast. (Ex. 1, p. 477-79.) The MRI showed (1) bulging of the L3-L4 and L4-L5 intervertebral discs without nerve root effacement associated therewith the patient in the passive neutral posture; (2) straightening of the lumbar lordosis with the patient in the passive neutral posture consistent with a pattern of muscle spasm; and (3) fibroid uterus with dominant submucosal leiomyoma measuring approximately 2.2 cm in diameter. (*Id.* at 478-79.)

On May 23, 2011, petitioner established new patient care with Ochsner spine services with complaints of lower leg pain, burning, numbness, coldness, and tingling. She described her back pain as "mechanical in nature, worse with activity, especially walking" and described her lower extremity pain as "burning, aching pain in her bilateral calves and feet" which "ha[d] been going on for several years" and "relieved with Vicodin." (Ex. 1, p. 570.) Petitioner reported that her symptoms began years prior and had worsened more recently. (Ex. 1, p. 461.) She further indicated that she was able to perform her daily routine with these symptoms and was able to work despite her condition. (Ex. 1, p. 464.) Petitioner was diagnosed with degenerative disc disease, lumbago, and lateral lower extremity radiculopathy. (Ex. 1, pp. 570-71.)

On July 5, 2011, petitioner called her PCP Dr. Ferrier to schedule an appointment. (Ex. 1, p. 546.) Petitioner reported "pain in her lower legs for years – she would like to be tested for diabetes." (*Id.*) She further reported problems with night sweats and recurrent yeast infections. (*Id.*) On July 11, 2011, petitioner presented with a deep nodule in her right calf, which was a lipoma that was late excised. (Ex. 1, p. 460.) Petitioner had been prescribed Vicodin over an extended period of time, first for her shoulder pain and later for her bilateral leg pain. (*E.g.*, Ex. 1, pp. 574-57, 465.)

On January 5, 2012, petitioner saw Dr. Deryk G. Jones regarding her right shoulder pain and was diagnosed with right shoulder rotator cuff inflammation with possible biceps tendinopathy and recurrent weakness of the anterior subscapularis tendon. (Ex. 1, p. 443.)

On January 16, 2012, petitioner saw her primary care provide ("PCP"), Dr. Janine M. Ferrier, with complaints of sore throat and bilateral ear pain that began three weeks prior. (Ex. 1, p. 442.) Petitioner also complained of postnasal drip, hoarseness, shortness of breath, cough, fatigue, and intermittent fever. (*Id*.) Physical exam findings for mouth and throat were "[n]o tonsillar enlargement. Positive pharyngeal erythema and pustule on the right." (*Id*.) Petitioner was diagnosed with acute pharyngitis and was prescribed clindamycin (antibiotic) and Diflucan (antifungal). (*Id*.)

ii. Vaccination and Initial Treatment

On February 6, 2012, petitioner burned her hand and went to the Ochsner Medical Center Emergency Room for treatment. (Ex. 1, p. 684.) At the emergency room, petitioner received a Tdap vaccine in her left dorsal gluteal muscle. *See Skinner-Smith v. Sec'y of Health & Human Servs.*, No. 14-1212V, 2016 WL 3180635 (Fed. Cl. Spec. Mstr. Apr. 27, 2016). Petitioner was discharged on the same day. (Ex. 1, p. 688.)

A couple of days following her vaccination on February 9, 2012, petitioner saw Dr. Ferrier for a follow up. (Ex. 1, p. 441.) Petitioner complained of left hip pain and lower back pain after receiving the Tdap vaccination and that the area around the injection was red, inflamed, and painful. (*Id*.) Upon examination, Dr. Ferrier noted that petitioner's left hand burn was dorsal between the first and second finger and that petitioner was "positive induration of left gluteus with erythema." (*Id*.) Petitioner was assessed with cellulitis/left gluteal abscess and was referred to general surgery as well as prescribed Bactrim. (*Id*.)

A handwritten note dated February 13, 2012, indicates that petitioner presented to Dr. Michael C. Townsend for a consultation for her buttock abscess. (Ex. 1, p. 439-40.) He diagnosed petitioner with cellulitis of the buttocks and abscess. (*Id.*) The remainder of Dr. Townsend's notes are illegible. The next day, February 14, 2012, petitioner returned to Dr. Townsend. (Ex. 1, p. 451.) Dr. Townsend noted that petitioner had a "localizing area of induration without frank purulence" on her left buttocks, but that her cellulitis was resolved. (*Id*.) His impression also included that petitioner had a localizing, minimally tender mass, and at that point, petitioner should continue with antibiotics. (*Id*.)

On February 24, 2012, petitioner called Dr. Ferrier's office regarding her tetanus shot reaction. (Ex. 1, p. 542.) The note indicates that

> [Petitioner] had a reaction and was put on antibiotics and pain med. [Petitioner] was referred to Dr. Townsend to lance or remove. Dr did not do either. [Petitioner] still in pain (pain in legs/groin area), has swelling. [Petitioner] wanting pain med. to get her thru. [Petitioner] will be calling the other dr. [Petitioner] would like to see Dr. Ferrier soon[.]

(*Id.*)

Thereafter, on February 24, 2012, petitioner returned to the emergency room with complaints of fever. (Ex. 1, p. 692.) The records noted that petitioner's chief complaint was "since [tetanus] shot on 2/6 has had problems with fever, leg swelling and [fatigue]." (*Id*.) Petitioner reported that her fever began suddenly about 17 days ago, chills and sweating, night sweats, body aches, joint swelling, itching, rash, and dry skin. (*Id*.) Petitioner indicated that she has received a Tdap vaccination prior without any reaction. (*Id*. at 693.) On physical examination, Dr. McNulty observed "no soft

tissue or body tenderness, no joint swelling or tenderness." (*Id.* at 662.) He "[did] not see any swelling of the thighs lower legs or feet[,] no erythema of the thighs or legs." (*Id.*) Dr. McNulty noted petitioner's neck was "supple, no adenopathy noted." (*Id.*) Petitioner's blood and urine cultures were collected, and the results were normal. Petitioner was also transported for an x-ray, but discharged on the same day. (Ex. 1, pp. 693-96.)

Petitioner went back to the emergency room three days later, on February 27, 2012 with complaints of joint pain, stating that her symptoms began on February 6, 2012 after receiving Tdap immunization. (Ex. 1, p. 698.) Petitioner reported that on the evening of her vaccination, she felt malaise and some aching fever, and by the next day she had some swelling at the injection site and groin area. On physical exam, petitioner had some enlarged inguinal lymph nodes and some darkening and hyperpigmentation of her skin around her inguinal area and neck. (*Id*. at 705.) Additionally, it was noted that she did not have any kind of obvious rash or redness at the injection site on her left buttock, but there was mild tenderness and a "little knot there." (*Id*.) Dr. Patricia C. Porada's assessment was that petitioner likely had a reaction to the Tdap vaccination, possibly a delayed serum sickness type or hypersensitive type reaction. (*Id*. at 706.) Petitioner was discharged on the same day with a primary diagnosis of fever of unknown origin. (*Id*. at 703.) Dr. Porada added that a reaction can last up to 21 days and noted that "there are other potential causes for [petitioner's] persistent symptoms, but these all seem to be related to the tetanus shot as these symptoms all developed after her tetanus injection. (*Id*. at 706.)

On February 29, 2012, petitioner saw Dr. Ferrier for a "followup of emergency room visit for cellulitis." (Ex. 1, p. 436.) It was noted that petitioner completed her antibiotics and her cellulitis was improved, but that she still had fatigue, fever, myalgias, joint pain, swelling, headaches, back pain, and spams down the back of her legs. (*Id*.) Petitioner was assessed with myalgia and fatigue and additional testing was ordered.

iii. Post Initial Treatment Records

On March 2, 2012, petitioner returned to Dr. Ferrier's office for a follow-up visit. (Ex. 1, p. 538.) Petitioner was referred to rheumatology "ASAP for rheumatoid arthritis, positive CCP antibodies." (*Id.*) Petitioner was informed of her results, including low vitamin D.

On March 7, 2012, petitioner had an allergy evaluation with Dr. Jamie R. Lurie. (Ex. 3, p. 1.) Petitioner indicated that she had a burn on her hand which led to her to ER, where she received a tetanus shot. Petitioner reported that about 30 minutes to an hour after the shot, petitioner had nausea, fatigue, and aching at the site of the injection, and the next day, she had joint pain, swelling, fever, and "her nerves were firing." (*Id*.) Petitioner reported that she returned to her PCP, who referred petitioner to general surgery for possible infection from the shot, but there was nothing to drain. Additionally, on February 24, almost three weeks following her vaccination, petitioner went to the ER with fatigue, fever, chills, joint pain, and rash and swelling at the vaccination site. At this

visit with Dr. Lurie, petitioner reported that her symptoms improved, but she was still suffering from pain in her hip where the vaccine was administered, night sweats, fatigue, loss of appetite, middle low back pain. (*Id*.) Dr. Lurie stated that petitioner had serum sickness as a reaction to Tdap vaccine with typical symptoms of fatigue, rash, fever, joint pain, and swelling at the site. Dr. Lurie also posited that petitioner may have had an immunologic reaction to her vaccination and referred petitioner to a rheumatologist. (*Id*. at 3.)

On April 17, 2012, petitioner saw Dr. Reginald D. Sanders for musculoskeletal pain at the referral of Dr. Lurie. (Ex. 4.) Petitioner denied any prior musculoskeletal pains and that she developed generalized stiffness and pain in her left buttock after receiving a tetanus shot. (*Id*. at 1.) Moreover, petitioner reported that she "has not gotten back to normal since the shot," and she has pain in the left side of her body as well as joint pain. Petitioner was assessed with polyarthralgia. (*Id.*) It was noted that petitioner did not appear to have systemic inflammatory rheumatic disease and that petitioner declined further laboratory studies.

On April 30, 2012, petitioner presented to her PCP Dr. Ferrier complaining of a sore throat, sinus congestion, and cough. (Ex. 1, p. 426.) She indicated that her symptoms "started weeks ago" and "have improved." (*Id.*) Petitioner was assessed with an upper respiratory tract infection. (*Id.*)

On May 30, 2012, petitioner presented to Dr. Jack Jacob for an annual gynecological examination. (Ex. 2, pp. 10-14.) Petitioner complained of "mark reaction to pert. and Tet. shot." (*Id.* at 10.) In petitioner's past medical / surgical history, Dr. Jacob noted "tentative [rheumatoid arthritis] after receiving PTAP [*sic*] (2/6/12)." (*Id.*) Dr. Jacob further noted that petitioner was self-reliant in her usual daily activities. (*Id.* at 11.) Petitioner's assessment was otherwise normal. (*Id.* at 13.)

On June 6, 2012, petitioner presented to another rheumatologist, Dr. Tamika Webb-Detiege, complaining of arthralgias and positive CCP. (Ex. 1, p. 418.) Petitioner recalled that hours after her tetanus vaccination she developed "severe joint pain, fatigue, sweating, swelling of the hands, swelling and pain in the legs and hips especially on the left, or rash that started to peel on her face and hands, fever, night sweats and an overall feeling of malaise." (*Id.*) She further noted enlarged lymph nodes in her groin, blisters on her tongue, hoarseness in her voice, peeling around her nails, tinnitus, and blurred vision." (*Id.*) Petitioner reported to Dr. Webb-Dietiege that her symptoms had since improved, though she continued to have achiness, involving mainly her left leg, fatigue, and night sweats. (*Id.*) Her pain improved with the use of Vicodin and ibuprofen, twice daily. (*Id.*) Petitioner also noted family history of rheumatoid arthritis. (*Id.* at 419.) Petitioner was assessed with arthralgias where "symptoms began after tetanus shot which was associated with cellulitis of buttocks," positive CCP, fatigue, night sweats, and dry mouth. (*Id.* at 422.)

Petitioner returned to Dr. Webb-Detiege on June 27, 2012, with a chief complaint of arthralgias and positive CCP. (Ex. 1, p. 412.) Petitioner reported "120 minutes of morning stiffness," though she reported feeling better, with less joint pain and less mental confusion. (*Id*.) She described pain in "muscle below knees and above feet."

(*Id.*) Petitioner reported difficult sleeping "since this started." (*Id.*) Her arthritis joint survey in the cervical spine showed no widening of the atlanto-odontoid relationship in flexion, though the osseous elements of the cervical spine were degenerated at C5-6 with large osteophyte and slight interspace narrowing. (*Id.* at 415.) She showed no arthritis in her knees, hands and wrist, or feet. (*Id.*) Petitioner was assessed with arthralgias, positive CCP, fatigue, night sweats, dry mouth ("negative SSA and SSB"). (*Id*.)

On August 8, 2012, petitioner was seen at the emergency department for joint pain. (Ex. 1, p. 5.) Petitioner's radiology results revealed no evidence of synovitis. (*Id*. at 6.) Petitioner saw her PCP on August 23, 2012 for leg pain, sore throat, sinusitis, and back pain. (*Id*. at 17.) Petitioner reported that her sore throat started about a week ago and that she noticed redness of her lower legs and aching sensation after undergoing a nuclear tag test. (*Id*. at 22.) Petitioner also reported intermittent pain in her left buttock, leg, and foot since receiving a tetanus vaccination. (*Id*.) Petitioner was assessed with acute pharyngitis, back pain, arthralgias, and vitamin D deficiency. (*Id*. at 23.)

On September 21, 2012, petitioner had an ultrasound and venous examination with Dr. George E. Barnes. (Ex. 6.) It was noted that petitioner began having pain in her left lower extremity on February 6, 2012, that had been increasing dramatically and progressively. Dr. Barnes indicated that petitioner associated her symptoms with her tetanus vaccination. (*Id*. at 1.) Additionally, in a handwritten note, petitioner also wrote that she believed "DTAP compromised my health […] most of others [symptoms] including high blood pressure level, elevated anti-CPP level, rheumatoid arthritis, weight loss, hair loss, depleted vitamin D-level, impaired vision, sleep apnea, extreme leg pain at site location (lower left buttock); swollen/inflamed lymph node, in groin region etc." (*Id*. at 3.) Petitioner also answered that petitioner experienced varicose veins after trauma and had pain, swelling, spider veins, skin discoloration, and night cramps as associated with her varicose veins. (*Id*. at 4.) Dr. Barnes noted that petitioner had a history of venous varicosities, but only recently experiencing symptoms. (*Id*.) The ultrasound showed evidence of venous incompetence associated with history of several months of left lower extremity pain syndrome. (*Id*.) She was assessed with left leg pain and was recommended for surgery and for a complete duplex scan study. (*Id*. at 7.)

On September 30, 2012, petitioner returned to Dr. Ferrier for a blood pressure check and complained of swelling in her legs and swollen nodes in her groin. (Ex. 1, p. 46.) Additionally, petitioner reported continued left leg pain. (*Id*.) Petitioner then saw Dr. Ferrier again on October 2, 2012 to address her arthralgias, myalgias, and positive anti-CCP results. (*Id*. at 53.) Here, petitioner reported that her symptoms began after receiving her tetanus shot and that serum sickness was suspected. (*Id*.) Under review of systems, petitioner was positive for fatigue, red appearance of hands with cold exposure, polyuria, dry mouth, dyspnea on exertion, and jaw pain. (*Id*.) Dr. Ferrier noted that petitioner's symptoms relating to arthralgias began after tetanus shot, "which was associated with cellulitis of buttocks." (*Id*. at 55.)

On October 2, 2012, petitioner returned to Dr. Webb-Detiege for a follow-up regarding her arthralgias, myalgias, and positive anti-CCP. (Ex. 1, p. 52.) She reported "feeling better with the joint pain." (*Id.*) She complained of pain in her left leg, in the groin and down the leg, as well as a "blotchy appearance." (*Id.* at 52-53.) She reported swelling in her right and left legs, in the thighs. (*Id.*) Petitioner continued to report night sweats. (*Id.* at 53.) She presented with a facial rash. (*Id.*) Petitioner now reported family history of rheumatoid arthritis in her grandmother, mother, and maternal aunts. (*Id.*) Dr. Webb-Detiege assessed petitioner with arthralgias, positive CCP, fatigue, night sweats, dry mouth, in addition to venous insufficiency of the legs. (*Id.* at 55.)

Petitioner saw Dr. Ferrier on January 11, 2013 for an immune system evaluation with complaints of sinus problem, including chills, congestion, coughing, ear pain, headaches, neck pain, and sore throat. (Ex. 1, p. 105.) Petitioner summarized that within two weeks of her tetanus shot in February 2012, she experienced severe arthralgias, hair loss, rash, fever blisters, nails splitting, and elevated labs. Since then, she has had recurrent throat and sinus infections, fatigue, insomnia, memory loss, night sweats, jaw tightness, sinusitis, ear infection, and pharyngitis. However, petitioner has seen a rheumatologist and extensive workup has all been normal. (*Id*.) Petitioner also reported that she has had 5-6 antibiotics treatment since February. (*Id*.) Petitioner was assessed with chronic sinus infection and arthralgia. (*Id*. at 107.)

Petitioner had a consultation with Dr. Jeffrey Coco on February 7, 2013. (Ex. 3, p. 11.) Under reason for visit, it was listed that petitioner had Tdap vaccination and had stiffness, pain, sweating, heart racing, and nausea the night of her shot and within 48 hours, she saw her PCP. Also, the record indicated that petitioner saw Dr. Lurie after experiencing leg swelling, sores in mouth, hair loss, vision changes, and was placed on antibiotics and referred for surgical intervention. Moreover, petitioner was transitioned to narcotics to treat her joint pain. (*Id*.) Again, petitioner was listed as having serum sickness and it was noted that Dr. Coco discussed the Vaccine Program with petitioner at this visit. Petitioner was told to avoid all further vaccines. (*Id*. at 12.)

Petitioner frequently visited her PCP for various reasons throughout the year, including upper respiratory infection, allergy test, conjunctivitis, sore throat, leg pain, anemia, and venous insufficiency. (Ex. 1, pp. 127,131, 133, 152, 160, 168.) Petitioner avoided receiving any further vaccinations, indicating that she was hesitant due to adverse reaction from tetanus shot. (Ex. 1, p. 131.)

On July 15, 2013, petitioner was examined by Dr. Olusegun O. Osinbowale for venous insufficiency consultation. (Ex. 1, p. 168.) Petitioner reported that since receiving the tetanus shot, petitioner had been experiencing hot/cold sensation in both legs, night sweats, arthralgias, swollen ankles, and leg erythema. (*Id*.) Dr. Osinbowale assessed petitioner with venous insufficiency, unspecified myalgia and myositis, and skin sensation disturbance, adding that there was discussion of the possibility of petitioner having primary venous insufficiency rather than secondary to her other complaints. (*Id*. at 171.)

On September 3, 2013, petitioner presented to hematologist / oncologist Dr. Fu for an initial anemia consultation. (Ex. 1, p. 202.) Petitioner's medical history listed anemia, degenerative disc disease, vitamin D deficiency, arthralgias, recurrent upper respiratory infections, and urticaria (hives). (*Id.*) She reported "fatigue easily. I am sick only after the tetanus shot in Feb 2012." (*Id.* at 204.) Petitioner further reported skin rash, shortness of breath, muscle pain, acute join pain, sweating, swelling lymph node, leg swelling, muscle spasms, hair loss, dry mouth, and "[l]eft leg burning sensation after tetanus shot in feb 2012." (*Id.*) On physical examination, Dr. Fu observed no noticeable or palpable swelling, redness, or rash around the throat or on the face and no swollen or erythematous joints. (*Id.* at 207.) Dr. Fu concluded that "[t]he fact that [petitioner] has isolated cytopenia (anemia) with normal WBC and platelet count suggest[s] that that the possibility of bone marrow failure such as MDS, myelofibrosis, bone marrow infiltration, etc is low, although pure red cell anaplasia can not be excluded." (*Id.* at 208.) Of note, Dr. Fu observed that petitioner had "mild elevation of plt count," which, in the setting of nonspecific symptoms such as myalgia, arthralgia, skin rash, finger tingling numbness, is "likely due to chronic inflammation." (*Id.*) However, Dr. Fu wanted to rule out lymph proliferative disorder, MPD, B12 deficiency, and monogammapathy. (*Id.*) Dr. Fu planned run a routine anemia work up, including a blood smear review—and to consider a bone marrow biopsy if the blood work was unrevealing. (*Id.*)

On September 11, 2013, petitioner returned to her gynecologist Dr. Jacob, for a follow-up examination. (Ex. 2, pp. 18-21.) Petitioner's history included "chronic inflammation to the tetanus inj[ection], with many organ damage." (*Id.* at 18.) Dr. Jacob reported again that petitioner was self-reliant in her usual daily activities. (*Id.* at 19.) She described feeling poorly, with reports of malaise and anxiety. (*Id.*) Petitioner further reported muscle aches and pain localized in one or more joints, as well as dizziness and dyspnea. (*Id.*)

On January 13, 2014, petitioner presented to internist Dr. Green, complaining of a sore throat, upper respiratory infection, and nasal congestion. (Ex. 1, pp. 298-99.) She reported to Dr. Green that she suffered from recurrent lymph node infections. (*Id.* at 298.) Petitioner likewise reported that she was experiencing generalized arthralgias, which she attributed to her tetanus injection on February 6, 2012. (*Id.*) On physical examination, Dr. Green observed that petitioner's "pharynx was infected but without exudate" and her sinuses were tender to palpation. (*Id.* at 299.) She was assessed with chronic joint paint, lymphadenitis, acute pharyngitis, and chronic rhinitis." (*Id.*) Dr. Green prescribed antibiotics.

On March 31, 2014, petitioner had an electrodiagnostic study of her left upper and lower extremities, which revealed a delay of left median sensory distal latency that is compatible with mild left carpal tunnel syndrome, but was otherwise normal. (Ex. 5.) Petitioner's clinical summary included that she received a tetanus injection with subsequent fever, stiffness, and pain all over, which has persisted since vaccination. (*Id*. at 1.)

On May 28, 2014, petitioner presented to her PCP, Dr. Ferrier, in follow-up to her emergency room visit for facial swelling. (Ex. 1, pp. 409-10.) Petitioner reported that she had facial swelling primarily on the right side, with her right eye swollen shut. (*Id.* at 409.) She reported to Dr. Ferrier a sensation of heaviness on the right side of her face. (*Id.*) Petitioner additionally reported fatigue, persistent night sweats, persistent and intermittent swelling, initially in her extremities, now extending up to her face, associated with a tingling sensation. (*Id.*) She further reported skin discoloration associated with flareups. (*Id.*) Dr. Ferrier assessed petitioner with improving facial swelling and recommended Zyrtec and Ranitidine. (*Id.* at 410.)

On August 4, 2014, petitioner sought treatment from her PCP, Dr. Ferrier, for diffuse pain, complaining of burning sensation in her hands and feet. (Ex. 12, p. 3-4.) Petitioner then returned on September 4, 2014 with complained of right leg pain at the site of lipoma excision. (*Id*. at 11.) Additionally, petitioner saw Dr. Osinbowale on September 8, 2014 for a follow up appointment regarding her venous insufficiency. (Ex. 12, p. 16.) Petitioner reported chronic intermittent neuropathic pain radiating from the left gluteal region to the calf, burning sensations, cold sensations, and tingling and intermittent numbness in her extremities. (*Id*.) Dr. Osinbowale indicated that petitioner's symptoms were unlikely vascular in origin. (*Id*. at 18.)

On November 10, 2014, petitioner presented to Dr. Nelson, complaining of eye pain in both eyes, "stabbing pain for couple of months," left more than right. (Ex. 12, pp. 37-38.) She commented that her peripheral vision decreased since she was last seen (5/28/2014), on the right and left eye lateral side, though not a blind spot, but a delayed focus. (*Id.* at 37.) Petitioner complained of swollen eyelids in the morning, with the right eye feeling heavy. (*Id.*) Dr. Nelson assessed petitioner with bilateral eye pain and visual disturbance. (*Id.* at 37-38.) Specifically, petitioner explained that she will "walk by husband" and not know that he is in the room. (*Id.* at 38.) She described "problem[s] w tetanus injection in 2012 which has led to a host of problems and she did research which said visual problems could happen too." (*Id.* (internal citation omitted).) Petitioner's eye exam was within normal limits, but Dr. Nelson ordered a visual field test to rule out scotoma. (*Id.*)

Petitioner had an ophthalmology evaluation with Dr. Andrew W. Lawton for problems with her peripheral vision on December 1, 2014. (Ex. 11.) Petitioner reported that she noticed problems with her vision since she received the Tdap vaccination in 2012, specifically saying that she was "poisoned, adverse reaction." (*Id*. at 5.) Petitioner also added that she had other problems since her vaccination aside from her vision issues, including chronic inflammation. (*Id*.) With regards to her vision, petitioner reported that "she does see things to her sides. She will walk by her husband and not see." However, petitioner's peripheral vision testing was normal. (*Id*.) Petitioner was assessed with Keratoconjunctivitis sicca and subjective visual disturbance of both eyes. (*Id*. at 5-6.)

Petitioner returned to see Dr. Ferrier on January 27, 2015, for abdominal pain, with complaints of loss of appetite, nausea, vomiting, and diarrhea. (Ex. 12, p. 59.)

Petitioner reported that "her symptoms are cyclical after getting a tetanus several years ago." (*Id*.) Petitioner was assessed with paresthesia with regards to her back pain, shoulder pain, sore throat, seizures, and fatigue. (*Id*. at 60-61.) Overall, petitioner visited Dr. Ferrier frequently for various concerns including sore throat, ear pain, cough, upper respiratory infection, back pain, and swelling. (*Id*. at 72, 81, 86, 107.)

On February 25, 2015, petitioner visited Dr. Jones for a right shoulder evaluation. (Ex. 11, p. 7.) According to her history of present illness, petitioner had a rotator cuff repair in 2009, a vaccine injury in 2011, and global neurological symptoms. (*Id*. at 10.) Petitioner's shoulder pain was described as chronic, starting more than one year ago with a history of trauma. (*Id*.) On physical exam, petitioner tested positive in various tests on her right and not on her left. (*Id*. at 11-12.) Petitioner was ordered to continue pain management with Dr. Ferrier. (*Id*. at 14.) Petitioner's MRI found a partial tear of the supraspinatus tendon. (*Id*. at 24.) On March 11, 2015, petitioner had a follow up with Dr. Jones following her MRI studies. (*Id*. at 29.) Dr. Jones recorded that petitioner was unable to get MRA due to potential allergy to dye and petitioner was unable to obtain steroid injection due to concerns of potential reaction. (*Id*.) Following this visit, petitioner decided to proceed with surgery and physical therapy. (*Id*. at 34-35.)

Petitioner had a neurology consultation on April 16, 2015, with Dr. Frank S. Oser. (Ex. 11, p. 36.) Petitioner had complaints of numbness in her feet and spasms extending from the feet and lower legs into the low back area, where onset was after receiving her tetanus shot. (*Id*. at 38.) Petitioner stated that "there was some sort of an immune reaction that took place, and associated with multiple allergic reactions, as well as diffuse arthralgias and myalgias among other things." (*Id*.) Dr. Oser indicated that petitioner was positive for all questions asked during review of systems except for syncope, hearing loss, and incontinence. (*Id*. at 39.) She was diagnosed with numbness, pain in limb, lumbago, memory loss, and anemia. (*Id*. at 36.) Dr. Oser concluded that petitioner needs daily treatment of hydrocodone to address her back and leg pain, foot numbness, and other joint pains. (*Id*. at 40.) However, he indicated that petitioner's neurological exam was benign despite an abnormal mental status. Petitioner was referred for formal neuropsychological testing. (*Id*.) Petitioner's EMG, conducted on May 29, 2015, showed no evidence of radiculopathy, large fiber neuropathy, or small fiber neuropathy. (*Id*. at 65.)

Petitioner had an ophthalmology appointment on August 3, 2016, at Ochsner South Shore Region. (Ex. 13.) Her visit summary listed her current problems including anemia, arthralgia, joint pain, venous insufficiency, shoulder pain, biceps tendinitis on right, and more. (*Id*. at 1.) Since petitioner's last visit on June 23, 2016, petitioner indicated that her visual disturbance increased and she would get random tingling around the eyes. (*Id*. at 12.) Petitioner also complained of headaches, flashes of light, frequent floaters, and more. Petitioner was diagnosed with visual disturbance and referred to seek outside neurology care. (*Id*. at 13.)

On August 16, 2016, petitioner saw Dr. Tere Vives for a neuro-ophthalmology consultation. (Ex. 13, p. 14.) Petitioner completed a questionnaire and listed under the

chief complaint that "TDAP vaccine injury (02/06/2012) caused acute visual disturbances without resolve." Additionally, it was noted that petitioner's visual problems persisted since receiving the Tdap vaccination. (*Id*.) Additionally, petitioner indicated that she experienced trauma, migraine, allergies, ear infection, attention deficit disorder since her "TDAP vaccine injury." (*Id*.) Dr. Vives diagnosed a reaction to her tetanus shot and orbital pain. (*Id*. at 25.) Petitioner was prescribed gabapentin (Neurontin) and vitamin B12 and an MRI was ordered. (*Id*. at 26-27.) However, petitioner reported to Dr. Patterson on August 24, 2016, that she had an allergic reaction to the gabapentin.[8] (Ex. 12, p. 144.) The MRI studies were conducted on August 30, 2016, and were interpreted as unremarkable. (Ex. 13, pp. 32-36.) On September 6, 2016, Dr. Vives referred petitioner to neurologist Jesus Lovera. (*Id*. at 34.)

On October 18, 2016, petitioner had a neurology consultation with Dr. Jesus F. Lovera. (Ex. 13, p. 37.) At this visit, petitioner reported that she was healthy and started having problems in Feb 2012. Petitioner indicated that she felt sharp pain at the injection site that radiated down the side of her leg and thereafter, her injection site became red and she was treated for cellulitis. (*Id*.) Petitioner indicated that she continued to experience ongoing symptoms, including spasms, heaviness sensation on the legs, impaired concentration and focus, decreased appetite, dizziness, blurred vision, and paresthesia. (*Id*.) Dr. Vives told Dr. Lovera that petitioner did not have optic neuritis but that there's a concern for an ongoing neuroimmunological problem. (*Id*.) Petitioner's brain MRI was unremarkable, but her lumbar spine radiograph showed lumbar spondylosis and partially visualized uterine fibroids. (*Id*. at 38-39.) Dr. Lovera assessed petitioner with weakness of both lower extremities and tetanus vaccine side effects. (*Id*. at 40.) Dr. Lovera wrote that petitioner "had a reaction to tetanus vaccination four years ago. She has a plethora of symptoms that have persisted since the reaction." (*Id*.)

On November 7, 2016, petitioner underwent MRI of the thoracic spine without contrast. (Ex. 15, p. 9-10.) Petitioner's history reported that she suffered midback and neck pain, more prominent on the left with burning paresthesia and bilateral lower extremity weakness. (*Id.* at 9.) Petitioner was assessed with mild, early changes from thoracic spondylosis causing no canal or foraminal stenosis. (*Id.*) In his impression, Dr. Harlin noted that petitioner continued to move on repeat imaging sequences, degrading some of the images and limiting the evaluation of cord signal, especially. (*Id.* at 10.) On most of the gradient axial images, there appeared to be abnormal cord signal, but Dr. Harlin indicated that it was not correlated with T2 sequences or STIR sagittal, which confirms that it is most likely motion artifact. (*Id.*) Judging by the sagittal T2 and STIR images, Dr. Harlin noted no obvious cord signal abnormalities, but very small, focal cord signal abnormalities which could have been obscured by the artifact. (*Id.*) Dr. Harlin observed changes from cervical spondylosis were causing mild central canal stenoses at C4-C5, C5-C6, and C6-C7. (*Id.*) He also observed "multilevel bilateral foraminal stenoses." (*Id.*)

[8] Petitioner reported that the gabapentin was prescribed for optic neuritis; however, that diagnosis does not appear in Dr. Vives's record. Dr. Vives confirmed as part of her referral to neurology that petitioner did not have optic neuritis. (Ex. 13, p. 37.)

Petitioner had a chronic pain consult on April 21, 2017, with Dr. Gassan M. Chaiban. (Ex. 11, p. 63.) Petitioner was reported to have a "long-standing history of neuropathic pain dating back to a tetanus injection in 2010[9] which resulted in cellulitis and an immunologic response which corresponded with the onset of the patient's pain." (*Id*.) Dr. Chaiban noted that petitioner has been evaluated by multiple specialists but without any clear diagnosis. (*Id*.) Dr. Chaiban ordered flexion extension x-rays to be conducted and depending on the results, Dr. Chaiban wanted to enroll petitioner in physical therapy. Additionally, Dr. Chaiban directed petitioner to follow up with psychiatry, neurosurgical, and surgical evaluations. (*Id*. at 68-69.)

On June 20, 2017, petitioner sough a neurosurgical evaluation for nerve injury with complaints of "generalized body pain and dysesthesia after tetanus injection." (Ex. 11, p. 78.) It was recorded that petitioner began having severe left leg pain and dysesthesia "after a supposed needle injury to the sciatic nerve." (*Id*.) The impression was that petitioner had "post-tetanus injection polyradiculoneuropathy," and was referred to Dr. Daniel G. Larriviere for further evaluation. (*Id*. at 82.) Petitioner saw Dr. Larriviere on June 30, 2017. (*Id*. at 87.) Petitioner reported similarly as to prior visits, the symptoms she experienced immediately following her Tdap vaccination as well as the following days. In addition, petitioner reported that "[d]uring the ensuing years since her injection, she experiences constant pain, burning, tingling, and formication throughout her entire body, including her scalp." (*Id*.) Dr. Larriviere noted that her exam was normal and prior workup was unremarkable, and that petitioner did not have polyneuropathy. An EMG was then ordered to confirm any evidence for neuropathy. (*Id*. at 91.)

On July 12, 2017, petitioner returned to Dr. Lovera for her "ongoing autoimmune condition." (Ex. 15, pp. 6-11.) Petitioner reported that her condition was getting worse. "She feels hot all the time, every time she ingests something no matter what she gets a bad feeling of burning in her back and spreads through all of her body." (*Id.* at 6.) Likewise, "she also complains of pain over her upper and lower extremities. She endorses fatigue, malaise. She drops things and fell twice during last couple of months." (*Id.*) Petitioner indicated that her short-term memory was impaired. (*Id.*) Petitioner endorsed blurry, double vision, worse in the morning and evening. (Ex. 15, p. 6.) Petitioner recalled a trip to the hospital due to hypertension "in the 170's" with numbness and paresthesia on the face and head. (*Id.*) She presented to the ER and was treated for her blood pressure. (*Id.*) Petitioner reported that she is "normally not hypertensive." (*Id.*) Additionally, petitioner complained of hyperpigmentation on her skin, worsening since the last visit—"[s]he has seen dermatology and they attributed this to the tetanus shot." (*Id.*) Dr. Lovera assessed petitioner with dysphagia and "tetanus vaccine side effect." (Ex. 15, p. 11.) Reviewing petitioner's November 11, 2016 spinal MRI, Dr. Lovera noted that there were no cord lesions on her cervical and thoracic spine MRIs. (*Id.*) Dr. Lovera planned to continue reviewing petitioner for

[9] This particular record had a disclaimer, indicating that the note was generated using voice-recognition software and therefore there may be typographical errors. (Ex. 11, p. 63.) Of note, petitioner's tetanus shot was in 2012.

symptomatic management, though he was "[n]ot sure that immunosuppressant agents would be helpful." (*Id.*) He noted that he spent 50% of the time counseling petitioner and he "agree[d] her symptoms are possibly related to her tetanus shot." (*Id.*)

On August 18, 2017, petitioner presented to her PCP Dr. Ferrier for a follow-up after presenting to the emergency department for paresthesia. (Ex. 12, p. 209.) She presented to Dr. Ferrier complaining of tingling sensations involving the left side of her body. (*Id.*) She noticed the "peak in pain" around the middle of the month. (*Id.*) Petitioner further reported fatigue, diffuse myalgia, bruising, joint pain, hoarseness, memory loss, and perspiration along her torso. (*Id.*) She described pain shooting down her spine, spreading to her extremities. (*Id.*) Likewise, she reported feeling lightheaded, with pain behind her eyes. (Ex. 12, p. 209.) Her symptoms were improving, however. (*Id.*) Dr. Ferrier assessed petitioner with paresthesia and ordered her to continue taking vitamin supplements and monitor her blood pressure. (*Id.* at 10.)

On November 1, 2017, petitioner returned to Dr. Ferrier for a follow-up visit regarding her hypertension. (Ex. 37, p. 14.) Petitioner was not tolerating antihypertensives. (*Id.*) She complained of spasms in her left leg, making walking difficult. (*Id.*) She told Dr. Ferrier that her left knee was warm, with ecchymoses. (*Id.*) Petitioner further complained of an aching sensation in the bottom of her foot; swelling in her left hip, worse with weight bearing; decreased grip strength; and night sweats. (*Id.*) Petitioner's diagnoses included essential hypertension and polyneuropathy. (*Id.* at 15.)

On November 6, 2017, petitioner presented to Dr. Jones complaining of left knee pain. (Ex. 38, p. 1.) Petitioner complained of joint pain, back pain, joint swelling, muscle cramps, and muscle weakness; she denied night sweats and denied numbness or paresthesia. (*Id.*) On physical examination, petitioner's left knee, right hip, left and right shoulder tests were normal, though petitioner demonstrated a deformity in her left knee. (*Id.* at 2-4.) She had 4/5 strength in her left quadriceps and hamstring. (*Id.* at 4.) Petitioner was assessed with left knee pain (unspecified chronicity), arthralgia (unspecified joint), chronic right shoulder pain, and fibromyalgia. (*Id.* at 5.)

On February 6, 2018, petitioner returned to Dr. Ferrier for a follow-up for her hypertension and chronic pain. (Ex. 37, p. 38.) She denied any chest pain or shortness of breath, but complained of headache, blurred vision, excessive fatigue and nausea. (*Id.*) Petitioner reported her ambulatory blood pressures were good, though her blood pressures were higher in the right arm. (*Id.*) Dr. Ferrier ordered her to return for follow-up in 3 months. (*Id.* at 39.)

On March 19, 2018, petitioner returned to Dr. Webb-Detiege with a chief complaint of joint pain. (Ex. 38, p. 7.) Dr. Webb-Detiege noted that petitioner had "chronic fatigue, immunologic issues and pain since tetanus shot in 2012." (*Id.*) Petitioner described night sweats, feeling like "her nerves are on fire and [] can hear her heart race." (*Id.*) She complained of 24-hour stiffness and difficulty staying on task. (*Id.*) Petitioner was negative for symptoms of lupus; but positive for fatigue, fever, dry mouth, dry eyes, cough, chest pain, headaches, adenopathy and easy

bruising/bleeding. (*Id.* at 7-8.) On physical examination, petitioner had pain on palpation for 12/18 tender points for fibromyalgia. (*Id.* at 8.) She also demonstrated zero swollen and zero tender joints. (*Id.*) Petitioner was assessed with arthralgias ("symptoms began after tetanus shot which was associated with cellulitis of buttocks"), myalgias, positive CCP, fatigue, night sweats, dry mouth, venous insufficiency of the legs, and optic neuritis.[10] (*Id.* at 10.) Dr. Webb-Detiege ordered repeat ANA, labs, and an arthritis survey. (*Id.*)

On July 17, 2018, petitioner returned to Dr. Ferrier again for a follow-up of her hypertension. (Ex. 37, p. 87.) She denied chest pain, blurred vision, excessive fatigue, nausea or vomiting but complained of shortness of breath and morning headaches. (*Id.*) Petitioner reported that she was involved in a motor vehicle accident in April and developed hand swelling immediately after the accident. (*Id.*) She also reported left shoulder popping. (*Id.*) Dr. Ferrier indicated that petitioner's blood pressure was well controlled and ordered her to follow-up with an orthopedist and continue pain medication for fibromyalgia. (*Id.* at 88.)

On August 14, 2018, petitioner presented to Dr. Ferrier complaining of right shoulder and arm pain, pain in the right side of her neck, right wrist weakness, hand swelling and difficulty stretching her fingers. (Ex. 37, p. 103.) She further complained of numbness in her right upper extremity. (*Id.*) According to petitioner her symptoms began 10 days prior. (*Id.*) Dr. Ferrier recommended salon pas for the right wrist pain. (*Id.* at 104.)

On October 15, 2018, petitioner presented to Dr. Jones with bilateral shoulder pain, right greater than left. (Ex. 38, p. 11.) She described a fall that caused a "shocking" pain in her shoulder one month prior. (*Id.*) Petitioner continued to have aching and burning in her right arm and shoulder. (*Id.*) She observed swelling into her arm, causing difficulty with ADLs. (*Id.*) Dr. Jones noted petitioner "had a vaccine injury in 2011 and has had global neurological symptoms." (*Id.*) Dr. Jones reviewed petitioner's bilateral shoulder x-ray showed mild degenerative joint disease. (*Id.*) She was assessed with right shoulder pain (unspecific chronicity), left shoulder pain (unspecific chronicity), rotator cuff syndrome in the right shoulder, fibromyalgia, biceps tendinitis in the right shoulder, and arthralgia (unspecific joint). (*Id.* at 15.) Dr. Jones ordered an MRA of petitioner's right shoulder. (*Id.* at 15-16.) The next day, petitioner presented to Dr. Sisco-Wise, in the same office, who ordered an EMG to evaluate petitioner for possible peripheral nerve compression. (*Id.* at 17.)

On November 19, 2018, petitioner presented to Dr. Ferrier for a follow-up on her hypertension. (Ex. 37, p. 143.) She continued to experience joint pain but noted that physical therapy and water therapy were helping. (*Id.*) She described neck pain, worse on the right; numbness, tingling, and burning sensations in her right arm; and right-hand pain. (*Id.*) Dr. Ferrier assessed petitioner with cervicalgia and prescribed hydrocodone and ordered cervical spine MRI. (*Id.* at 144.)

[10] Dr. Webb-Detiege noted that petitioner's records indicated that Dr. Lovera ruled out optic neuritis, but petitioner wished to see Dr. Webb-Detiege "because of her concern of an ongoing neuroimmunological problem." (Ex. 38, p. 10.)

On January 22, 2019, petitioner presented to Dr. Chaiban for a follow-up on her chronic pain. (Ex. 38, p. 21.) Petitioner's EMG/NCV showed mild carpal tunnel syndrome. (*Id.*) Petitioner was continuing occupational therapy, and improving, but it was discontinued secondary for a concern of cervical radiculopathy. (*Id.*) Dr. Chaiban noted petitioner's long-standing history of neuropathic pain dating back to her tetanus injection, having been seen by multiple specialists, including rheumatology, hematology/oncology, neurology, cardiology and "there has not been a clear diagnosis at this time." (*Id.*) He noted that in the past petitioner "had a positive rheumatoid factor and she has thrombocytosis, there is a question of orthostatic hypotension versus venous insufficiency and this has been undergoing workup." (*Id.*) She continued to describe "burning tingling sensations" in her bilateral lower extremities, abdomen, and face, with occasional facial droop. (*Id.*) Dr. Chaiban referred petitioner for an allergy/immunology consult and suggested a sural nerve biopsy or cervical burst stimulation at St. Jude. (*Id.* at 28.)

On March 27, 2019, petitioner presented to PA-C Erin Diebold with a subcutaneous mass on her medial right elbow. (Ex. 38, p. 29.) Onset of her symptoms began approximately one year prior, with gradual worsening. (*Id.*) She developed progressive weakness and numbness in her fourth and fifth digits and thumb. (*Id.*) PA-C Diebold noted petitioner previously had two masses removed which were diagnosed as lipomas. (*Id.*)

On April 1, 2019, petitioner presented to Dr. Smith for a consultation regarding her lipoma. (Ex. 38, p. 32.) Dr. Smith noted in the HPI that petitioner had been diagnosed with fibromyalgia and peripheral neuropathy "as a reaction to a vaccine in 2012."[11] (*Id.*) Dr. Smith further noted that petitioner had not been seen by neurology or rheumatology in over a year. (*Id.*) Dr. Smith assessed petitioner with right brachial artery aneurysm but ordered repeat imaging because petitioner's "[r]epresentative images are not convincing." (*Id.*)

On June 3, 2019, petitioner presented to Dr. Trinh with a chief complaint of right arm lymphadenopathy. (Ex. 38, p. 34.) Upon reviewing petitioner's labs, right arm ultrasound, right arm vascular ultrasound, and MRI of her humerus, Dr. Trinh assessed petitioner with chronic pain syndrome, right-hand and wrist arthritis, right epitrochlear lymphadenopathy, positive CCP, and multiple antibiotic allergies. (*Id.* at 35.) Dr. Trinh ordered follow-up laps, MRI of her right hand, wrist, and forearm, and follow-up visits with Drs. Webb and Townsend. (*Id.*)

On June 5, 2019, petitioner presented to Dr. Ferrier for a follow-up of her hypertension. (Ex. 37, p. 215.) She reported decreased sensation in her left leg and a throbbing sensation in her right arm. (*Id.*) She further reported diffuse body aches, fatigue, nausea and vomiting following her blood draw. (*Id.*)

[11] By this time petitioner had already had a telephone interview with Dr. Lapp, though the resulting report does not specifically confirm a diagnosis of fibromyalgia. (Ex. 16.) Petitioner was later evaluated by Dr. Lapp in person in November of 2019. (Ex. 21.)

On June 13, 2019, petitioner returned to Dr. Webb-Detiege for a follow-up. (Ex. 38, p 37.) She reported "24-hour stiffness during flare[s]" and described taking 4 hours to get ready in the morning. (*Id.*) She described flares for the past five days to two weeks. (*Id.*) Petitioner further reported losing sensation in her hands. (*Id.*) In addition to her prior diagnoses, Dr. Webb-Detiege assessed petitioner with hypertension ("worsens with flare of symptoms"). (*Id.* at 40.)

On June 26, 2019, petitioner presented to Dr. W. Edward Davis III for an allergy consultation. (Ex. 38, p. 41.) Dr. Davis noted that petitioner was last seen in Allergy by Dr. Hassett on January 11, 2013. (*Id.*) He noted that petitioner "attributes multiple symptoms to her [tetanus shot] reaction, most of which have been neurologic and muscular." (*Id.*) In a detailed survey, petitioner indicated, in part, that her symptoms occur sometimes two to three times a week, based on dietary intake, and in response to "outdoor elements and/or contact with various chemicals or products…flare ups are random and can appear regardless of precautions and avoiding known allergies." (*Id.* at 42.) She further indicated that "food allergies only became relevant after TDAP vaccine injury." (*Id.* at 43.) Dr. Davis assessed petitioner with chronic rhinitis ("consider allergic"), chronic cough with shortness of breath ("consider allergic component"), history of adverse reaction to tetanus injection, and fibromyalgia. (*Id.* at 44.) He ordered neuro-ophthalmology and neurology follow-ups. (*Id.*)

On August 7, 2019, petitioner returned to Dr. Trinh for a follow-up on her right arm lymphadenopathy. (Ex. 38, p. 45.) She indicated that she was still awaiting MRI and reported continued right arm pain and worse swelling since the prior visit. (*Id.*) Dr. Trinh noted that an extensive infectious work-up was negative, including bartonella, toxo, syphilis, HIV, and EBV. (*Id.* at 46.) She further noted "[s]uspect underlying autoimmune process cause of right epitrochlear [lymphadenopathy]." (*Id.*)

On August 8, 2019, petitioner presented to Dr. Robin Davis for a neurology consult. (Ex. 38, p. 48.) Dr. Davis discussed with petitioner that some of her weakness may be accounted for by the carpal tunnel noted her EMG. (*Id.*) Petitioner was "insistent that she has ulnar Neuropathy not median neuropathy despite the converse being observed on her EMG." (*Id.*) Dr. Davis remarked that her exam was notable only for multiple functional signs and she complained of 10/10 pain whenever she is touched. (*Id.*) Of note, Dr. Davis discussed with petitioner her (1) right carpal tunnel syndrome (2) chronic pain syndrome and (3) excessive daytime sleepiness. (*Id.*) Upon review of petitioner's EMG, Dr. Davis confirmed her bilateral carpal tunnel syndrome "however the patient refutes this." (*Id.* at 48-49.) Petitioner also insisted that she suffered from polyneuropathy, though her EMG in 2018 and 2018 showed only evidence of carpal tunnel syndrome. (*Id.* at 49.) Dr. Davis noted that she did not receive records from Ochsner neurology, however. (*Id.*) Dr. Davis was unable to identify the primary neurologic cause for petitioner's chronic pain but noted that she agreed with petitioner's PCP who recommended refraining from adding new medications. (*Id.* at 48.) Dr. Davis also referred petitioner to Sleep Disorders for her excessive daytime sleepiness. (*Id.*)

On August 21, 2019, petitioner presented to Dr. Townsend with tender nodule on her right medial arm. (Ex. 38, p. 52.) Dr. Townsend assessed petitioner with tender

lymphadenopathy and recommended an excisional biopsy. (*Id.* at 54.) On September 11, 2019, petitioner presented for a follow-up after her reactive lymph node was removed. (*Id.* at 56.)

On September 12, 2019, petitioner returned to Dr. Ferrier for another follow-up for hypertension. (Ex. 37, p. 249.) Additionally, she reported that she was not sleeping at night. (*Id.*) Petitioner complained of persistent right hand and wrist pain. (*Id.*) Her MRI showed findings which could be consistent with ulnar abutment syndrome. (*Id.*)

On September 16, 2019, petitioner returned to Dr. Webb-Detiege. (Ex. 38, p. 57.) Petitioner noted "she is having a flare since Saturday." (*Id.*) She complained of fatigue, fever, trouble swallowing and dry mouth, dry eyes, shortness of breath, chest pain, headaches, adenopathy, and easy bruising. (*Id.* at 57-58.) Dr. Webb-Detiege assessed petitioner with undifferentiated connective tissue disease (UCTD) "manifested by myalgias and arthralgias, reactive lymph node at right elbow, ANA, CPP, and fatigue." (*Id.* at 60.) Dr. Webb-Detiege ordered labs and messaged petitioner's eye doctor for clearance for Plaquenil for her UCTD. (*Id.*)

On October 7, 2019, petitioner presented to a new physician, Dr. Ronald French Jr., complaining of pain and swelling in her hands. (Ex. 38, p. 63.) Dr. French Jr. noted that petitioner had been seen by several different doctors for this issue. (*Id.*) He noted that petitioner's recent MRI showed inflammatory changes of the right wrist. (*Id.*) Dr. French Jr. assessed petitioner with inflammatory arthritis of the right hand and wrist, ulnar impaction syndrome in the right wrist, and right carpal tunnel syndrome. (*Id.* at 65.) Petitioner was given a corticosteroid injection in her right wrist and a wrist brace. (*Id.*) Dr. French Jr. recommended possible surgery for ulnar shortening osteotomy. (*Id.*) Petitioner returned to Dr. French Jr. on January 23, 2020, after undergoing ulnar shortening osteotomy and carpal tunnel release. (*See* Ex. 38, pp. 71-73 (s/p two weeks).) On March 9, 2020, petitioner returned to Dr. French Jr. for a post-op follow-up and was "doing well, pain is minimal, definitely improving." (*Id.* at 77.)

On March 23, 2020, petitioner returned to Dr. Ferrier for a follow-up visit. (Ex. 37, p. 301-02.) Petitioner complained of right forearm pain following surgery, but also reported that sensation was returning to her fingertips in her right hand. (*Id.* at 301.) Dr. Ferrier assessed petitioner with mildly elevated blood pressure but noted improvement; and planned to continue pain control for her fibromyalgia and polyneuropathy. (*Id.* at 302.)

On May 6, 2020, petitioner had a telemedicine visit with Dr. Ferrier, complaining of stress. (Ex. 37, p. 318.) Petitioner further complained of dry skin, hair loss, mouth sores, fatigue, insomnia, back pain, right shoulder weakness, swollen lymph nodes, ear pain, and jaw stiffness. (*Id.* at 318-19.) Dr. Ferrier prescribed Ambien for petitioner's insomnia. (*Id.* at 320.)

On June 24, 2020, petitioner presented to for a follow-up with Dr. Ferrier, complaining of bilateral leg and knee pain and additional lipoma. (Ex. 37, p. 333.) Dr. Ferrier assessed petitioner with knee pain, unspecified chronicity, lipoma, and

hypertension, secondary to pain, but improving. (*Id.* at 334.) Subsequent ultrasound did not reveal lipoma. (*Id.* at 372.) Petitioner continued to report left leg pain, stinging pain and bilateral ankle and foot swelling, hair loss, lack of sleep (secondary to pain), headaches (due to lack of sleep), back pain, and perspiration down her back. (*Id.*) In December 2020, petitioner additionally complained of being forgetful and dropping things due to pain exacerbation. (*Id.* at 394.)

On March 1, 2021, petitioner returned to Dr. French Jr. with residual numbness and tingling in her right ring and small finger. (Ex. 38, p. 81.) Petitioner indicated that she wished to restart physical therapy on both hands. (*Id.*) Dr. French Jr. indicated that he was "[n]ot sure why she is having the numbness," so he ordered a nerve conduction study of both arms. (*Id.* at 83.) A subsequent nerve conduction study of both hands showed mild carpal tunnel syndrome bilaterally, no evidence of cubital tunnel or ulnar nerve compression. (*Id.* at 84.) Dr. French Jr. administered another corticosteroid injection and continued petitioner on anti-inflammatory medication. (*Id.* at 86.) Dr. French Jr. referred petitioner to Dr. Alvah Tyson Wickboldt Jr. for her neck pain. (Ex. 38, pp. 95-99.) Dr. Wickboldt reviewed petitioner's prior EMG and MRIs, but "given the length of time she has been dealing with symptoms" he explained that resolution was unlikely. (*Id.* at 99.) He referred petitioner for cognitive behavioral therapy. (*Id.*)

As of May 2021, petitioner presented to Dr. Ferrier complaining of leg pain. (Ex. 38, p. 102.) She described a heaviness sensation in her leg and shooting pain up her right leg to her groin. (*Id.*) Dr. Ferrier assessed petitioner with right leg pain (awaiting ultrasound), hypertension (elevated, likely secondary to pain), and right hip pain. (*Id.* at 102-03.)

b. As Reflected by Testimony/Affidavits

Petitioner averred that she received the Tdap vaccination in her left buttocks in the emergency room on February 6, 2012. (Ex. 7.) Petitioner stated that the nurse administering the vaccination suggested the buttock and petitioner did not protest although she thought it was strange. (*Id*. at 2.) According to petitioner it was "chaotic" at the emergency room that day and the nurse appeared to petitioner to be "rushed, distracted, and not competent." (*Id*.) Additionally, petitioner affirmed on July 2, 2017 that she has scarring with atrophy and a persistently bothersome bump at the vaccination site. (Ex. 10.) Petitioner also indicated that the injection site was painful upon touch with burning and itching. (*Id*.)

Petitioner testified that prior to vaccination she was social and active, comparing herself to the "Energizer bunny." (Tr. 9-10.) In contrast, she described her post-vaccination life as follows:

> I'm feeling horrible. I am not well, and I am afraid that I'm not going to get better because I'm not getting better. And I just can't do anything normal like I would be able to be very active and be more in control of being organized and not fatigued. Anything I try to do makes me tired. Especially when I try to do things, I get stressed, because I can't complete the task because I'm

> tired all the time. And I've even tried to stay in the bed longer to rest, even to sleep, but still when I awaken, it's like I've never slept. And I've told Dr. Ferrier, all my physicians, numerous, numerous, I'm just tired, I'm just tired. So when I try to do a normal day's activity, which that no longer exists for me -- I don't have any normalcy; I live day to day, because I have a lot of, I guess you would say, symptoms that's just recurring. And the pain is unbearable. Like right now I'm getting tired waiting, because I want to sleep, and I'm trying to stay focused, so I can participate. And I got a little sleep last night, but still when I awake, the hoarseness is there. I can tell when I'm really bad because it's like I hit a wall, oomph. And even if I try to push past it, my mind is saying I can do it, but my body's saying, we're not doing that. Literally you're not doing that.

(Tr. 7-8.)

On cross-examination, respondent's counsel explored details of petitioner's medical history and petitioner provided testimony regarding her subjective experience of the symptoms discussed in the medical records. This related in large part to understanding her sleep patterns and how she experienced what was reported as insomnia and night sweats by her physicians. (Tr. 15-20.) Petitioner also indicated that the leg pain she experienced pre-vaccination was not severe, only "normal" achiness, and that she only ever took Vicodin for her shoulder problem. (Tr. 20-21.) Petitioner disagreed with the medical record of May 23, 2011 (Ex. 1, p. 570) characterizing her pain problems as "longstanding." (Tr. 21-29.) Petitioner characterized her back and leg pain as residual effects of her shoulder problem that were ultimately resolved by her later 2012 surgery. (*Id*.) Petitioner also disagreed with a characterization in the medical records (Ex. 1, p. 574) from September of 2010 of her having "recurrent" throat infections, preferring to characterize them as either periodic or "off and on." (Tr. 30-32.) Petitioner confirmed she had an upper respiratory infection in January of 2012 (Tr. 32-33) and reviewed the record of her January 16, 2012, encounter with Dr. Ferrier (Ex. 1, p. 442). Petitioner acknowledged having the symptoms reported in the record, including cough, fatigue, and intermittent fever. (Tr. 34-35.)

IV. Expert Opinions

a. Petitioner's Experts

i. Janine M. Ferrer, M.D.

On November 2, 2016, Dr. Ferrier, petitioner's primary care physician, wrote a letter addressing petitioner's claim. (Ex. 8.) Dr. Ferrier stated that petitioner received a Tdap vaccine in her left hip in 2012 and experienced pain and redness around her injection site. (*Id*.) Thereafter, petitioner experienced intermittent fatigue, fever, myalgias, joint pains, intermittent swelling, and headaches. Additionally, Dr. Ferrier wrote that petitioner also had other symptoms including decreased appetite, nausea, spasms, and burning sensation in her left lower extremity. Dr. Ferrier stated that

"[m]any of the symptoms [petitioner] has experienced may be attributable to her vaccination, including injection site pain and redness, fever, headaches nausea, chills, and bodyaches [sic]." (*Id*.) Dr. Ferrier indicated that petitioner continued to experience symptoms intermittently.

ii. Charles Lapp, M.D.

Dr. Lapp currently is the medical director of the Hunter-Hopkins Center in North Carolina. (Ex. 20.) He received his medical degree from Albany Medical College in 1974 and completed his residency in internal medicine and pediatrics at North Carolina Memorial Hospital. (*Id*.) He has experience in diagnosis and management of CFS and Fibromyalgia since 1985. (Ex. 16.) Dr. Lapp has published various articles covering many topics and recently took part in an article about CFS and Myalgic Encephalomyelitis. (Ex. 20, p. 3.)

Petitioner was evaluated by Dr. Lapp on November 12, 2019 following a phone consultation on February 29, 2019.[12] (Ex. 21.) As part of her history of present illness, Dr. Lapp noted that petitioner experienced nausea, fatigue, and injection site pain within 30 to 60 minutes following receipt of the Tdap vaccination to her left buttock on February 6, 2012. Additionally, the following day, petitioner experienced widespread arthralgias, pain in the left hip and back, discomfort in the left leg, and swelling in her hands and legs. From there, petitioner was diagnosed with cellulitis of the left buttock, diagnosed with serum sickness following a rheumatology consult, and developed more symptoms including malaise, insomnia, memory loss, headaches, body pain, recurrent sore throat, cervical and inguinal lymphadenopathy. (*Id*. at 1.) Dr. Lapp noted that petitioner's symptoms persisted and that she "is almost never free of severe pain, which

[12] Although the opinions of treating physicians are not binding (*see* § 13(b)(1)), the Federal Circuit has recognized that "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.'" *Capizzano v. Sec'y of Health & Human Servs.,* 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen v. Sec'y of Health and Human Servs.,* 418 F.3d 1274, 1280 (Fed. Cir. 2005)). Accordingly, such opinions are often considered "quite probative." *Id*. This logic has also been applied in the context of diagnosis. *See*, *e.g.*, *D'Angiolini v. Sec'y of Health & Human Servs.*, No. 99-578V, 2014 WL 1678145, at *24 (Fed. Cl. Spec. Mstr. Mar. 27, 2014) (finding a treating physician's opinion regarding diagnosis "worth a great deal" and "almost definitive evidence on that point"), *mot. for rev. denied*, 122 Fed. Cl. 86 (2015), *aff'd*, 645 F. Appx. 1002 (Mem.) (Fed. Cir. 2016). However, the extra weight often assigned treating physician opinions is premised on the notion that, in addition to being qualified to offer a medical opinion, the treating physicians were eyewitnesses with personal knowledge of the unfolding of a petitioner's condition. *Nuttall v. Sec'y of Health & Human Servs*., 122 Fed. Cl. 821, 832-33 (2015) (explaining that the Federal Circuit "found that a treating physician who was familiar with the patient both before and after the alleged vaccine injury is likely to be in a better position than an expert retained after the fact" to opine with respect to vaccine causation), *aff'd* 640 Fed. Appx. 996 (Mem.) (Fed. Cir. 2016). Here, Dr. Lapp's evaluation does not fit that context. He had one phone consultation and one in-person evaluation with petitioner, both of which occurred years after the alleged onset of her condition. Moreover, the evaluation was for purposes of developing Dr. Lapp's opinion in this case and did not occur in the ordinary medical treatment context. For these reasons, while recognizing that Dr. Lapp's ability to conduct an in-person exam and interview contributed to the basis for his opinion and likely added to what he was able to observe in making to his assessment, his opinion does not qualify for any added enhancement as a treating physician in the context of the record for this case.

comes from all over, from muscles, bones, and joints." (*Id*.) At this evaluation, petitioner reported moderate to severe symptoms at rest, but severe symptoms with activity. (*Id*. at 2.) Dr. Lapp also listed Tdap and all vaccines as part of petitioner's allergies. (*Id*. at 3.)

Under a review of systems, Dr. Lapp noted that petitioner experiences many symptoms including flu-like feelings, recurrent sore throat, blurred vision, recurrent sinus congestion and drainage, frequent queasiness, and more. (Ex. 21, p. 3.) Upon examination, Dr. Lapp noted petitioner was positive for joint tenderness and limited range of motion at the right wrist. (*Id*. at 4.) He also noted some elevated levels from her laboratory. (*Id*.) Dr. Lapp assessed petitioner with fibromyalgia, CFS, sleep disorder, as well as dysphagia, irritable bowel syndrome, amenia, vitamin D deficiency, and several other conditions. (*Id*. at 4-5.)

Dr. Lapp reports that immune challenges, like immunizations, can cause CFS. (Ex. 16, p. 3.) He explains that a shift in the immune response towards a TH2 profile results in a fatiguing illness after vaccination; and moreover, overproduction of pro-inflammatory cytokines can cause alterations in the cardiovascular and cognitive systems. Dr. Lapp indicates that an immune imbalance toward a TH2 immune state is observed in patients with CFS. He states that, "it is well known by researchers in this field, that CFS is frequently triggered by infections and various immune challenges, including vaccinations." (*Id*.) Therefore, Dr. Lapp opines that petitioner has CFS and Systemic Exertion Intolerance Disease, and that petitioner's condition was triggered by her receipt of the Tdap vaccination on February 6, 2012. (*Id*.)

In a supplemental report, Dr. Lapp provides a response to the reports from Drs. Oddis and He. (Ex. 22.) Dr. Lapp points out that routine laboratory and diagnostics are typically normal in CFS and fibromyalgia patients. He responds that a one-time shoulder pain, backaches, and leg pain cannot explain the physical and cognitive symptoms that petitioner experienced all over her body since her vaccination. Again, Dr. Lapp emphasizes that petitioner's rheumatologist concluded that petitioner had a reaction to her vaccination. (*Id*. at 1.) He disagrees that petitioner's condition was caused by an infection or cellulitis. Dr. Lapp indicates that "[f]ever and swelling occurred at the injection site within one hour of the injection, which is too rapid for infection; and within one day the patient experienced diffuse joint pain, a clear sign of immune reaction." (*Id*.) Dr. Lapp again asserts that petitioner developed fever, swelling, arthralgias, and other symptoms that meet the criteria for Fibromyalgia and CFS. (*Id*. at 2.)

During the hearing, Dr. Lapp testified in accordance with his prior reports. (Tr. at 41-171; 176-244.) He further explained the immunology underlying his theory and addressed specific medical record entries that he opines support his interpretation that petitioner experienced onset of her CFS within two weeks of her Tdap vaccine. He also discussed the relevant diagnostic criteria for CFS in detail and explained that he believes petitioner's treating physicians misinterpreted manifestations of petitioner's CFS as serum sickness.

b. Respondent's Experts

i. You-Wen He, M.D., Ph.D.

Dr. He currently teaches as a professor of immunology at Duke University Medical Center and oversees four clinical trials for cancer immunology. (Ex. C.) Dr. He also serves as a reviewer for several journals. He received his medical degree from The Fourth Military Medical University in Xian, China in 1986 and his doctorate in microbiology and immunology from the University of Miami School of Medicine in 1996. (Ex. C, Tab 1.) He has ongoing research focusing on T cell receptor-activated autophagy and immune-modulating antibody for lung cancer treatment. (*Id*. at 6.)

Upon review of the medical records, Dr. He concludes that petitioner had chronic conditions that did not result in any definitive diagnosis. (Ex. C.) Dr. He opines that CFS is poorly understood and may be related to several possible causes including infection, immune dysfunction, endocrine-metabolic dysfunction, and neuropsychiatric factors. (*Id.* at 3 (citing Stephen J. Gluckman et al., *Clinical features and diagnosis of myalgic encephalomyelitis/chronic fatigue syndrome,* 11(4) UPTODATE 1 (2019) (Ex. C, Tab 2.)).) Although Dr. Lapp cited to a case report relating vaccination and CFS, Dr. He states that there is insufficient support for causation between vaccination and CFS. In his opinion, it is more likely that petitioner's chronic condition was infection-induced since petitioner had cellulitis after her receipt of her February 6, 2012. (*Id*. at 3.)

During the hearing, Dr. He testified in accordance with this report. (Tr. at 282-309.) He also provided specific criticisms of the immunology Dr. Lapp presented during the hearing.

ii. Chester V. Oddis, M.D.

Dr. Oddis received his medical degree at Pennsylvania State University, College of Medicine in 1980. (Ex. D, Tab 1.) He currently holds a teaching position as a professor of medicine in the division of rheumatology and clinical immunology at the School of Medicine at the University of Pittsburg. (Ex. D.) He is board certified in internal medicine and rheumatology. Dr. Oddis specialized his research in myositis and interstitial lung disease. (*Id*.)

Regarding petitioner's history, Dr. Oddis notes that petitioner was never diagnosed with either CFS or Fibromyalgia and that all her laboratory and diagnostic studies were normal. (Ex. D, p. 3.) Additionally, Dr. Oddis points out that petitioner had musculoskeletal problems and was treating her chronic pain following right shoulder surgery prior to receiving the Tdap vaccination in February 2012. (*Id*. at 3-4.) Dr. Oddis notes that when petitioner complained of diffuse pain, petitioner's rheumatologist and immunologist diagnosed petitioner with "arthralgia," or joint pain without evidence of inflammation. (*Id*. at 5.)

Dr. Oddis opines that petitioner had chronic pain syndrome prior to vaccination and that petitioner does not meet the criteria for the diagnosis of CFS. (*Id*. at 4-5.) He indicates that petitioner has some features, but many of her symptoms were non-specific and therefore disagrees with Dr. Lapp's diagnosis. Dr. Oddis also notes that the basis of Dr. Lapp's report "sets up the potential for an extremely biased report where a physician can suggest many of the clinical features/diagnostic criteria to a patient and then report them." (*Id*. at 5.) Aside from contesting petitioner's diagnosis, Dr. Oddis also opines that petitioner had "self-limited and non-specific symptoms after the Tdap vaccination," that never manifested into any treatable condition.

On Dr. Lapp's theory regarding CFS and vaccination, Dr. Oddis disputes the association and notes that "CFS is often triggered and perpetuated by an ongoing microbial infection and that was also not the case with [petitioner]." (*Id*. at 6.)

During the hearing, Dr. Oddis likewise testified in accordance with his report. (Tr. at 245-281.)

V. Discussion

a. Diagnosis

When faced with disagreement among qualified experts regarding the identification and nature of a disputed injury, the Federal Circuit has concluded that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record before applying the *Althen* test to determine causation." *Lombardi v. Sec'y of Health & Human Servs*., 656 F.3d 1343, 1351-53 (Fed. Cir. 2011). Importantly, however,"[t]he function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)).

Nonetheless, petitioner must "specify [her] vaccine-related injury and shoulder the burden of proof on causation." *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1346 (Fed. Cir. 2010). "Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury – the Act specifically creates a claim for compensation for 'vaccine-related injury or death.'" *Stillwell v. Sec'y of Health & Human Servs*., 118 Fed. Cl. 47, 56 (2014) (quoting 42.U.S.C. § 300aa-11(c)). And, in any event, a petitioner must prove by a preponderance of the evidence the factual circumstances surrounding her claim. § 300aa–13(a)(1)(A).

In this case, petitioner has a complex overall medical history. Initially, petitioner pleaded only that she suffered an abscess and unspecified "related injuries," the symptoms of which she alleged had become chronic. (ECF No. 1, p. 1.) Following her

expert's assessment, she narrowed the "related injuries" to a diagnosis of CFS in her prehearing brief. (ECF No. 132.) However, Drs. Lapp and Oddis raise questions about a number of specific conditions. On petitioner's behalf, Dr. Lapp opines that petitioner does have CFS and comorbid fibromyalgia; however, he denies that she suffered any serum sickness as documented in the medical records. (Tr. 148.) Respondent's expert, Dr. Oddis, disagrees that petitioner has either CFS or fibromyalgia and further opines that petitioner suffered a pre-existing chronic pain syndrome. (Tr. 255-56.) Dr. Oddis does not have any opinion regarding the serum sickness diagnosis contained in the medical records. (*Id.* at 280-81.) There are also references in the medical records to possible rheumatoid arthritis. (Ex. 1, pp. 419, 422, 538; Ex. 2, p. 10.) Finally, both experts agree that petitioner likely suffered the cellulitis documented in the medical records. (Tr. 182, 290-91.)

i. Cellulitis

Petitioner's medical records reflect that on February 9, 2012, she presented to Dr. Ferrier for symptoms that included pain, redness, and inflammation at the site of her Tdap injection.[13] (Ex. 1, 441.) On examination, she had "positive induration of left gluteus with erythema." (*Id*.) The assessment was cellulitis/left gluteal abscess. (*Id*.) Both Dr. Lapp and Dr. Oddis agree that a temporary cellulitis was present. (Tr. 182; Tr. 279-80.) Accordingly, there is preponderant evidence petitioner suffered cellulitis.

ii. Serum sickness

When petitioner presented for care at the emergency department on February 27, 2012, she described symptoms beyond those associated with her previously diagnosed cellulitis and this was felt to be "most likely a reaction to the tetanus shot and *possibly* a delayed serum sickness type hypersensitivity reaction . . . ." (Ex. 1, p. 706 (emphasis added).) On March 7, 2012, petitioner had a follow up with an allergist, Dr. Lurie. (Ex. 3, pp. 1-3.) Dr. Lurie characterized petitioner as a patient with "serum sickness non IgE immunologic reaction to DTap vaccine." (*Id*. at 3.) This was based on her symptoms being "typical" of such a reaction and it was assumed they would resolve within weeks. (*Id*.) By June of that year, later records characterize serum sickness as having been previously "suspected." (Ex. 1, p. 412 ("serum sickness was suspected"); Ex. 1, p. 418 (Dr. Lurie felt symptoms "may be related to serum sickness"); Ex. 1, p. 52 (repeating in October 2012 that "serum sickness was suspected").)

On November 2, 2016, petitioner's primary care doctor, Dr. Ferrier, wrote a letter indicating that following her Tdap vaccination, petitioner experienced, *inter alia*, "intermittent fatigue, fever, and myalgias." (Ex. 8.) She opined that "[m]any of the symptoms she has experienced may be attributable to her vaccination, including injection site pain and redness, fever, headache, nausea, chills and body aches. She continues to experience symptoms intermittently." (*Id*.) However, Dr. Ferrier did not

[13] The previously assigned special master also confirmed that petitioner's Tdap vaccine was injected in a corresponding location and I have adopted that finding as my own. (*See* n. 4, *supra*.)

specifically invoke serum sickness in her letter. Nor was Dr. Ferrier among those physicians who included an impression of serum sickness in petitioner's post-vaccination treatment records.

Taking the medical records as a whole, it does not appear that serum sickness was ever definitively diagnosed. Dr. Lapp also opines that petitioner did not ever have serum sickness. He bases this on two factors: the symptoms attributed to serum sickness are better explained by his subsequent diagnosis of CFS and the symptoms did not resolve on the appropriate time course for a serum sickness reaction. (Tr. 151, 230.) On respondent's behalf, Dr. Oddis declined to offer an opinion as to whether petitioner suffered a serum sickness. He indicated that it may be "reasonable," but noted that it is generally a difficult diagnosis to substantiate. (Tr. 280-81.) Dr. He declined to offer any opinion as to diagnosis. (Tr. 292.)

On this record, there is not preponderant evidence that petitioner suffered a serum sickness reaction.

iii. Chronic pain syndrome / lower extremity pain

Dr. Oddis opined that prior to vaccination (and continuing afterward), petitioner suffered from "chronic pain syndrome." (Ex. D, p. 4.) Dr. Lapp agreed on petitioner's behalf that chronic pain syndrome is a valid diagnostic entity generally, and further indicated that "I think technically you could say she does have a chronic pain syndrome because she has lumbago, low back pain, and she has a pain that radiates down the leg which has not been explained despite numerous studies to try to explain it." (Tr. 241.)

Importantly, however, Dr. Oddis is unpersuasive to the extent he would suggest that a chronic pain syndrome in itself constitutes an explanation for the entirety of petitioner's presentation. Dr. Oddis opines that petitioner's pre-vaccination musculoskeletal complaints and her post-vaccination presentation represent "a continuum." (Tr. 259.) He ultimately summarized his opinion as follows: "I would just reiterate that if somebody is on narcotics for one to two years, that implies pain, and that pain is chronic. And that pain was well characterized in the medical record and it predated vaccination." (Tr. 263.) To support this view, Dr. Oddis cited the following: Ex. 1, p. 432 (medical record regarding chronic shoulder pain); *Id*. at 465 (medical record regarding leg pain); *Id*. at 477 (medical record regarding bulging lumbar discs); *Id*. at 570 (medical record regarding lower back pain of a mechanical nature); and *Id*. at 546 (petitioner requesting diabetes screening for lower leg pain) (Tr. 257-58; Ex. D, p. 3-4).

Absent from Dr. Oddis's opinion is any discussion of diagnostic standards for a chronic pain syndrome or any broader explanation of when the label is appropriately applied. Instead, he discusses seemingly disparate musculoskeletal symptoms with at least suspected diagnoses and labels them as a syndrome based on petitioner's treatment with narcotic medication. During the hearing, Dr. Oddis was asked what

basis he had for including petitioner's shoulder pain in his assessment of chronic pain syndrome when it appeared to have a clear mechanical cause treated by surgery. (Tr. 259-60.) He responded that he only included that as an example of a musculoskeletal complaint prior to vaccination and that he is "perfectly agreeable to taking that out of the chronic pain picture I have painted thereafter." (Tr. 260.) Accordingly, on later questioning, Dr. Oddis was asked:

> Q: We talked a little bit earlier about the idea of the chronic pain syndrome before vaccination and what went into that. Hypothetically, if I concluded that I could find an explanation for every complaint the Petitioner had before the vaccination, how would that change your opinion, if at all?
>
> A: It wouldn't change my opinion. I just saw it as a continuum.

(Tr. 277.) To the extent Dr. Oddis views the course of petitioner's symptom presentation differently than Dr. Lapp – and disagrees that the vaccination at issue represented any inflection point – that raises a potential question under *Althen* prong two, as discussed below. However, it is not credible to further suggest that petitioner's medical history should be entirely explained by a pain syndrome and viewed as a continuum of that syndrome without any regard to the etiology of petitioner's specific musculoskeletal complaints.

During the hearing, Dr. Lapp explained that under the Fukuda criteria, which he relies upon in part and which is discussed further below, diagnosis of CFS must exclude conditions that could plausibly explain the relevant symptoms, particularly the fatigue. (Tr. 52; *The CDC (Fukuda 1994) Definition for Chronic Fatigue Syndrome,* CFids-Me.org, https://www.cfids-me.org/cdcdefine.html (last updated Mar. 30, 2008) (Ex. 27).) Specifically, the Fukuda criteria explain what types of conditions exclude a diagnosis of CFS. (*Fukuda Definition, supra,* at Ex. 27.) These include active medical conditions that may explain chronic fatigue, diagnosable illnesses that may not have completely resolved during treatment (if they explain fatigue), major depressive disorders, substance abuse, and severe obesity. (*Id.*) The criteria indicate that "[a]ny unexplained abnormality detected on examination or other testing that strongly suggests an exclusionary condition must be resolved before attempting further classification." (*Id.* at 2.) However, the criteria specify that the following does not exclude a diagnosis of CFS: "[a]ny isolated and unexplained physical examination finding, or laboratory or imaging test abnormality that is insufficient to strongly suggest the existence of an exclusionary condition." (*Id.*) Here, Dr. Oddis's testimony is inadequate to establish either that the proposed pain syndrome is a condition that can entirely explain petitioner's relevant symptoms, especially including fatigue, or that the findings he cites "strongly suggest" an exclusionary condition. Rather, Dr. Oddis acknowledged during cross examination that a patient with CFS and fibromyalgia can have other medical problems. (Tr. 275.)

Dr. Oddis's willingness to apply a pain "syndrome" label to petitioner's medical history based mainly on her longer-term treatment with narcotics is also inconsistent with his skepticism regarding other aspects of petitioner's medical history. For example,

Dr. Oddis was critical of Dr. Lapp's CFS diagnosis in large part because it was not also diagnosed by the treating specialists. (Tr. 254-55.) Yet, his chronic pain syndrome diagnosis is similarly absent from the earlier, contemporaneous medical records.[14] Additionally, to the extent his opinion hinges on longer term treatment with narcotics, he was willing to express skepticism of petitioner's physicians for overprescribing antibiotics and suggested it was relevant to assessing her history longitudinally. (Tr. 275-76.) Yet, his pain syndrome assessment appears to take the advisability of petitioner's narcotics prescriptions at face value. Doing so is not necessarily incorrect; however, Dr. Oddis appears to apply his skepticism selectively.

Thus, while petitioner experienced pre-vaccination lower extremity pain that was not definitively explained, there is not preponderant evidence that this condition, whether labeled as a chronic pain syndrome or not, excludes the diagnosis of CFS proposed by Dr. Lapp.

iv. Rheumatoid arthritis

Petitioner tested positive for anti-CCP antibodies, a precursor to rheumatoid arthritis, and rheumatoid arthritis was considered by her treating physicians. (*See, e.g.,* Ex. 1, p. 538.) During the hearing, however, both Dr. Lapp and Dr. Oddis agreed that petitioner did not have clinical Rheumatoid arthritis during the period at issue. Dr. Lapp opined that rheumatoid arthritis may have developed later based on certain x-ray findings, but that a later diagnosis of rheumatoid arthritis is not incompatible with his opinion regarding CFS. (Tr. 232-33.) Dr. Oddis opined that petitioner's antibody results do not necessarily result in clinical symptoms of rheumatoid arthritis and confirmed that he does not believe petitioner had rheumatoid arthritis clinically. (Tr. 278-79.) Accordingly, there is not preponderant evidence that rheumatoid arthritis explains any of petitioner's symptoms.[15]

[14] It appears that a "chronic pain syndrome" was referenced in petitioner's medical records beginning in 2019. (Ex. 38, p. 34.) On June 3, 2019, petitioner presented for evaluation of a right arm lymphadenopathy. Dr. Trinh characterized her history as including a "history of chronic pain syndrome." (*Id.*) In that same record, however, Dr. Trinh indicated that petitioner had developed CFS subsequent to her February 2012 Tdap vaccination. (*Id.*) Accordingly, Dr. Trinh's notation does not contradict Dr. Lapp's opinion. Additionally, in August of 2019, petitioner presented to neurologist Robin Davis, M.D., with regard to "numerous complaints." (Ex. 38, p. 48.) Dr. Davis was unable to identify a primary neurologic cause and assessed a chronic pain syndrome. (*Id.*) Importantly, however, Dr. Davis indicated that she did not have access to petitioner's prior medical records and considered herself uninformed of petitioner's prior history. (*Id.*) Accordingly, it would not be accurate to interpret Dr. Davis as offering any opinion as to petitioner's overall course.

[15] The updated medical records filed after the hearing show that petitioner was diagnosed with undifferentiated connective tissue disease on September 16, 2019, based in part on the CCP finding. (Ex. 38, p. 60.) In making that diagnosis, Dr. Webb-Detiege appears to suggest that it could account for both myalgia and fatigue. (*Id.*) This could warrant further expert opinion with respect to whether it should in itself call the proposed CFS diagnosis into question. However, because I have in any event concluded pursuant to *Althen* that petitioner's CFS was not vaccine-caused, it is not necessary to resolve that question.

v. Fibromyalgia

Petitioner testified that she was diagnosed with fibromyalgia by Dr. Ferrier subsequent to her 2012 Tdap vaccination. (Tr. 36.) However, fibromyalgia is not listed as a diagnosis in her earlier medical records and Dr. Ferrier did not otherwise mention fibromyalgia in her letter to the court. (Ex. 8.) The updated medical records petitioner filed after the hearing seem to suggest Dr. Ferrier added fibromyalgia to petitioner's problem list in December of 2019 based on Dr. Lapp's assessment. (Ex. 37, p. 276.) Petitioner was assessed as having fibromyalgia by Dr. Jones on November 6, 2017. (Ex. 38, pp 1-6.) However, the basis for that assessment is unclear as Dr. Jones noted no tenderness on physical exam. Subsequently, in March of 2018, Dr. Webb-Detiege conducted a tender point exam that documented tenderness at 12 of 18 points; however, she did not specifically diagnose fibromyalgia. (Ex. 38, pp. 7-10.) Later, on September 16, 2019, Dr. Webb-Detiege documented only 8 of 18 tender points. (*Id*. at 58.) Dr. Lapp opines that petitioner does have fibromyalgia based on his own evaluation while Dr. Oddis opines that she did not based on the medical records. (Tr. 133-34, 255-56.)

Fibromyalgia is commonly comorbid to CFS, but it is not necessary to the diagnosis. (Gluckman et al., *supra,* Ex. C, Tab 2, pp. 7-8.) In this case, Dr. Lapp confirms that the fibromyalgia he opines is present is merely a comorbidity of petitioner's CFS. (Tr. 136.) He also confirmed during the hearing that, although he does opine that fibromyalgia could in general be vaccine-caused, he is not aware of literature to support that assertion and has not included fibromyalgia in his causal opinion. (Tr. 208-09, 232.) Accordingly, petitioner's claim does not turn on whether any of her symptoms can be properly characterized as fibromyalgia and that specific question need not be resolved.

vi. Chronic fatigue syndrome (CFS)

Finally, the most extensively litigated diagnosis in this case is CFS. Petitioner was not diagnosed with CFS by any of her treating physicians prior to her evaluation by Dr. Lapp in 2019, roughly seven years post-vaccination. Accordingly, the question of whether she can be diagnosed with CFS turns on the persuasiveness of the experts.

CFS, also sometimes referred to as myalgic encephalomyelitis, is a condition characterized by severe debilitating fatigue that lasts for more than six months. (L.D. Devanur & J.R. Kerr, *Chronic fatigue syndrome,* J. CLIN. VIROLOGY 1, 2 (2006) (Ex. 17).) It is diagnosed clinically and also involves muscular, infections, and neuropsychiatric symptoms, and sleep disturbances. (*Id.*) The name CFS persists because it remains a syndrome without a definitely established etiology. However, the alternative term myalgic encephalomyelitis is meant to connote that it is a condition of widespread inflammation and multisystemic neuropathology. (B.M. Carruthers et al., *Myalgic encephalomyelitis: international consensus criteria,* 270 J. INTERN. MED. 1 (2011) (Ex. 24).)

During the hearing, Dr. Lapp explained that there are numerous different sets of diagnostic criteria to screen for CFS. (Tr. 156.) In this case, however, he specifically discussed only three – the so-called Fukuda criteria issued by the CDC in 1994, a 2003 set known as the Canadian criteria that was later updated in 2011 to become the international case definition criteria ("ICC"), and a set developed by the IOM in 2015. (Tr. 49-58, 64-66; Carruthers et al., *supra,* at Ex. 24; *Fukuda Definition, supra,* at Ex. 27; *IOM 2015 Diagnostic Criteria,* CDC.GOV, https://www.cdc.gov/me-cfs/healthcare-providers/diagnosis/iom-2015-diagnostic-criteria.html (last updated Apr. 27, 2021) (Ex. 28).) The Canadian criteria is more symptom based. It is generally considered effective but cumbersome and Dr. Lapp disfavors it for that reason. (Tr. 65.) It was not discussed at length in this case.

According to Dr. Lapp, the Fukuda criteria are primarily used for research as they have exclusion requirements that are not conducive to clinical use. (Tr. 51-52.) Nonetheless, he did opine that application of that criteria supports petitioner's case. (Ex. 21, p. 4.) Dr. Lapp suggested the IOM criteria is less strict than the Fukuda criteria and should be considered a "screening tool" for CFS. (Tr. 57.) If a person meets the IOM criteria, they should be referred to a specialist or further screened using the Fukuda criteria. (*Id*.) According to Dr. Lapp, if a person met the IOM criteria but not the Fukuda criteria, they should be monitored as a presumptive case of CFS to see how symptoms develop. (Tr. 156-57.) However, Dr. Lapp considers that possibility to be "very rare." (*Id*.) In this case, Dr. Lapp applied both the Fukuda criteria and the IOM criteria and concluded that petitioner meets both. (Ex. 21, p. 4.)

For his part, Dr. Oddis stressed that sets of diagnostic criteria are primarily for clinical trials and that "you have to be more open-ended when you look at the individual patient in the clinical setting." (Tr. 249.) Although Dr. Oddis never disputed that CFS constitutes a valid diagnostic entity, during the hearing he was difficult to pin down with regard to any further detail, seeming to betray skepticism that CFS should be applied as a diagnosis in most cases (he prefers "fibromyalgia with chronic fatigue"). (Tr. 265-73.) Ultimately, however, while Dr. Oddis explained that he does not use the Fukuda criteria in his own practice, he agreed that a person meeting the Fukuda criteria could be said to be suffering CFS. (Tr. 272-73.) In his own report, Dr. Oddis relied on the 2015 IOM criteria to discuss whether petitioner has CFS. (Ex. D, p. 4.)

In light of the above, there is preponderant evidence that *either* the Fukuda criteria *or* the IOM criteria could be considered sufficiently authoritative to support a diagnosis of CFS. The 2015 IOM criteria include three mandatory "symptoms" accompanied by at least one of two "additional manifestations." (*IOM Criteria, supra,* at Ex. 28, p. 1.) Thus, under this criteria diagnosis requires (1) a substantial impairment in the ability to engage in pre-illness levels of activity that lasts for at least six months and is accompanied by fatigue,[16] (2) post-exertional malaise, (3) unrefreshing sleep, and (4)

[16] The fatigue is further characterized as often profound, of new onset (not life-long), not the result of ongoing or unusual excessive exertion, and not substantially alleviated by rest. (*IOM Criteria, supra,* at Ex. 28, p. 1.)

either cognitive impairment or orthostatic intolerance. (*Id*.) The Fukuda criteria requires chronic fatigue meeting a specific definition (similar in description to the IOM criteria)[17] accompanied by four or more of eight additionally listed symptoms[18] as well as the absence of any of a number of exclusionary conditions.[19] (*Fukuda Definition, supra,* at Ex. 27, pp. 1-2.)

On respondent's behalf, Dr. Oddis testified that, although he disagrees that petitioner has all of the features required for CFS, he agrees that petitioner had chronic fatigue. (Tr. 255.) Further to this chronic fatigue, Dr. Lapp's CFS diagnosis rests on the presence of malaise, insomnia, cognitive difficulties, lymphadenopathy in the neck and groin, and arthralgia. (Tr. 155.) This is based in part on his own assessment with petitioner, but also cites support from the contemporaneous medical records. (S*ee* Tr. 84-86 (discussing record of February 24, 2012 (Ex. 1, p. 661, et seq.) reporting myalgia, muscle pain, and dizziness); Tr. 86-88 (discussing record of February 27, 2012 (Ex. 1, pp. 675, et seq) reporting swollen lymph nodes); Tr. 89-90 (discussing record of March 7, 2012 (Ex. 3, p. 1) reporting nausea, fatigue, pain at the injection site); Tr. 90-92 (discussing record of April 17, 2012 (Ex. 4, pp. 1-2) diagnosing polyarthralgia and reporting musculoskeletal pain and insomnia).) Although Dr. Oddis is correct to note that none of petitioner's treating physicians diagnosed CFS, his own competing assessment is diminished by his lack of persuasiveness in asserting the presence of a pain syndrome to otherwise explain petitioner's presentation. It should also be noted that, as Dr. Lapp explained, it is not even appropriate to consider a diagnosis of CFS until symptoms have persisted for at least six months. (Tr. 150.) Accordingly, CFS diagnosis generally does involve hindsight. Nor is there any competing consensus from petitioner's treating physicians that would offer any other diagnosis to holistically explain her history or evidence any exclusionary condition. As Dr. Lapp frames it, the question is ultimately whether petitioner had enough symptoms to qualify for the CFS diagnosis. (Tr. 159.)

During the hearing respondent's counsel also challenged Dr. Lapp on several considerations relating to specific characteristics of chronic fatigue under the diagnostic standards. Cross examination largely consisted of discussing certain medical record

[17] Specifically: "[c]linically evaluated, unexplained persistent or relapsing chronic fatigue that is of new or definite onset (i.e, not lifelong), is not the result of ongoing exertion, is not substantially alleviated by rest, and results in substantial reduction in previous levels of occupational, educational, social, or personal activities." (*Fukuda Definition, supra,* at Ex. 27, p. 1.)

[18] The additional symptoms are: (1) substantial impairment in short-term memory or concentration, (2) sore throat, (3) tender lymph nodes, (4) muscle pain, (5) multi-joint pain without swelling or redness, (6) headaches of a new type, pattern, or severity, (7) unrefreshing sleep, and (8) post-exertional malaise lasting more than 24 hours. (*Fukuda Definition, supra,* at Ex. 27, p. 1.)

[19] Conditions that exclude a diagnosis of CFS are: "Any active medical condition that may explain the presence of chronic fatigue, such as untreated hypothyroidism, sleep apnea and narcolepsy, and iatrogenic conditions such as side effects of medication," some diagnosable illnesses that may relapse or not completely resolve, such as malignancies, or chronic cases of hepatitis B or C, or "any past or current diagnosis of a major depressive disorder with psychotic or melancholic features," alcohol or other substance abuse, or severe obesity. (*Fukuda Definition, supra,* at Ex. 27, pp. 1-2.)

entries that may cast doubt on Dr. Lapp's assessment of the relevant symptoms. (Tr. 167-70 (raising that Ex. 14, p. 3 does not indicate fatigue); Tr. 176-79 (raising Ex. 2, pp. 11, 19 as records from May of 2012 and September of 2013 noting petitioner to be self-reliant in daily activities); Tr. 185-87 (raising Ex. 1, p. 662 as February 24, 2012 physical exam with no notation of muscle pain). Dr. Lapp provided specific answers to these points; however, a broader point is reflected in the literature discussed below with respect to *Althen* prongs two and three, which suggests that it is not unusual for CFS symptoms to present intermittently for long periods (months to years) before becoming constant. Accordingly, inconsistency over time within the medical records regarding reported symptoms is not necessarily informative to the question of petitioner's ultimate diagnosis.

Respondent's counsel also raised a further challenge with regard to whether petitioner has untreated sleep apnea. Under the Fukuda criteria, sleep apnea is an exclusionary criterion. (*Fukuda Definition, supra,* at Ex. 27, p. 1.) Under the IOM criteria, unrefreshing sleep is a core criterion. (*IOM Criteria, supra,* at Ex. 28, p. 1.) Respondent's counsel questioned whether petitioner can be said to suffer unrefreshing sleep if other conditions are preventing her from sleeping through the night. (Tr. 162-67.) Dr. Lapp explained, however, that broken sleep patterns are typical of CFS. (Tr. 167.) Unrefreshing sleep means that the patient feels the same or worse upon waking as they did the night before. (Tr. 164-67.) In petitioner's own case, she does have unrefreshing sleep and does not have confirmed sleep apnea. (Tr. 164-66.) Dr. Lapp also explained that tiredness and sleepiness are not synonymous and that unrefreshing sleep results in tiredness. (Tr. 193-95.)

Based on the record as a whole, Dr. Lapp is persuasive in opining that petitioner can be diagnosed with CFS.

b. *Althen* Analysis

As explained above, in order to establish causation-in-fact petitioner must preponderantly prove the three elements of the so-called *Althen* test. That is, petitioner must show: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1278. Once petitioner has presented a prima facie case, respondent may still preponderantly demonstrate petitioner's injury was nonetheless due to factor(s) unrelated to vaccination. *Id*.

i. Cellulitis

Petitioner's allegedly vaccine-caused cellulitis was the initial basis for the petition in this case. The *Althen* analysis for that injury may be addressed very briefly as the outcome is not controversial. *Althen* prong one is met insofar as both Dr. Lapp and Dr. Oddis agree that a contaminated needle puncture can cause cellulitis. (Tr. 240-41, 280.) With regard to *Althen* prongs two and three, the finding of fact issued in this case

confirms the Tdap vaccine was administered in the same buttock as petitioner's cellulitis. (*See* n. 4, *supra*.) Additionally, petitioner's medical records show that she sought medical attention for her cellulitis within days of her vaccination. (Ex. 1, 441.) The medical records clearly associate her cellulitis to the site of her Tdap injection. (*Id*.) Petitioner has further represented that prior to administration, the syringe and nurse's gloves had been placed on a table surface she had observed to be dirty. (Ex. 14, pp. 3-4; Tr. 39.) Dr. Lapp opined that this history of unclean administration and subsequent infection are sufficient to support a causal opinion supporting vaccine-causation. (Tr. 240.) Respondent has offered no evidence to suggest that petitioner's cellulitis was caused by any factor unrelated to her vaccination. Dr. Oddis deferred to the medical records with regard to the cellulitis diagnosis. (Tr. 280.)

Thus, even though it has not been the focus of litigation, petitioner's cellulitis constitutes a stand-alone vaccine injury separate from her CFS. However, given that the cellulitis was a short-lived condition, this raises the question of whether it can satisfy the Vaccine Act's severity requirement without respect to the broader constellation of chronic symptoms that petitioner characterizes as CFS. In order to state a claim for a vaccine-related injury under the Vaccine Act, a vaccinee must have either:

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

§300aa-11(c)(1)(D).

As of February 14, 2012, follow-up treatment confirmed the cellulitis to be resolved, but with a residual tender mass at the injection site. (*Id*. at 451.) Subsequent exams did confirm petitioner continued to have an abnormality at the site of injection after her cellulitis had resolved and throughout the remainder of February 2012. (Ex. 1, p. 676 (exam noting "small pea sized area of induration" at injection site); *Id*. at 698 (exam noting "little knot" as of February 27, 2012); *Id*. at 436 (exam noting "palpable nodule" as of February 29, 2012). These notations document only the first month of petitioner's injury. Thereafter, the focus of petitioner's medical records shifted to her other complaints; however, petitioner did specifically complain of continued left buttock pain related to her vaccination at encounters of August 30, 2012 (Ex. 1, p. 22) and September 21, 2012 (Ex. 6, pp. 2-3), which are both beyond six months from the date of her vaccination. Petitioner also testified that as of the time of the hearing she still has that nodule, explaining that "[w]hen I feel it, I can take it and squeeze it . . . ." (Tr. 14.)

In *Wright v. Secretary of Health and Human Services*, the Federal Circuit explained that within the meaning of the statute a "residual effect" is "suffered" if it is a somatic condition that is detrimental (meaning endured with distress, especially painfully) and represents a lingering sign or symptom of the original injury. 22 F. 4th 999, 1006 (Fed. Cir. 2022). A "complication" is similarly understood, but without

representing an "essential part of the disease."[20] *Id.* Here, petitioner's medical records corroborate that petitioner had a "knot" or "nodule" remaining *after her cellulitis had resolved* and nothing in the medical records suggests that this remaining defect ever subsequently resolved. She is also reported in the contemporaneous medical records as having complained of left buttock pain for over six months. Petitioner also testified that her minor disfigurement persisted to the present day and Dr. Lapp testified that it is medically reasonable to conclude that the disfigurement petitioner described in her testimony constitutes scar tissue from her cellulitis. (Tr. 13-14, 240-41.) Dr. Oddis effectively agreed. (Tr. 280.) Accordingly, there is preponderant evidence that petitioner's cellulitis caused complications or residual effects that lasted for more than six months.[21]

All of this is sufficient to preponderantly establish that petitioner's cellulitis was caused-in-fact by her vaccination and that petitioner's cellulitis caused complications or residual effects that lasted for more than six months. Petitioner is therefore entitled to compensation for her cellulitis injury. Importantly, however, Dr. Lapp disclaimed any causal connection between petitioner's cellulitis and her alleged CFS. (Tr. 212; Ex. 22, p. 1.) Accordingly, petitioner's entitlement to compensation for her cellulitis has no

[20] It has also been suggested that the Federal Circuit's *Wright* decision should counsel close analysis of the record where the injury at issue is considered "minor." *Cummings v. Sec'y of Health & Human Servs*., No. 20-1358V, 2022 WL 962520, at *4 (Fed. Cl. Spec. Mstr. Feb. 24, 2022). Thus, for example, in *Bangerter v. Secretary of Health & Human Services*, temporary weight gain in an infant that was attributable to medication taken in treatment of a vaccine injury was not "suffered" within the meaning of the statute for the reasons discussed in *Wright*. No. 15-1186V, 2022 WL 439535, at *37 (Fed. Cl. Spec. Mstr. Jan. 18, 2022). Key to that determination was the fact that the vaccinee was an infant, his weight normalized again as he grew, and petitioner was unpersuasive in suggesting that the temporary weight gain had any effect on the child's growth and development in the interim. Accordingly, while the temporary weight gain was clearly noticed by the parents, it had not represented any detrimental effect. Here, petitioner's scarring or induration is by all reasonable accounts minor and inconspicuous, leaving this a close question. However, whereas weight may be gained or lost throughout life and may be subject to a range of interpretations as to what is healthy or appropriate, scarring is a harm in itself – that is, a scar is indisputably damage to tissue. Moreover, in this case it appears to be permanent. Thus, petitioner's scar tissue might be said to be inherently detrimental regardless of whether it is painfully endured. In any event, however, petitioner did also report experiencing continued pain in her buttock. (Tr. 13; Ex. 1, p. 22; Ex. 6, pp. 2-3.)

[21] Theoretically, petitioner's testimony could be definitively corroborated by requiring petitioner to reveal her disfigurement for review, likely in a photograph. In this case, however, the condition is located in a relatively sensitive area of the body. Moreover, neither petitioner's nor respondent's expert suggested any need to visually inspect petitioner's skin before accepting her testimony based on their general medical knowledge. In *Kirby v. Secretary of Health and Human Services*, the Federal Circuit held that where medical records are silent as to whether a condition remains ongoing, a petitioner can demonstrate the severity requirement through corroborated testimony and expert opinion confirming her symptoms are consistent with her diagnosed injury. 997 F.3d 1378, 1381-82. On a more thoroughly contested issue involving a less sensitive area of the body, photographic evidence may be appropriate. Here, that added step is not warranted. Petitioner's testimony is corroborated both by its acceptance by both parties' experts as well as the medical records documenting the abnormality to have remained after resolution of the initiating cellulitis. Moreover, even if the contemporaneous medical records are inadequate to fully corroborate the fact of the scar tissue, the contemporaneous medical records do indicate that petitioner reported pain at that location for greater than six months.

bearing on whether she is also entitled to compensation for her alleged CFS. That question must be answered by a separate *Althen* analysis relative to that injury.

ii. CFS

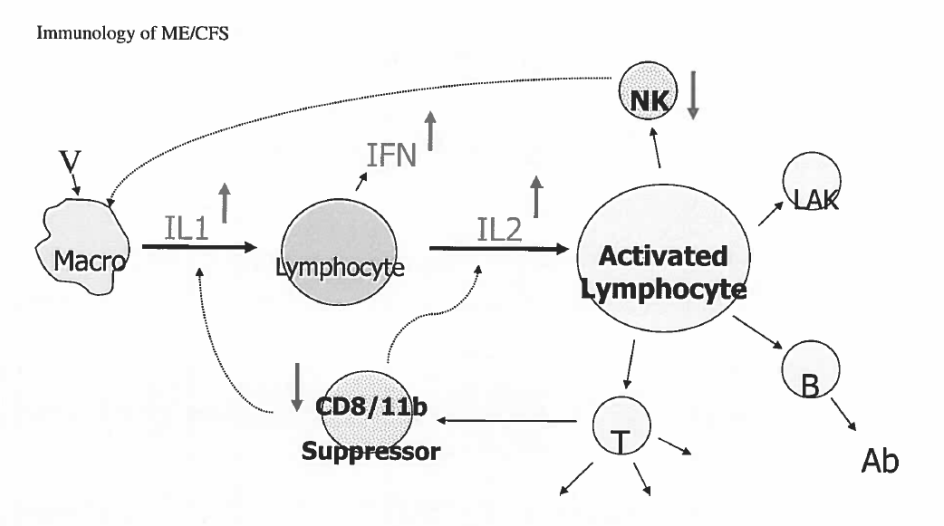
1. *Althen* Prong One[22]

Under *Althen* prong one, a petitioner must provide a "reputable medical theory," demonstrating that the vaccine 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) (citations omitted). To satisfy this prong, petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548. Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549. Generally, however, petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu,* 569 F.3d at 1378-79 (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). In this case, petitioner has not met her burden under *Althen* prong one relative to her CFS.

There is no dispute that CFS is an immune-related condition the cause(s) of which remain unknown. (Ex. C, p. 3; Ex. 16, p. 3.) Dr. Lapp offered some indication that it might have an autoimmune component, but ultimately explained that the reason CFS patients tend to have autoantibodies is unknown. (Tr. 146.) Rather, the understanding that CFS is an immune-related condition is largely based on the observation that it is generally preceded by a flu-like illness and has been associated with certain viruses. (Devanur & Kerr, *supra,* at Ex. 17, pp. 2, 5; IOM (Institute of Medicine), *Beyond Myalgic Encephalomyelitis/Chronic fatigue syndrome,* NAT. ACAD. PRESS 1, 15 (2015) (Ex. 23).)

Dr. Lapp further hypothesizes, however, that an infection (or, according to him, also a vaccine) can cause what becomes a chronic immune dysregulation due to an uncontrolled production of cytokines. During the hearing, Dr. Lapp illustrated this by reference to the below diagram presented during the hearing and later filed as Exhibit 33.

[22] In her pre-hearing brief, petitioner actually presented two theories of causation. (ECF No. 132, pp. 12-13.) The first is the one discussed below. The second theory was that petitioner's cellulitis constituted an infection that in turn caused her CFS. This was based on Dr. He's statement in his expert report that petitioner's infection was a more likely contributor to her CFS than vaccination. (*Id*. at 13.) As noted in the preceding section, however, petitioner's own expert disclaimed any causal relationship between petitioner's cellulitis and her CFS. (Tr. 212; Ex. 22, p. 1.) During the hearing Dr. He also clarified, in effect, that the fact that he indicates a local infection such as cellulitis is more likely than a vaccine to contribute to CFS does not mean he opines that either is likely to cause CFS. (Tr. 290-92.) Dr. He agreed with Dr. Lapp that cellulitis is unlikely to have caused CFS. (*Id.*)



(Ex. 33.)

According to Dr. Lapp, when a foreign antigen (marked as a V in the upper left of the diagram) comes in contact with a macrophage as part of the body's immune response, the macrophage releases cytokines, specifically the cytokine Interleukin-1 ("IL-1"). (Tr. 139.) IL-1 in turn causes lymphocytes to release further cytokines, specifically "IL-2." (*Id.*) Dr. Lapp indicates that IL-2 is then responsible for multiplying the immune response by entering the bloodstream and activating lymphocytes to begin a number of different processes, including producing different kinds of T-cells as well as what are called "natural killer" ("NK") cells. (Tr. 140.) NK cells circulate in the blood and destroy infected cells.[23] (*Id.*) Important to Dr. Lapp's theory, one of the T-cells produced as part of the immune response is "CD8/11b," which acts as a suppressor of the IL-1 that initiated the process depicted. (Tr. 140-41.) Without the CD8/11b suppressor cells, the immune response will not down-regulate as it should. (Tr. 140, 223-24.) Dr. Lapp suggests that those with CFS have low NK activity as well as dysfunction in the CD8/11b suppressor response, explaining the chronicity of CFS. (Tr. 140-41.) This leads to perpetuation of cytokine production and cytokine production leads to the symptoms of CFS.[24] (Tr. 141.) This underlying immunology speaks to the chronicity of CFS but does not in itself reveal what potential triggers may provoke CFS.

[23] Dr. He challenged this understanding of the immune response. He characterized Dr. Lapp's diagram as "severely outdated" and raised specific objection to the understanding that macrophages (as opposed to dendric cells) begin the process and the specific role of NK cells. (Tr. 286-87.) To the extent Dr. He appeared to suggest in testimony that these differences in discussing the immune system should be viewed as fatal to petitioner's theory, he did not specifically explain why.

[24] Dr. He was also critical of Dr. Lapp's reliance on the "CD8/11b" suppressor cell terminology, suggesting it is no longer consistent with how these cells are currently characterized in the field of immunology. (Tr. 287.) As with the critique noted in n. 23, *supra*, Dr. He's testimony was not entirely clear as to the significance of this issue. Because Dr. He did not fully explain his criticisms of Dr. Lapp's understanding of the immunology, and because this case ultimately turns on other factors, I assume for purposes of this decision that Dr. Lapp's diagram at Exhibit 33 reasonably depicts the relevant immune response without actually deciding that issue. Dr. He agreed that CFS symptoms are ultimately related to overproduction of cytokines. (Ex. C, p. 3 (expressing agreement with limited aspects of Ex. 16, p. 3).)

Important to Dr. Lapp's theory of vaccine causation, the T-cell response can be further divided into two profiles, "Th1" and "Th2." (Tr. 60-61.) These two profiles produced different cytokines. (*Id*.) Ordinarily, in a healthy body there is a balance between these two profiles favoring the Th1 profile, which is the profile that helps the body respond to viruses and yeasts. (Tr. 61.) However, CFS is thought to be a disorder leading to an imbalance toward the Th2 profile. (Tr. 58 (citing Devanur & Kerr, *supra,* at Ex. 17).) According to Dr. Lapp, the literature demonstrates the symptoms of a fatiguing illness, such as CFS, as being related to the cytokines produced as part of the Th2 profile. (Tr. 58, 60-61.) Dr. Lapp posits that the pertussis component of the Tdap vaccine has been shown to result in the production of IL-4, which has in turn been shown to initiate a shift toward a Th2 profile. (Tr. 59.) Thus, because Dr. Lapp suggests that vaccinations "for all intents and purposes" cause low-grade infections (Tr. 138-39), he opines that the initial Th2 shift caused by the pertussis-containing vaccination can lead to a chronic disease-causing shift to a Th2 profile due to the low NK activity and CD8/11b dysfunction among those susceptible to CFS.[25] Four articles are key to Dr. Lapp's theory – Mu and Sewell (1993), Rook and Zumla (1997), Devanour and Kerr (2006), and Hardcastle, et al (2015). (Exs. 35, 34, 17, 18.) However, these articles fall short of demonstrating what Dr. Lapp claims they support.

In 1993, Mu and Sewell, examined the effects of pertussis toxin in mice. (Hong-Hua Mu & William Sewell, *enhancement of Interleukin-4 production by pertussis toxin,* 61(7) INFECT. & IMMUNITY 1 (1993) (Ex. 35).) They found that administering pertussis toxin resulted in increased production of IL-4 and a promotion of an IgE response. (*Id*.) This paper does not specifically address CFS; however, Dr. Lapp testified that this study "states specifically that when pertussis is administered to mice cells and to human beings, that [it] . . . directly stimulates Interleukin 4, which then drives the immune system toward a Th2 status. And that, of course, is accompanied by other autoantibodies and other cytokines that cause the symptoms that these patients are having." (Tr. 144.) The inference here is that a pertussis-containing vaccine, such as petitioner's Tdap vaccine, would act in the same manner.

Subsequently, in 1997, Rook and Zumla hypothesized that Gulf War Syndrome, which is considered a fatiguing condition similar to CFS, may be due to a systemic shift in cytokine balance toward a Th2 profile. (G.A. Rook & A. Zumla, *Gulf War syndrome:*

[25] Dr. Lapp also cited a case report of a patient purportedly experiencing "autoimmune inflammatory syndrome induced by adjuvants" or "ASIA" for the proposition that "[r]esearch has shown that vaccines with adjuvants can result in chronic heightened immune response." (Ex. 16, p. 3 (citing Ex. 19); Tr. 64, 152.) Again, however, he indicated that he could not explain why CFS patients have a tendency to have autoantibodies. (Tr. 146.) Accordingly, he has not substantiated the relevance of literature addressing autoimmune disease. In any event, Dr. Lapp confirmed during the hearing that while he believes the ASIA concept supports his opinion, ASIA is not necessary to his opinion. (Tr. 238.) ASIA has been heavily criticized in prior cases. *See, e.g., D'Angiolini v. Sec'y of Health & Human Servs.*, No. 99-578V, 2014 WL 1678145, at *60 (Fed. Cl. Spec. Mstr. Mar. 27, 2014), *mot. for review den'd*, 122 Fed. Cl. 86 (2015), *aff'd*, 645 F. App'x. 1002 (Fed. Cir. 2016); *Rowan v Sec'y of Health & Human Servs.*, No. 10-272V, 2015 WL 3562409 (Fed. Cl. May 18, 2015); *Harris v. Sec'y of Health & Human Servs.*, No. 10-332V, 2014 WL 3159377, at *16 (Fed. Cl. Spec. Mstr. June 10, 2014).

Is it due to a systemic shift in cytokine balance towards a Th2 profile? 349 LANCET 1 (1997) (Ex. 34).) Among other factors discussed, Rook and Zumla asserted that soldiers had been administered multiple vaccinations capable of shifting from a Th1 immune profile to a Th2 profile. In support of this assertion, they cited the above-discussed Mu study for the proposition that vaccines adjuvanted with pertussis are "potently Th2."[26] (Rook & Zumla, *supra,* at Ex. 34, p. 2.) Dr. Lapp asserts that this provides further evidence that a pertussis-containing vaccine can itself "cause a shift in the immune system toward a Th2 pattern and bring on the symptoms of chronic fatigue syndrome." (Tr. 59.) However, even by the authors' own characterization, this paper presents merely a hypothesis. Moreover, the authors cited a number of factors that working together may account for their observations. Specifically, in addition to some of the vaccinations at issue being adjuvanted with pertussis, the authors found it significant that the soldiers received an usually high antigen load given the multiple immunizations administered. They also found it significant these exposures occurred in a war zone (leading into increased cortisol and decreased dehydroepiandrosterone), and that soldiers were also exposed to carbamate and organophosphate insecticides. (Rook & Zumla, *supra,* at Ex. 34, p. 2.) The latter two factors are especially notable because they could potentially act independent of any vaccination.

In 2006, Devanur and Kerr conducted a review of CFS literature, including Rook and Zumla's 1997 paper. (Devanur & Kerr, *supra,* at Ex. 17.) Rook and Zumula were cited for the proposition that the pertussis adjuvant in the anthrax vaccine may cause a systemic shift in the immune response toward Th2. (*Id.* at 7.) However, Devanur and Kerr suggested that the potential relationship between Gulf War Syndrome and vaccinations may be stronger than between vaccinations and CFS because the immunization schedule administered to the soldiers was "intensive" and involved multiple vaccinations. (*Id*.) They also again noted the stress of wartime deployment and further observed that experimental evidence in mice suggested a causal role for the anti-nerve gas agent pyridostimine. (*Id*.) In any event, respondent has also filed more recent literature casting doubt on the hypothesis, suggesting the evidence that Gulf War Syndrome is vaccine-caused is limited and has "inadequate support" and further discussing other more likely causes. (Roberta F. White et al., *Recent research on Gulf War illness and other health problems in veterans of the 1991 Gulf War: Effects of toxicant exposures during employment,* 74 CORTEX 1 (2016) (Ex. C, Tab 3).)

With respect to CFS more broadly, Devanur and Kerr explained that the pathogenesis of CFS is likely multifactorial but not completely understood. (Devanur & Kerr, *supra,* at Ex. 17, p. 2.) In particular, "the precise role played by the immune response remains to be clarified." (*Id*.) The authors note, consistent with Dr. Lapp's opinion, that "[v]arious studies suggest that CFS exhibits a Th2 profile of CD4 helper T lymphocyte responsiveness." (*Id*. at 3.) However, the authors also explain that a number of studies have demonstrated other potentially relevant immune findings. For example, CFS patients have been shown to have significantly increased neutrophil

[26] Rook and Zumla do not indicate what specific vaccines are adjuvanted with pertussis toxin; however, Devanaur and Kerr (discussed below) suggest that the anthrax vaccine received by Gulf war soldiers is adjuvanted with pertussis toxin. (Ex. 17, p. 7.)

apoptosis and decreases in circulating IgG. (*Id*.) According to the authors, these findings suggest the presence of an *ongoing infection* and a deficiency in anti-viral immune activity. (*Id*.) Based on this literature review, the authors conclude that "[t]aken together, these findings suggest that an underlying infection may be present in these individuals and that the immune system is chronically activated in response." (*Id*.)

Finally, the most recent of the papers stressed in this case, is a 2015 study by Hardcastle, et al, examining immune proteins in CFS. (Sharni Lee Hardcastle et al., *Serum immune proteins in moderate and severe chronic fatigue syndrome/myalgic encephalomyelitis patients,* 12(10) INT. J. MED. SCI. 1 (2015) (Ex. 18).) The study compared cytokine profiles among three groups – healthy controls, moderate cases of CFS, and severe cases of CFS. According to Dr. Lapp, this study is significant for two reasons. First, it confirms the above-discussed decrease in NK cell and CD8 T cell activity. Second, it shows that symptom presentation in CFS is correlated to cytokine activity. (Tr. 62-63, 141-42.) Hardcastle, et al., indicate that prior studies have been inconsistent in identifying alterations in cytokine patterns among CFS patients. (Hardcastle et al., *supra,* at Ex. 18, p.1.) However, these prior studies involved only moderately affected patients. The Hardcastle study purports to be the first to include severe cases of CFS. (*Id*. at 5.) Importantly, however, the Hardcastle study found no statistically significant difference in IL-4 among the groups studied, effectively acknowledging that the study did not replicate prior studies that had suggested a Th2 profile based on increased IL-4. (*Id.* at 4.) The ability of the pertussis toxin generally to enhance IL-4 in mice as observed by Mu and Sewell was the starting premise for Dr. Lapp's suggestion that a vaccine could trigger CFS – meaning this study directly undercuts Dr. Lapp's extrapolation from Mu and Sewell's mouse model.

In sum, Dr. Lapp has presented a mouse model that suggests pertussis toxin may increase IL-4. (Mu & Sewell, *supra,* at Ex. 35.) This finding contributed to a preliminary hypothesis that a different, but potentially similar condition of Gulf War Syndrome, might have multiple vaccinations among a number of other underlying causal factors. (Devanur & Kerr, *supra,* at Ex. 17; Rook & Zumla, *supra,* at Ex. 34.) However, more recent literature filed by respondent has cast doubt on that hypothesis and Dr. Lapp himself has filed a study that failed to find any significant increase in IL-4 among actual CFS patients. (White et al., *supra,* at Ex. C, Tab 3; Hardcastle et al., *supra,* at Ex. 18.) On the whole, while Dr. Lapp is persuasive in suggesting CFS may involve an aberrant chronic immune response and that CFS symptoms may be cytokine-related, the literature suggests the underlying immune response implicated in CFS is not well understood and with little to no evidence directly supporting vaccine causation. This does not preponderantly support petitioner's claim that the Tdap vaccine can cause CFS.

Moreover, it is also difficult to square Dr. Lapp's suggestion that vaccines are implicated as "low grade infections" (Tr. 138-39) with his additional acknowledgment that, whatever the immune trigger, "it would have to be a significant challenge" (Tr. 210). When asked what he meant by a "significant" challenge, Dr. Lapp turned back to the fact, noted above, that most CFS cases (more than seventy percent) follow infections.

(Tr. 210.) Dr. Lapp acknowledged that a Tdap vaccine is not equivalent to an infection and does not reproduce within the body as a live infection; however, he would not agree that the immune system responds differently to a vaccine than an infection. (Tr. 211.) Instead, he suggested he does not know "one way or the other." (*Id*.)

In that regard, however, Dr. He indicated that vaccination and infection have "major" differences that are both qualitative and quantitative. (Tr. 285.) He explained that whereas an infection involves an uncontrolled response with systemwide immunopathic replication, the response to immunization is a controlled response happening only locally due to the fact that the vaccine antigen does not replicate like a live infection. (Tr. 286, 301-03.) When an immunization results in a systemic response, only the cytokines spread throughout the body. (Tr. 303.) That is, while an immunization or local infection sees an immune response in one part of the body that may stimulate cytokines that spread from that one location, a systemic infection stimulates cytokines throughout the body.

Dr. Lapp acknowledged that a small, localized infection "usually" would not cause CFS, explaining that the illnesses that precede CFS are "usually very significant illnesses." (Tr. 212; Ex. 22, p. 1.) And, again, as explained above, the Devanur and Kerr article relied upon by Dr. Lapp explains that there are prior studies that include specific immune findings beyond the Th2 shift suggestive of ongoing infection as the driver of CFS. (Devanur & Kerr, *supra,* at Ex. 17, p .3.)

In one prior case, Dr. Lapp's opinion has been accepted under *Althen* prong one as supporting vaccine-causation of CFS. *Bryan v. Sec'y of Health & Human Servs*., No. 14-898V, 2020 WL 7089841 (Fed. Cl. Spec. Mstr Oct. 9, 2020). Importantly, however, that case involved the flu vaccine rather than the Tdap vaccine at issue in this case. Among other differences, in that case Dr. Lapp presented a study demonstrating that CFS patients had statistically significantly increased IL-4 following the flu vaccine when compared to controls. *Id*. at *23 (discussing Brenu, et al., *The Effects of Influenza Vaccination on Immune Function in Patients with Chronic Fatigue Syndrome/Myalgic Encephalomyelitis*, 3 INT'L J. CLIN. MED. 551-54 (2012).) That study was important to informing the special master's conclusion that Dr. Lapp had established that the flu vaccine in particular can have an effect on the immune dysregulation typical of CFS. However, there is nothing in the record of this case comparable to the Brenu study in its ability to causally implicate the Tdap vaccine. Even with the benefit of the Brenu study, the *Bryan* special master observed that the evidence supporting petitioner's theory was "not robust." *Id*.

2. *Althen* Prongs Two and Three

Assuming arguendo petitioner had demonstrated that her Tdap vaccine is capable of causing CFS, she would also have to establish that it did cause CFS in this specific case. *Pafford*, 451 F.3d at 1356. This latter aspect of petitioner's prima facie showing is generally broken down into two further questions pursuant to *Althen* prongs two and three. The second *Althen* prong requires proof of a logical sequence of cause

and effect between the vaccination and injury. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281.

The second *Althen* prong, requiring proof of a logical sequence of cause and effect, is usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant,* 956 F.2d at 1148. In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

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

Here, these two prongs are closely intertwined and will be addressed together. On the surface, there is a striking temporality in this case. Petitioner received a Tdap vaccination on February 6, 2012, reported unusual symptoms beginning that same night, and sought follow up care rather promptly. (Ex. 1, p. 441.) Thereafter, Dr. Lapp opines that she developed classic signs of CFS within two weeks. (Tr. 97, 114, 152.) However, upon closer examination of Dr. Lapp's opinion, there is no basis for finding significance in that temporality. Even if petitioner could theoretically satisfy *Althen* prong three in the sense that what Dr. Lapp proposes is generally consistent with the

known patterns of CFS onset, the relevant literature shows these known onset patterns to be so broad, and the basis for identifying them so vague, as to prevent Dr. Lapp from either identifying a relevant timeframe during which causation could be inferred pursuant to *Althen* prong three and/or distinguishing petitioner's Tdap vaccine as a more likely cause of her CFS pursuant to *Althen* prong two.

Petitioner was never diagnosed with CFS by any of her treating physicians prior to consulting Dr. Lapp. Accordingly, while the treating physicians felt a vaccine reaction was possible, they did not offer any contemporaneous opinion that petitioner suffered vaccine-caused CFS. Instead, petitioner's claim is based entirely on Dr. Lapp's hindsight. Taking petitioner's symptoms and the close temporal relationship to vaccination, the treating physicians were willing to opine that petitioner was suffering an adverse vaccine reaction in the form of a likely serum sickness. (Ex. 1, p. 706; Ex. 3, pp. 1-3.) Dr. Lapp, however, has opined that petitioner never suffered any serum sickness reaction. Instead, he opines that the symptoms the treating physicians identified as serum sickness were actually symptoms of the CFS itself. (Tr. 230.) Moreover, even if petitioner did suffer a temporary serum sickness that explains her initial symptoms, Dr. Lapp further opined that "I have never known serum sickness to lead to chronic fatigue syndrome." (Tr. 231.) Additionally, to the extent he opined that petitioner suffered a vaccine-caused cellulitis, he also opined that the cellulitis would not have caused petitioner's CFS. (Tr. 212.) Thus, Dr. Lapp rejects either cellulitis or serum sickness as part of the relevant causal chain, thereby dismissing any causal connection between petitioner's CFS and any illness documented in the medical record that may have in turn been causally connected to the vaccination.

Instead, Dr. Lapp opines that petitioner's initial post-vaccination presentation constituted evidence of an inflammatory, cytokine-drive response. (Tr. 151-53.) He opines this is evidenced by fever and flu-like symptoms as well as by elevated sedimentation rate ("ESR"), elevated C-reactive protein ("CRP"), positive cyclic citrullinated peptide ("CCP"), and positive antinuclear antibodies ("ANA").[27] (*Id*.) However, Dr. Lapp has explained that CFS is itself an inflammatory condition and often is accompanied by a flu-like presentation. As discussed above, regarding *Althen* prong one, Dr. Lapp is unpersuasive in seeking to extend the association between active infection and CFS to the type of immune response that follows vaccination. Accordingly, neither these symptoms nor these lab results necessarily point to a specific inciting event. Additionally, in this case, petitioner's lab work during the immediate post-vaccination period showed normal CRP and only slightly elevated ESR. (Ex. 1, pp. 666, 668, 680.) The laboratory findings Dr. Lapp culled as significant (Tr. 132-33; Ex. 31) were drawn later. The earliest collection date for any sample from the lab results in petitioner's Exhibit 31 is from March of 2018.

[27] Petitioner's EBV early antigen was also positive, which he opines evidences a viral reactivation and a Th2 status. (Tr. 132-33, 151-53.) Dr. Lapp explained that the EBV early antigen relates to the chronic shift toward Th2 rather than the initial cause of petitioner's CFS and the test was not administered until June of 2019, so the result is not helpful regarding the period of onset. (Tr. 223-24; 240.)

This leaves the coincident timing as the main factor leading to a suspicion of vaccine causation. Here, too, however, Dr. Lapp is unpersuasive in trying to leverage what is broadly true of CFS as evidence that this case of CFS is vaccine-caused. When pressed to clarify the timing of the immunology underlying his theory, Dr. Lapp testified that he was unable to offer specifics. (Tr. 235-36.) He agreed that there would be some latency, but suggested that it would generally be rapid, suggesting hours to days. (Tr. 236.) Dr. Lapp primarily based his opinion on two articles that speak to the pattern of onset for CFS, one by Evans and Jason and one by Chu, et al. (Meredyth Evans & Leonard Jason, *Onset patterns of chronic fatigue syndrome and myalgic encephalomyelitis,* 2(1) RES. CHRON. DIS. 1 (2018) (Ex. 30); Lily Chu et al., *Onset patterns and course of myalgic encephalomyelitis/chronic fatigue syndrome,* 7(12) FRONT. PEDIATR. 1 (2019) (Ex. 30). Dr. Lapp testified that

> retrospectively, I feel confident that the illness started at the time of the injection, and when you look at the records, by the time two weeks have passed, she had all of the symptoms of chronic fatigue syndrome, so she clearly – somewhere between immediately and two weeks, she definitely had the chronic fatigue syndrome . . . *so I think certainly her symptoms and the onset of her illness fell within the typical onset that was described by Chu and by Evans* . . .

(Tr. 152-53 (emphasis added).) However, these papers do not reliably identify any specific temporal relationship between CFS and a specific antecedent event.

In 2018, Evans and Jason conducted a study regarding onset patterns for CFS. (Evans & Jason, *supra,* at Ex. 29.) To the extent Evans and Jason look at underlying immune triggers, they explain that many of their participants identified specific cause(s) of their CFS, including infectious or viral causes. (*Id.* at 15.) Although the authors note that they screened more broadly for preceding events, they focused the study only on infectious illness. (*Id*. at 8.) Thus, flu-like symptoms were among the onset symptoms generally reported by respondents. (*Id*. at 24.) Importantly, however, the Evans and Jason study largely focuses on duration of onset (*i.e.* the time from first presenting symptom of CFS to full manifestation of the condition) rather than latency of onset from a preceding trigger (*i.e*. the time from the trigger to the first symptom).

Moreover, the percentage of participants who reported a preceding infection did not differ significantly depending on whether onset was sudden or gradual. (Evans & Jason, *supra,* at Ex. 29, p.9.) Nor did all participants that described a sudden onset identify an immediately preceding trigger. For example, participant three (of 14 from phase two)[28] described a sudden onset occurring within 24 hours and no immediately

[28] The study was conducted in two phases. First, participants completed a survey (the DePaul Symptom Questionnaire), which assesses demographic information, symptoms, and illness history. Second, a subset of participants participated in a "semi-structured" phone interview specifically regarding onset. (Ex. 29, p. 5.) The study had 181 participants meeting the Fukuda criteria for the first phase. (*Id.*) The phase one questionnaire allowed participates to choose from seven different characterizations of onset (meaning the period of time over which symptoms developed) ranging from 24 hours to three or more years). Fourteen participants were recruited to take part in the second phase, two people representing

preceding trigger. (*Id.* at 11 (Fig. 2).) Participants often identified more than one cause of their CFS (*Id*. at 15), described varying patterns of onset including waxing and waning presentations (*Id*. at 13), sometimes only recognized the progression of their condition in hindsight (*Id*. at 14), and sometimes placed onset based on moments of realization or "turning points," rather than actual distinct onsets (*Id*. at 10-13). Among those that did describe a "sudden" onset, the participants' understanding of the term "sudden" ranged from symptom development over a 24-hour period to symptom development over a three or more-year period. (*Id.* at 10.) On the whole, the Evans and Jason paper does not meaningfully contribute to petitioner's claim that her CFS can be temporally associated to her vaccination.

The second study cited by Dr. Lapp is Chu, et al.[29] (Chu et al., *supra,* at Ex. 30.) During the hearing Dr. Lapp confirmed that he felt the Chu study supported his theory vis-à-vis timing. (Tr. 238-39.) Upon review, however, the Chu study actually undercuts petitioner's assertion of a logical sequence of cause and effect between her vaccination and injury. Petitioner urges that her abrupt onset of CFS post-vaccination should be considered causally meaningful. In contrast, the Chu study suggests that petitioner has little basis for distinguishing between her vaccination and her earlier infection as the precipitating cause of her condition.[30]

Chu et al. observed that "[t]he most common onset pattern was a distinct change in health heralded by an infectious event followed by a gradual progression to becoming consistently sick." (Chu et al., *supra,* at Ex. 30, p. 8.) The authors explained that

> the time from the first intimation of illness to becoming consistently sick varied greatly: while 28% endorsed an onset period of a month or less, 38% noted it took over 6 months. Subjects who reported an infectious precipitant were no more likely to develop ME/CFS within 1 month or within 6 months compared to those who noted no infectious precipitant.

(*Id.* at 4.) Dr. Lapp himself characterized the study as suggesting that only half of CFS patients develop consistent CFS symptoms within six months of any initial symptom.

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each of the seven onset categories. (*Id*.) Accordingly, phase two of the study is very small. Thus, the authors generally seem to treat their results as anecdotal, generally characterizing the results as representing "themes" and characterizing the study as "qualitative" and with "rich descriptions" of onset. (*Id*. at 22.)

[29] The Chu study is a survey of 200 CFS patients. (Chu et al., *supra,* at Ex. 30, pp. 2-3.)

[30] The Chu paper includes a table that indicates that 10% of subjects identified a medical injection as a factor associated with the onset of their CFS. (Chu et al., *supra,* at Ex. 30, p. 4.) Importantly, however, nothing in the study provides information regarding the time between such injections and onset of CFS. Nor does the study otherwise provide any discussion sufficient to assess the reasonableness of the subjective claim of association. During the hearing, Dr. Lapp indicated that he spoke with Chu and purportedly confirmed that the medical injections at issue mostly referred to vaccination. (Tr. 72.) However, this is not confirmed by the paper itself, and in fact the paper confirms that patients having had a flu vaccination within the preceding four weeks were specifically screened out of the study population. (Chu et al., *supra,* at Ex. 30, p. 2.)

(Tr. 70-71.) For one-third of the subjects, the preceding infectious event manifested as respiratory symptoms. (Chu et al., *supra,* at Ex. 30, p. 9.)

In this case, petitioner saw Dr. Ferrier about three weeks prior to her vaccination, on January 16, 2012, with complaints of sore throat and bilateral ear pain that began three weeks prior. (Ex. 1, p. 442.) Petitioner also complained of postnasal drip, hoarseness, shortness of breath, cough, fatigue, and intermittent fever. (*Id*.) Petitioner was diagnosed with acute pharyngitis and was prescribed antibiotic and antifungal treatment (clindamycin and Diflucan respectively). (*Id*.) According to the Chu article, petitioner's symptoms are consistent with the type of preceding infection that can be causally related to CFS.[31] (Chu et al., *supra,* at Ex. 30, p. 9; Tr. 142, 151.) This encounter was prior to her February 6, 2012, vaccination and about five weeks prior to what Dr. Lapp identifies as the onset of petitioner's CFS. Moreover, Dr. Lapp himself testified that the fatigue petitioner reported in the context of this January pharyngitis cannot be distinguished from the fatigue she experienced post-vaccination.[32] (Tr. 158-59.) In that regard, during the Dr. Lapp testified:

> THE COURT: . . . Why are we treating the vaccination as the turning point instead of the January infection?
>
> THE WITNESS: Because it was an acute infection that's very similar to what she had before. It's not likely that that would carry through like that for that period of time.
>
> THE COURT: Well, even if –
>
> THE WITNESS: There was no evidence that it continued. She didn't have those symptoms at the time when she went to the ER for the burn.
>
> THE COURT: So in the context of chronic fatigue syndrome, is it the case that when you have an infectious precursor, you always have the infection leading seamlessly into the chronic fatigue?
>
> THE WITNESS: That's my experience, yes.

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[31] On redirect examination of Dr. Lapp petitioner's counsel raised that there is no literature confirming that CFS can be caused by a common cold or infection. (Tr. 242-43.) Importantly, however, the Chu article indicates that only about a third of participants had a specific type of infection documented. (Chu et al., *supra,* at Ex. 30, p. 4, Table 2.) Nearly 40% had what was characterized as respiratory infections (meaning sore throat, runny nose, cough, etc.). (*Id*.) Thus, to the extent petitioner would call into question the ability of an unspecified upper respiratory infection to cause CFS, she would also call into question the reliability of the Chu study itself.

[32] In order for a symptom to be attributable to CFS under the Fukuda diagnostic criteria, it cannot predate the onset of fatigue. (Tr. 179.) Thus, in petitioner's own case, Dr. Lapp did not count sore throat as a symptom contributing to petitioner's CFS diagnosis under the Fukuda criteria based on his assessment of when the continuous fatigue began. (Tr. 180-82.) Nonetheless, Dr. Lapp distinguished between petitioner's prior bouts of sore throat from what he characterized as more continuous pharyngitis occurring later. (*Id*.)

> THE COURT: So there's never a period of latency between the infectious precursor and the chronic fatigue?
>
> THE WITNESS: That would be correct.

(Tr. 229-30.)

This is not persuasive in light of Dr. Lapp's reliance on Chu et al. Chu et al. contended that the "[i]deas about acuity and its link to infection should also be re-examined." (Chu et al., *supra,* at Ex. 30, p. 11.) The authors observed that "[s]ome past case definitions have included onset within a few hours or days as part of their criteria" while in "the majority of [their] subjects, the first intimation of illness to full-blown ME/CFS often occurred over months if not years." (*Id*.) The Chu authors noted that the prior Evans study participants held widely varying conceptions of what acute onset meant and further indicated that

> We also found that there was no link between subject endorsement of an infectious precipitant and the time span of ME/CFS development. Some believe that an acute onset is necessarily infectious or an infectious onset is necessarily acute. Past studies examining this relationship are mixed, with some agreeing and others disagreeing with our result. **Clinically, one infectious yet gradual onset sequence we have observed is a stuttering pattern whereby a subject experiences a severe infection, returns to near-normal functioning, but then experiences recurrent infections over months to years, recovering less each time, before succumbing entirely to ME/CFS.** Overall, we agree with Evans that onset patterns are complicated and that simple categories do not capture this complexity.

(Ex. 30, p. 11 (emphasis added).)

Thus, Chu et al., strongly suggest that it would be entirely in keeping with what is known of CFS to attribute petitioner's CFS to her prior January 2012 respiratory illness, or even a pattern of prior illnesses, rather than her vaccination. Both the Evans and Chu articles explain that the so called "succumbing" to CFS is not the same as onset, which may in fact occur nascently much earlier. In that regard, the actual onset of petitioner's CFS is not clear. Dr. Lapp essentially confirmed this during the hearing:

> THE COURT: And then the opposite side of the coin would be when you are looking at a patient and you have a suspected trigger and then you have the subsequent chronic fatigue syndrome, what is the outside limit for associating the two in terms of the timing?
>
> THE WITNESS: **I don't think there is any outside limit. The papers that -- the report on the onset of chronic fatigue syndrome, they describe**

> **a number of different scenarios.** I have had patients, for example, that have had mild symptoms of fatigue, occasional aches and pains, but like in this case, they were perfectly functional, going to work and were able to keep up house and have a normal lifestyle and that's gone on for years. And then they had a sudden onset of something like an infection, and following that infection, they promptly developed chronic fatigue syndrome. **So I'm not sure how you can really define that.** Usually if there's a trigger like we are talking about here, it's a fairly prompt onset of the symptoms. But then as in this case, they seem to develop over time. So this is where I'm – if you remember, the initial symptoms that she had, her arthralgias, hip pain, back pain, there was some nausea and fever, and then within two weeks she developed things like the severe fatigue and malaise. She developed the insomnia. She developed headaches, cognitive problems. They developed over time. **That's why I'm having difficulty answering your question**. And that's why I said yesterday, I think that the injection was clearly the trigger, but by two weeks, I felt that she was clearly looking like chronic fatigue syndrome, which was confirmed later on.

(Tr. 236-37 (emphasis added).) On redirect examination by petitioner's counsel, Dr. Lapp ultimately concluded:

> Q. The thing I want to ask you about specifically, the cold that she had the month before her vaccination, do you believe that any time a person gets a cold that any cold, so an infection, whether it's any virus, any bacteria, anything that could trigger a sore throat, that any of those, all of those can be a trigger to or known triggers to chronic fatigue syndrome?
>
> A. **I think they could be**. It's certainly not a common presentation that we get.

(Tr. 242-43.)

Even if there is the appearance of a temporal relationship here, Dr. Lapp has little basis for selecting petitioner's vaccination as the starting point of a logical sequence of cause and effect to suggest, pursuant to *Althen* prong two, that her vaccination caused her CFS. Nor has he persuasively addressed pursuant to *Althen* prong three what would constitute an appropriate temporal relationship between onset of CFS and an antecedent trigger. The Evans and Chu papers, coupled with Dr. Lapp's own testimony, suggest that the medical community's understanding of the onset of CFS lacks the degree of understanding or precision Dr. Lapp would need to pinpoint the actual onset of her condition and/or distinguish petitioner's vaccination as the initiating cause of her CFS.

VI. Conclusion

Petitioner's complete medical history eludes easy explanation, and she does have the undersigned's sympathy for everything she has endured regardless of the underlying cause. Clearly, petitioner herself has identified her Tdap vaccination as a key turning point in her health. However, based on a review of the record, including the expert medical opinion that has been provided, there is not preponderant evidence that petitioner's Tdap vaccine explains the entirety of her post-vaccination presentation. In light of all of the above, petitioner has preponderantly shown that she suffered cellulitis caused in fact by her February 6, 2012, Tdap vaccination. She has not preponderantly shown either that she suffered vaccine-caused CFS or that her broader CFS presentation is sequela of her vaccine-caused cellulitis. Accordingly, petitioner is entitled to compensation for her cellulitis injury only. A separate damages order will issue.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master