In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1659V

Originally filed: April 19, 2024

Refiled: May 13, 2024

* *

B.B.,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Danielle Strait, Maglio Christopher & Toale, Seattle, WA, for Petitioner
Margaret Armstrong, U.S. Department of Justice, Washington, DC, for Respondent

RULING ON ENTITLEMENT[1]

Oler, Special Master:

On November 1, 2017, B.B. ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program"). The petition alleges that B.B. developed a shoulder injury related to vaccine administration ("SIRVA") as a result of the tetanus diphtheria acellular pertussis (Tdap) vaccine she received on August 19, 2015. Pet. at 1. Petitioner no longer alleges a SIRVA, and instead

[1] Because this Ruling contains a reasoned explanation for the action in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Ruling 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, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

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

contends that her Tdap vaccination was injected low into her arm and caused her to develop a left deltoid tendinopathy. Pet'r's Motion at 1.

Upon review of the evidence in this case, I find that Petitioner has demonstrated that the vaccine she received caused her deltoid tendinopathy. Petitioner is therefore entitled to compensation.

I. Procedural History

Petitioner filed her petition on November 1, 2017. Pet., ECF No. 1. She filed additional evidence, to include medical records and affidavits on November 3, 2017 (Exs. 1-16) and December 18, 2017 (Exs. 17, 18). She filed a statement of completion on January 22, 2018. ECF No. 16.

Respondent filed his Rule 4(c) Report on October 15, 2018. Resp't's Rep., ECF No. 26. Respondent contended that this case was not appropriate for compensation because the medical records do not reflect that the onset of Petitioner's shoulder pain occurred within 48 hours of vaccination or that her pain was limited to her shoulder. Accordingly, she could not demonstrate that she suffered from a SIRVA. Resp't's Rep. at 5. This case was assigned to my docket on that same day. ECF No. 28.

Petitioner filed additional medical records on December 27, 2018 (Exs. 19-22) and February 14, 2019. Ex. 23.

I conducted a status conference on April 17, 2019 where I informed the parties that I tentatively found the onset of Petitioner's pain began within 48 hours of vaccination. *See* Scheduling Order dated April 17, 2019, ECF No. 33. I gave Respondent 60 days to indicate how he intended to proceed based on my impressions of the case. *Id*.

On May 16, 2019, Respondent filed a status report indicating he was willing to engage in settlement discussions. ECF No. 34. The parties discussed settlement over the next ten months. Then on March 11, 2020, the parties filed a joint status report stating that they were at an impasse in their negotiations. ECF No. 41. Petitioner requested 60 days to file an expert report. *Id*. I granted that request. *See* Non-PDF Scheduling Order dated March 11, 2020.

Petitioner filed an expert report from Dr. Marko Bodor on July 10, 2020 (Ex. 24), along with Dr. Bodor's CV and supporting medical literature. Exs. 25-33.

Respondent then filed a status report on August 3, 2020 indicating he was willing to resume settlement discussions. ECF No. 46. However, the parties filed a status report on December 21, 2020 stating that their settlement discussions were again at an impasse. ECF No. 51.

I conducted a status conference on January 6, 2021. The parties reiterated that their settlement discussions had not been successful, and requested to proceed on a litigation track. *See* Scheduling Order dated January 6, 2021, ECF No. 52. I informed the parties that with the records submitted, the evidence supporting Petitioner's case is similar to many that have been settled in

the Vaccine Program. I offered to provide the parties with cases I believed to be analogous with respect to pain and suffering in order to provide a settlement range. *Id*. The parties agreed that this would be helpful. I gave Respondent a deadline of April 6, 2021 to file an expert report. *Id*. On January 8, 2021, I entered an order into the docket requesting that Petitioner file a supplemental affidavit. *See* Scheduling Order dated January 8, 2021, ECF No. 52.

Petitioner filed a supplemental declaration on March 1, 2021. Ex. 34. On March 3, 2021, I issued an order where I gave the parties what I viewed as an appropriate range for pain and suffering and provided a list of cases that I found were analogous. *See* Scheduling Order dated March 3, 2021, ECF No. 56. I directed the parties to file a joint status report indicating whether they would like to continue informal settlement negotiations. *Id*.

On May 14, 2021, Respondent filed an expert report from Dr. Julie Bishop (Ex. A), along with Dr. Bishop's CV and one piece of medical literature. Exs. B, C.

The parties filed a joint status report on June 4, 2021 stating that additional settlement negotiations were unlikely to be fruitful. ECF No. 62. Petitioner requested to file a supplemental expert report. *Id*. I granted that request. *Id*.

Petitioner filed a supplemental expert report on August 2, 2021 (Ex. 36) along with supporting medical literature (Exs. 37-40). On November 4, 2021, Respondent filed a responsive report from Dr. Bishop. Ex. C. Petitioner then filed an additional expert report on January 7, 2022. Ex. 41.

I held a status conference on January 25, 2022. I told the parties that I would give them a 30 day deadline to indicate whether the record was complete for an entitlement determination. *See* Scheduling Order dated January 25, 2022, ECF No. 69. Petitioner filed a supplemental declaration on February 16, 2022. Ex. 44. Respondent filed a supplemental expert report from Dr. Bishop on April 11, 2022. Ex. D. Each party then filed one more responsive expert report. Exs. 45, E.

I then set a briefing schedule and the parties filed their respective briefs on entitlement. ECF Nos. 81, 83, 85. Respondent disputes that a deltoid tendinopathy is a medically recognized diagnosis, or that Petitioner suffers from that condition. Resp't's Response at 13. Respondent further contends that Petitioner has failed to present preponderant evidence in support of any of the *Althen* prongs. *Id*. at 17-22. Petitioner argues that she is entitled to compensation.

The parties filed status reports indicating the record was complete on May 12 and May 19, 2023. ECF Nos. 86, 87. This matter is now ripe for an adjudication.

II. Medical Records and Other Contemporaneous Documentation

A. Prior to Vaccination

On March 3, 2010, Petitioner presented to Fairbanks Urgent Care and described that she was in a motor vehicle accident (MVA) in September of 2009. She experienced severe whiplash from that accident. For the past month, her neck pain had progressively worsened and she

described pain, numbness, and tingling down her arms, left greater than right. Ex. 8 at 22. She was diagnosed with a cervical strain with radiculopathy. *Id.*

Petitioner visited Discover Chiropractic for the first time on December 3, 2010 for an adjustment. Ex. 5 at 24. Her chiropractic records do not mention the MVA. On December 30, 2010, Petitioner indicated that she felt "pretty good" and that her pain level was a 1 on a 10 scale. *Id.* at 23.

On November 15, 2014, Petitioner visited Discover Chiropractic and reported that a chicken coop trap door fell onto her head and that she had a headache for more than one week, and was experiencing stiff and sore shoulders, upper back, and neck. Ex. 5 at 11. She rated her pain as a 7 on a 10 scale. *Id.*

Petitioner returned to Discover Chiropractic four days later for shoulder, upper back, and neck soreness. Ex. 5 at 10. She rated her pain as a 3. *Id.*

Petitioner visited Discover Chiropractic on January 14, 2015 and March 6, 2015. Ex. 5 at 7, 8. During these visits, she complained of neck pain. Petitioner did not present to her chiropractor again until March 25, 2016 (after vaccination). *Id.* at 6.

Petitioner received her Tdap vaccination in her left deltoid on August 19, 2015. Ex. 1 at 1.

B. Post Vaccination

On October 12, 2015, a VAERS report notes that "pt began experiencing left arm pain and weakness which has continued to grow in intensity." Ex. 23 at 3. The date of onset is listed on the form as August 19, 2015, approximately two hours after vaccine administration. *Id.*

Petitioner filed email communications between herself and her husband which discuss the pain she experienced after vaccination. Ex. 11. On October 13, 2015, Petitioner wrote, "Just two days ago my arm was so bad I could not go to sleep. Deep, dull pain and burning sensation at the same time. The pain is interfering with hair washing, getting dressed or any situation that requires me to raise that arm." Ex. 11 at 1.

On October 14, 2015, Petitioner's husband emailed his father the following: "Before going to Switzerland B.B. got a Diphtheria/Tetanus/Pertussis immunization at our local Fred Meyer Pharmacy. She is having complications. Her arm is in pain and progressively numbing and has been like this since the immunization about 60 days ago." Ex. 11 at 2.

On October 15, 2015, a claims examiner for the pharmacy emailed Petitioner stating that "A claim was reported to us from the Fred Meyer store in regards to your Adacel TDAP vaccination. They reported that you were having arm pain since the vaccination at the injection site." Ex. 11 at 3.

On March 25, 2016, petitioner visited a chiropractor for left arm, shoulder, and upper back pain. Ex. 5 at 6. In response to the question, "Has there been a new aggravation or injury since

your last visit? If yes, please explain:", the record documents, "tetanus shot 8.19.15 Fred Meyer." *Id.* The record further notes that Petitioner was experiencing "pain and weakness in (L) deltoid/shoulder related to 8/19/15 tetanus booster." *Id.*

On April 14, 2016, Petitioner visited her doctor who assessed her with chronic left shoulder pain. Ex. 9 at 2. The record notes that Petitioner "had a tetanus shot in the left arm in August of 2015 and had severe pain afterwards." *Id.* at 3.

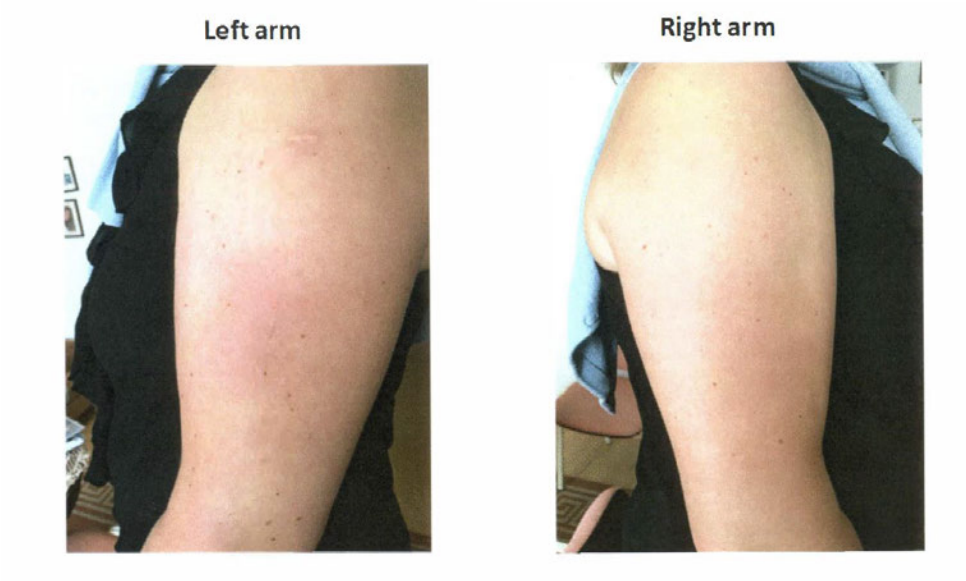
Petitioner visited Dr. Richard Cobden at the Fairbanks Orthopaedic Center on July 22, 2016. Ex. 4 at 37. The HPI documents that Petitioner "developed pain in her left deltoid area after a tetanus injection given over at the Fred Meyer West pharmacy on August 15, 2015. She left for Switzerland for 5 months shortly after but had continuing pain all the time up until now." *Id.* Petitioner described her pain "as a burning type of pain that shoots up into the left shoulder and neck, and down into the elbow region." *Id.* She was assessed with "neuroma of upper limb", and an "injury of peripheral nerves of neck." *Id.* Dr. Cobden's physical exam noted a "2x2 centimeter area of warmth and tenderness in the deltoid insertion area left shoulder." *Id.*

Petitioner visited neurologist Dr. C. Jansen on March 7, 2018 at the Gelderse Vallei Hospital in the Netherlands. Ex. 19 at 3. The record notes that 2.5 years ago, Petitioner received a vaccination that "hit a nerve." *Id.* Her arm became heavy and she experienced paresthesias at night. *Id.* The injection site is still very sensitive and she has weakness proximally. *Id.* During his physical examination, Dr. Jansen noted that there is a "[p]ainful place on the left upper arm, without real motor or sensory failure. No reflex deviation." *Id.* Dr. Jansen ordered an HTG and EMG. *Id.*

Petitioner followed up with Dr. Jansen on April 10, 2018. Dr. Jansen noted that the EMG and Doppler TOS [Thoracic Outlet Syndrome] showed no abnormalities. Ex. 19 at 2. As a result, Dr. Jansen concluded that "[n]o treatable cause for these local pain complaints are found." *Id.*

On September 4, 2018, Petitioner visited Laszlo Csiba, a neurologist at Debrecen University in the Netherlands. Ex. 21 at 1-8. Dr. Csiba documented that Petitioner complained her arm was sore at the vaccination site and that it felt as though something was stuck in her arm. *Id.* at 1. Dr. Csiba noted that the vaccination site was red and warm to the touch. He measured the skin temperature on both of Petitioner's arms and found that the left side measured at 36.96˚C while the right side was 34.6˚C. *Id.* Dr. Csiba wrote that "the touch and pain stimuli result[ed] in hyperesthesia[3] in the affected skin area (left upper extremity, latero-dorsal side)." *Id.* at 2-3. Dr. Csiba further documented that Petitioner's left sided triceps and ulnar reflexes were slightly decreased. *Id.* at 3. He took photographs of Petitioner's arms, remarking that the vaccination site on Petitioner's left arm was red when compared with the other extremity. *Id.* at 1.

[3] A painful sensation from a normally painless touch stimulus. DORLAND'S MEDICAL DICTIONARY ONLINE, www.dorlandsonline.com/dorland/definition?id=23773&searchterm=hyperesthesia (last visited April 10, 2024) ("DORLAND'S").



Id. at 7. Dr. Csiba ultimately opined that "the previous and present complain[t]s have [a] causal relationship with the vaccination resulting in chronic complain[t]s." *Id.* at 4.

III. Petitioner's Affidavits[4]

Petitioner filed three affidavits in support of her claim. Ex. 13 ("First B.B. Affidavit"); Ex. 34 ("Second B.B. Affidavit"); and Ex. 44 ("Third B.B. Affidavit").

Petitioner averred that she received her Tdap vaccine on August 19, 2015. First B.B. Affidavit at 1. She received the vaccination at the same time as her son and described that the technician who administered her vaccine was distracted. *Id.* When the technician inserted the needle into her arm, Petitioner stated that it was "way below the muscle in my arm where I would have expected to receive it and much lower than where my son received his." *Id.* Petitioner recalled experiencing an immediate pain, like an "electric shock." *Id.* Petitioner compared the sensation to her past experience receiving an infraorbital nerve block, an anesthetic she received years ago. *Id.* Throughout that day, Petitioner remembered having soreness at the injection site and a dull ache in her arm and shoulder. *Id.*

Petitioner's pain persisted for the following weeks and lifting her arm was difficult. First B.B. Affidavit at 2. Because of a work trip to Switzerland from September 3, 2015-January 21, 2016, Petitioner tried to manage her pain until it was no longer tolerable. *Id.*

After speaking with her father-in-law, a retired judge, Petitioner believed she may have an injury claim against the pharmacy and began journaling her symptoms. First B.B. Affidavit at 2. Petitioner traveled by train for a work conference in November 2015 and remembered she could not lift her luggage. *Id.* at 3. Around the end of December 2015, Petitioner's pain persisted, and she felt like the injection site had "something hard [] stuck in [her] arm at all times." *Id.*

[4] I have summarized the portions of Petitioner's affidavits that concern the issue of entitlement only.

Upon her return to the United States in February 2016, Petitioner's workload was very high and she felt like she did not have a chance to seek medical attention. First B.B. Affidavit at 3. Petitioner sought chiropractic care in March 2016. *Id*. Petitioner also visited the Tanana Clinic in April of 2016 and recalled her doctor did not seem to understand her complaints. *Id*. Petitioner established care with a new PCP in May 2016 but also found him to be dismissive of her shoulder pain after vaccination. *Id*. at 3-4. She averred that he told her "'"there's no way the tetanus shot would bother you after this much time." *Id*. at 3. Petitioner was discouraged because of this comment and did not raise her left arm problems with him again. *Id*. Petitioner saw an orthopedic specialist in July 2016, who believed she had a nerve injury. *Id*. at 4. Petitioner received chiropractic treatment and massage therapy which provided limited relief. *Id*.

Petitioner's second affidavit addressed specific questions from my January 8, 2021 order. ECF No. 53. Petitioner stated she had a lump at the injection site that was sore and sensitive to the touch. Second B.B. Affidavit at 1. Petitioner also stated that her limited capabilities to do household activities compelled her premature move back to the United States. *Id*. at 2. She was disappointed to leave a higher paying position in Switzerland and to uproot her children after a short period of time but found her situation untenable. *Id*. Only after reacclimating her children to Alaska and her job as a research assistant at the University in Fairbanks, did Petitioner seek medical care for her arm and shoulder pain. *Id*. Petitioner's husband also underwent two surgeries in 2016, which caused more household responsibilities to fall on her. *Id*. In November 2016, Petitioner tried one of her hobbies, cross-country skiing, and was only able to participate for 20 minutes before her pain caused her to stop; Petitioner would have been out for over an hour before her injury. *Id*.

In spring of 2017, Petitioner finally turned a corner regarding her arm and shoulder pain. Second B.B. Affidavit at 2-3. At the time she signed the affidavit, Petitioner worked in the Netherlands and had a 10 minute commute to work via bike; after this bike ride, her left arm would shake for the rest of the day. *Id*. at 3. B.B. has regained full range of motion but not full strength. *Id*. Petitioner estimated that she lost approximately 25% of her strength and endurance in her left arm. *Id*. She experiences difficulty typing but has regained the ability to perform self-care and household tasks if limited to short periods of times. *Id*. Petitioner reported her pain level was at a 1-2 (out of 10) daily, and 2-3 when aggravated. *Id*. at 4. Petitioner takes over the counter (OTC) medication for the pain and uses a heating pad a few times per month when she aggravates her arm. *Id*.

In her final affidavit, Petitioner clarified that she experienced her worst pain during the first year of her injury and her progress plateaued two years ago (in 2020). Third B.B. Affidavit at 1. Petitioner also described her current condition: dull, throbbing pain flares up to two to three times per week, with no reliable pattern; she also experiences soreness at the injection site, that is hot upon touch. *Id*. at 1-2. Petitioner reiterated she never fully recovered and lost about 25% of her strength and endurance in her left arm. *Id*. at 2. Lastly, Petitioner stated that she does not seek medical treatment because her providers have been dismissive, suggesting it will gradually improve over time, and medical care in the Netherlands has been limited during the COVID-19 pandemic. *Id*. at 3.

IV. Other Affidavits and Declaration

A. D.B., Petitioner's Son

D.B., then a minor, signed an affidavit on October 16, 2017. Ex. 14. D.B. received a Tdap vaccination at the same time as his mother on August 19, 2015. *Id.* at 1. D.B. had received his vaccine before his mother's; the administrator was making small talk with him while the administrator injected his mother's vaccine and he noticed that it was administered much lower on her arm than his vaccine was. *Id.* As they were leaving the Fred Meyers pharmacy, D.B. recalled his mother complaining of pain and being unable to lift her arm without it hurting; she asked him to do the same and he could do so without pain. *Id.*

D.B. stated that his mother continued to complain of pain after vaccination but he had not thought too much about it since they had been warned of pain lasting up to a week. Ex. 14 at 1. After they moved to Switzerland, D.B. stated his mother complained that the pain in her arm would wake her in the night and that basic activities such as driving, typing, and writing were painful. *Id.* at 2. He asked her to see a doctor but she was too busy. *Id.* D.B. stated that his mother still struggles with pain and difficulty in her arm. *Id.*

B. J.B., Petitioner's Husband

J.B. signed an affidavit on October 20, 2017. Ex. 15. J.B. averred that Petitioner told him of her vaccination the same day she received it because she thought it "felt like it hit a nerve." *Id.* at 1. J.B. further recalled around the week of September 7, 2015, his wife complained of pain and numbness in her arm; this was notable because they were living in a hotel in Switzerland looking for more permanent housing, and J.B. was awoken one night when Petitioner was searching for ibuprofen because she had "shooting, electrical pain going from her shoulder to her hand." *Id.* at 1-2. J.B. returned to the United States but during their phone calls, Petitioner would often complain about the difficulty of doing normal tasks such as dressing herself, or washing her hair because she could not raise her arm above her shoulder. *Id.* In the two years since her injury, J.B. has seen little improvement; Petitioner's injury is easily aggravated by simple household chores. *Id.* J.B. regularly asks Petitioner about her arm pain, to which she answers, "it stills hurts" or "it is still the same." *Id.* at 2-3.

C. Piroska Gorog, Petitioner's Friend

Ms. Gorog signed a letter to the Court on March 1, 2021. Ex. 35. In it, she recalled inviting Petitioner to a going-away BBQ party prior to her move to Switzerland. *Id.* Both Ms. Gorog and Petitioner were setting up a table and Petitioner complained of pain from a tetanus shot and indicated she would not be that helpful setting up for the party. *Id.* Ms. Gorog saw Petitioner's pain and discomfort and helped with packing and cleaning her house because she could not do basic things. *Id.*

V. Expert Qualifications and Reports

A. Petitioner's Expert: Dr. Marko Bodor

1. Qualifications

Dr. Marko Bodor received a B.A. in biology from Harvard College and a M.D. from the University of Cincinnati. Ex. 25 (hereinafter "Bodor CV") at 1. He also completed an internship in surgery at the University of California, San Diego, and residency in physical medicine and rehabilitation at the University of Michigan. *Id*. Dr. Bodor is board certified in physical medicine and rehabilitation, neuromuscular and electrodiagnostic medicine, pain medicine, and sports medicine. *Id*. Dr. Bodor has presented across the country and internationally and teaches as an assistant professor of neurological surgery at UCSF Medical School and assistant professor of physical medicine and rehabilitation at UC Davis. *Id*. at 6. Dr. Bodor has published approximately 26 peer-reviewed papers and 11 book chapters. *See id*. at 8-10.

2. Expert Opinion

Dr. Bodor has provided four expert reports in this case. Ex. 24 ("First Bodor Rep."); Ex. 36 ("Second Bodor Rep."); Ex. 41 ("Third Bodor Rep."); and Ex. 45 ("Fourth Bodor Rep."). I summarize Dr. Bodor's conclusions and will elaborate on certain areas in my analysis.

In his first report, Dr. Bodor opined that Petitioner's reported symptoms seem to be consistent with a SIRVA injury, however in the present case, Petitioner received the Tdap vaccination too low in her arm, whereas SIRVA injuries typically result from higher administration in the deltoid/shoulder area. First Bodor Rep. at 2. Dr. Bodor further opined that he did not believe that Petitioner had a neuroma as indicated in one of her medical records. *Id*. He described that it was common for patients to report numbness and tingling in the absence of a nerve injury. *Id.* He instead opined that Petitioner's injury was a "deltoid tendinopathy." *Id*. at 3.

Dr. Bodor stated that Petitioner specifically suffered an injury to the deltoid tendon at its insertion onto the mid-humerus. First Bodor Rep. at 2. He opined that deposition of the vaccine can result in long-standing inflammation and pain or in a nociceptive response. *Id*. at 3.

Dr. Bodor disagreed with Dr. Bishop's assertion that Petitioner had a prior chiropractic shoulder treatment. Second Bodor Rep. at 1-2; Third Bodor Rep. at 1; Fourth Bodor Rep. at 1. Dr. Bodor opined the records were clear that Petitioner did have some chiropractic treatment but believed it was regarding her back and neck pain, and not specific to the shoulder area as Dr. Bishop contended. Second Bodor Rep. at 1-2. Dr. Bodor agreed with Dr. Bishop that none of Petitioner's medical or treatment providers noted any loss of range of motion however there is documentation of left arm weakness. *Id*. at 2. He opined these findings are "consistent with the likely anatomical source of [Petitioner's] pain, the deltoid insertion, as opposed to the typical location where we see lesions in the rotator cuff in SIRVA, the infraspinatus or teres minor tendon which would be expected to result in impairment of shoulder rotation." *Id*.

Dr. Bodor also addressed Petitioner's lack of a SIRVA diagnosis in her medical records. Dr. Bodor noted that SIRVA is not a commonly used or described injury and only about 50% of orthopedists knew of this injury in an informal survey performed three years ago. Second Bodor Rep. at 3. Despite Petitioner's lack of a SIRVA diagnosis, Petitioner was diagnosed with a

neuroma[5] by Dr. Richard Cobden, an orthopedist. *Id*. Dr. Bodor's takeaway from Dr. Cobden's diagnosis was that it is confirmatory in that Petitioner had a left arm pain and that there were no useful treatments for this condition. *Id*.

Dr. Bodor concluded each of his reports by reiterating his opinion that Petitioner's Tdap vaccine caused her shoulder injury. First Bodor Rep. at 4; Second Bodor Rep. at 4; Third Bodor Rep. at 2; Fourth Bodor Rep. at 2.

B. Respondent's Expert: Dr. Julie Bishop

1. Qualifications

Dr. Julie Bishop received a B.S. in microbiology and a M.D. from Cornell University. Ex. B (hereinafter "Bishop CV") at 1. Dr. Bishop completed a general surgery internship and orthopaedic residency at George Washington University. Bishop CV at 1-2. Dr. Bishop also completed a shoulder surgery fellowship at Mt. Sinai Hospital and sports medicine visiting fellowship at the University of Pittsburgh. *Id*. at 2. Dr. Bishop is a professor of orthopaedics at the Ohio State University and serves as chief of the division of shoulder surgery, vice chair of finance of the department of orthopaedic surgery, and team physician for the Ohio State Department of Athletics. *Id*. at 1, 2. Dr. Bishop has won a number of awards including: OSU Faculty Teaching Award 2021, OSU Orthopaedic Educator of the Year 2019, Best Doctors in America 2010-21. *Id.* at 3-5. Dr. Bishop is on a number of national and OSU committees and editorial boards. *Id*. at 5-9. Dr. Bishop has authored approximately 87 peer-reviewed papers and 17 book chapters. *Id*. at 9-22.

2. Expert Opinion

Dr. Bishop submitted four reports in this case. Ex. A ("First Bishop Rep."); Ex. C ("Second Bishop Rep."); Ex. D ("Third Bishop Rep."); and Ex. E ("Fourth Bishop Rep.").

Dr. Bishop opined that Petitioner's medical records lack any documentation of loss of range of motion but also stated there was a general dearth of medical records that demonstrate Petitioner suffered a shoulder injury at all. First Bishop Report at 7-8. Dr. Bishop emphasized that the lack of contemporaneous medical records close in time to Petitioner's injury was suggestive that Petitioner had minimal to no pain. *Id*. at 8-9. Furthermore, when she did seek treatment months later, many of her records do not mention left shoulder pain. *Id*. at 9. In the limited instances where it is mentioned, it is self-reported by Petitioner but there is no treatment or additional actions taken by her medical providers. *Id*.

[5] Neuroma: a tumor growing from a nerve or made up largely of nerve cells and nerve fibers. DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=33770 (last accessed April 4, 2024).

Dr. Bishop further criticized Dr. Bodor's deltoid tendinopathy diagnosis. First Bishop Report at 9-10. Dr. Bishop stated that "deltoid tendinopathy" was not a diagnosis in the ICD-10[6] and she has never diagnosed someone with that condition in her numerous years of practice. *Id.* at 10. Dr. Bishop's remaining reports restate these conclusions and reiterate her opinion concerning the lack of medical records that confirm Petitioner's injury.[7]

Dr. Bishop concluded each report with her opinion that there is no evidence Petitioner's left arm symptoms are due to her vaccination. First Bishop Rep. at 10-11; Second Bishop Rep. at 3; Third Bishop Rep. at 4; Fourth Bishop Rep. at 2.

VI. Applicable Law

A. Petitioner's Burden in Vaccine Program Cases

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that she suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873* (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine

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[6] ICD-10 or International Classification of Diseases, Tenth Revision. Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/icd/icd10.htm (last accessed April 4, 2024).

[7] Dr. Bishop's reports contain comments dismissing the evidence that supports Petitioner's case. For example, she found that Dr. Csiba's neurology evaluation of Petitioner was "not relevant or useful" because his objective findings were not documented by other providers. First Bishop Rep. at 8. She opined that Petitioner's son was likely untruthful in his affidavit because "it is highly unlikely that 1) a 15-year-old boy was actually watching and paying attention to his mother receiving her vaccination and then 2 years later 2) recall that it was given lower than his vaccine." *Id.* at 9. She ultimately concluded that "there is no objective evidence/documentation or support that the symptoms B.B. reports in her left arm are due to the vaccination…" *Id.* at 10-11 (emphasis added). While Dr. Bishop may believe there is no persuasive objective evidence linking Petitioner's reports to vaccination, that is not the same as a complete lack of objective evidence. The examples noted above diminished the credibility of Dr. Bishop's overall opinion.

Program award based solely on her assertions; rather, the petition must be supported by either medical records of by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Secretary of Health and Human Services*. 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccinations she received caused her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

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

Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs*., 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility … in many cases may be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish her overall entitlement to damages by preponderant evIdence. *W.C. v. Sec'y of Health & Hum. Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

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

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

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

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically acceptable temporal relationship." *Id*. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. 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 & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013). *Koehn v. Sec'y of Health & Hum. 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).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate

diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020).

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

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475 at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

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

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

Finally, although this decision discusses some but not all of the medical literature in detail, I have reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VII. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, her claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that she suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

A. Diagnosis

As a threshold matter, a petitioner must establish she suffers from the condition for which she seeks compensation. *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). "The 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 & Hum. Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). "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 & Hum. Servs.*, 118 Fed. Cl. 47, 56 (2014) (quoting 42.U.S.C. § 300aa-11(c)). Accordingly, 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 a causation analysis pursuant to *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005). *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343, 1351-53 (Fed. Cir. 2011).

In this case, Petitioner alleges that she suffers from a deltoid tendinopathy. Respondent contends that a deltoid tendinopathy is not a recognized diagnosis.[8] First Bishop Rep. at 10; Resp't's Resp. to Pet'r's Motion at 13.

[8] Although I have considered Respondent's position that there is no ICD-10 diagnostic code specific to deltoid tendinopathy, I do not find this absence indicates that no such condition exists. As Petitioner aptly noted in her reply brief, the existence of categories called "other" and "unspecified" suggests that not every diagnosable condition is specifically listed in the ICD-10.

While none of Petitioner's treating physicians diagnosed her with a deltoid tendinopathy, they did assess her with various conditions, to include pain and weakness in the left deltoid (Ex. 5 at 6); chronic left shoulder pain (Ex. 9 at 2); neuroma of the upper limb (Ex. 4 at 38); and permanent nerve/tissue injuries (Ex. 21 at 3).[9] While these diagnoses are all different, each of these doctors documented that Petitioner experienced left arm/shoulder pain after vaccination.

A tendinopathy is defined as "any pathologic condition of a tendon."[10] Because there is a tendon that inserts onto the humerus,[11] it follows that this particular tendon could become damaged. Dr. Bodor concluded that Petitioner suffers from deltoid tendinopathy. He specifically opined that Petitioner likely experienced an injury to the deltoid tendon at its insertion onto the mid-humerus that has resulted in chronic inflammation and pain. First Bodor Rep. at 2-3. Dr. Bodor based his opinion on both Petitioner's description that the vaccine was administered low on her arm, as well as the medical records which document skin warmth and erythema overlying the deltoid muscle insertion. Ex. 4 at 37; Ex. 21 at 1, 7. Although he did not examine the Petitioner, Dr. Bodor has the benefit of a review of all the medical records, to include the records that rule out a neurological cause of Petitioner's pain.

Dr. Bodor further based his diagnostic opinion on his clinical experience. He described a similar case on my docket where the vaccination was also injected at the deltoid insertion on the humerus. First Bodor Rep. at 3. In that case, *Lally v. Sec'y of Health & Hum. Servs.*, No. 17-1426, 2021 WL 1851857 (Fed. Cl. Spec. Mstr. March 24, 2021) (stipulation), Dr. Bodor performed an anesthetic injection at the deltoid insertion. This injection immediately reduced the petitioner's pain from 7/10 to 1/10, "confirming that location as the pain generator." First Bodor Rep. at 3. Dr. Bodor's experience with this same condition is relevant to the issue of diagnosis in this case.

Based on the above, I find that Petitioner has presented preponderant evidence through the opinion of Dr. Bodor that she suffers from a deltoid tendinopathy.

B. *Althen* Prong One

Under *Althen's* first prong, the causation theory must relate to the alleged injury. Petitioner must provide a "reputable" medical or scientific explanation, demonstrating that the vaccines received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir.

[9] Both experts agree that Petitioner did not have a neuroma or a nerve injury. First Bishop Rep. at 9; First Bodor Rep. at 2.

[10] DORLAND'S, www.dorlandsonline.com/dorland/definition?id=49152&searchterm=tendinopathy (last visited April 10, 2024).

[11] The fibers of the deltoid "converge inferiorly to a short, substantial tendon which is attached to the deltoid tubercle on the lateral aspect of the midshaft of the humerus." *See* David Johnson, *Pectoral Girdle and Upper Limb*, in Gray's Anatomy: The Anatomical Basis of Clinical Practice 809 (Susan Standring et al. eds., 40th ed. 2008).

1994). It must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioner contends that the Tdap vaccine was administered into Petitioner's left deltoid tendon at its insertion onto the mid-humerus. First Bodor Rep. at 3. Dr. Bodor described that "the mechanism of injury is deposition of the vaccine components into unintended tissues that either cause local inflammation or triggers a nociceptive response without the presence of inflammatory cells." Pet'r's Brief at 15; citing First Bodor Rep. at 3.

Although the injury in this case is distinct from a SIRVA, the mechanism proposed by Dr. Bodor is analogous to the mechanism described in SIRVA cases, where injection of the vaccine into an area other than the deltoid muscle results in inflammation and pain.

Dr. Bodor submitted medical literature that supports his proposed causal mechanism. Atanasoff et al. described 13 patients who developed persistent shoulder dysfunction following vaccination. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 VACCINE 8049-52 (2010) (filed as Ex. 42) (hereinafter "Atanasoff"). The authors noted, "The proposed mechanism of injury is the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." *Id.* at 8049. Wright et al. similarly proposed the existence of "a robust local immune-mediated inflammatory reaction if vaccine antigen is injected into synovial tissues under the deltoid muscle." Wright et al., *Influenza Vaccine-related Subacromial/Subdeltoid Bursitis: A Case Report*, 13 RADIOLOGY CASE 6, 24-31 (2019) (filed as Ex. 38) (hereinafter "Wright").

Bodor et al. described a five patient series where the patients experienced chronic shoulder pain after vaccination. Bodor et al., *Ultrasonic aspiration for vaccination-related shoulder dysfunction*, 7 HELIYON 1-10 (2021) (filed as Ex. 47) (hereinafter "Bodor Article"). Dr. Bodor was able to determine that "the distal infraspinatus and teres minor tendons, their insertions and or the adjacent bone" were the source of pain in each of the patients. *Id.* at 7. He then conducted an ultrasonic aspiration and debridement procedure, which he opined, "remove[d] vaccine from that location" and resulted in the near complete resolution of pain. First Bodor Rep. at 3; Bodor Article at 7-8. Dr. Bodor hypothesized that the success of the procedures was attributable to "the resolution of tendinopathy, antigen-mediated pain or immune-mediated inflammation." *Id.* at 8. This case series demonstrates that "vaccine deposition can result in long-standing pain." First Bodor Rep. at 3.

Okur et al. described a group of patients who have post-vaccination inflammation visible on imaging studies. Okur et al., *Magnetic resonance imaging of abnormal shoulder pain following influenza vaccination*, 43 SKELETAL RADIOL 1325-31 (2013) (filed as Ex. 30). Similarly, the Uchida and Erickson articles both demonstrate that the improper injection of vaccine antigens can result in a destructive inflammatory process. Uchida et al., *Subacromial bursitis following human papilloma virus vaccine misinjection*, 31 VACCINE 27-30 (2012) (filed as Ex. 31); Erickson et al, *Lytic Lesion in the Proximal Humerus After a Flu Shot*, 9 JOURNAL OF BONE AND JOINT SURGERY 3, 1-5 (2019) (filed as Ex. 32).

Hirsiger et al. described that 12 of 16 subjects with a suspected SIRVA had evidence of inflammatory tissue damage on imaging. Hirsiger et al., *Chronic inflammation and extracellular*

matrix-specific autoimmunity following inadvertent periarticular influenza vaccination, 124 JOURNAL OF AUTOIMMUNITY 1-13 (2021) (filed as Ex. 46) (hereinafter "Hirsiger"). Dr. Bodor opined that these subjects may have chronic immune-mediated inflammation, although there was evidence of transient autoimmunity, "SIRVA was not associated with progression to autoimmune disease during two years of follow-up." Hirsiger at 1.

Each of these studies supports Dr. Bodor's theory that the improper administration of vaccine components outside the deltoid muscle can result in chronic inflammation and pain of a tendon near the injection site. Petitioner has presented preponderant evidence in support of the first *Athen* prong.

C. *Althen* Prong Two

Under *Althen's* second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (omitting internal citations). *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* prong. *Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 WL 3609993, at *25 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (Fed. Cl. 2013), *aff'd*, 540 Fed. Appx. 999 (Fed. Cir. 2013).

The evidence in the record, taken as a whole, supports Petitioner's contention that the Tdap vaccine "did cause" her condition. I discuss the evidence below that I find persuasive with respect to *Althen* prong two.

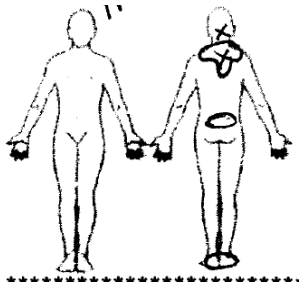
1. Onset of Petitioner's Shoulder/Arm Pain

Petitioner was generally in good health when she received the Tdap vaccine. Although she was in a motor vehicle accident in 2009, and had been receiving treatment from a massage therapist through 2015, I find that this previously documented pain is distinguishable from the pain she experienced as a result of vaccination.

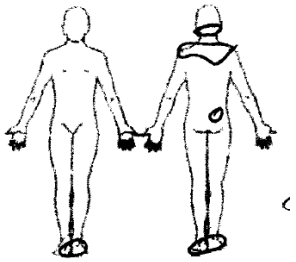
The only medical record where Petitioner sought treatment for her MVA was from March 3, 2010. Petitioner described experiencing neck pain along with numbness and tingling in her arms on that date. While she did seek chiropractic treatment for neck pain after this 2010 visit, neck pain is distinct from the shoulder and arm pain she described after vaccination.

Similarly, Petitioner's stiff and sore shoulders that she reported to her chiropractor in November of 2014 is distinct from her post-vaccination shoulder and arm pain. On November 15, 2014, Petitioner visited her chiropractor and reported that a chicken coop trap door fell onto her head. The record documents that she had a headache for more than one week, and was experiencing

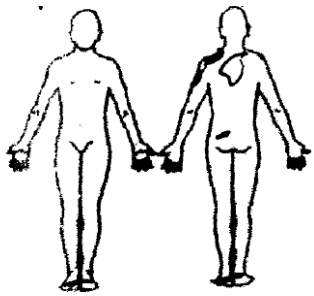
a stiff and sore upper back, neck, and shoulders. Ex. 5 at 11. The record contains a visual depiction of Petitioner's pain.



Id. Petitioner presented to her chiropractor for one additional visit where she mentions this same soreness. On November 19, 2014, the record documents Petitioner's pain as follows:



Id. at 10. This drawing is very similar to the November 15 version. However, Petitioner's pain after vaccination is depicted differently in the March 2016 chiropractic record.



Id. at 6. This record clearly shows that Petitioner was experiencing left shoulder pain that extended down to her deltoid muscle. None of the other chiropractic records draw the area of pain as the left shoulder and arm. The images on these three records persuasively demonstrate that Petitioner's pain after vaccination was different than the pain she experienced when the chicken coop trap door fell on her head.

Petitioner received the Tdap vaccine on August 19, 2015. Although she did not visit a doctor for this condition for approximately seven months, she and her husband did send emails in mid-October 2015, which establish that Petitioner experienced pain the day of vaccination. Ex. 11 at 1, 2. Further, they communicated with the pharmacy where the vaccine was administered, which resulted in the filing of a VAERS report on October 12, 2015. This documentation is highly relevant to my determination on onset. Although they are not medical records, these documents

represent objective evidence that on a specific date, Petitioner and her husband complained that Petitioner experienced onset of left arm/shoulder pain the day of vaccination. I have previously determined that non-medical record evidence can serve as persuasive evidence in determining the onset of shoulder pain. *Shackelford v. Sec'y of Health & Hum. Servs.*, No. 16-1509, 2018 WL 11344760, at *10-11 (Fed. Cl. Spec. Mstr. Oct. 24, 2018) (finding that a printed article entitled "Went for a Flu Shot, Got a Shoulder Injury Instead" with a date stamp on the bottom corroborated Petitioner's claims in her affidavit that her pain began within 48 hours of vaccination). The VAERS report specifies that onset of pain was two hours after vaccination.

Petitioner described in her affidavit that she experienced shoulder pain the same day that she received her Tdap vaccine. First B.B. Affidavit at 1. Her husband and son corroborated this statement. Ex. 14 at 1; Ex. 15 at 1.

Further, Petitioner's medical records support a same-day onset of left arm and shoulder pain. On March 25, 2016, petitioner visited a chiropractor for left arm, shoulder, and upper back pain. Ex. 5 at 6. This record notes that Petitioner was experiencing "pain and weakness in (L) deltoid/shoulder related to 8/19/15 tetanus booster." *Id.* On April 14, 2016, Petitioner visited her doctor who assessed her with chronic left shoulder pain. Ex. 9 at 2. The record notes that Petitioner "had a tetanus shot in the left arm in August of 2015 and had severe pain afterwards." *Id.* at 3. Petitioner's visit with Dr. Cobden on July 22, 2016 documents that Petitioner "developed pain in her left deltoid area after a tetanus injection given over at the Fred Meyer West pharmacy on August 15, 2015. She left for Switzerland for 5 months shortly after but had continuing pain all the time up until now." Ex. 4 at 37. Based on the above, I conclude that Petitioner experienced onset of pain on the day of vaccination.

While it is an often-cited tenet in the Vaccine Program that a close temporal interval between a vaccination and an injury does not prove causation, I find it would be inappropriate to ignore what appears to be the obvious cause of Petitioner's left shoulder/arm pain. The near-immediate onset of Petitioner's pain weighs heavily in her favor in my determination that the vaccine "did cause" her condition. *See* Wright et al., noting that "Clinical history and timing related to vaccination are the most important findings" in diagnosing vaccine related shoulder dysfunction. Wright at 25.

2. Objective Evidence of Deltoid Insertion Injury

The medical records from Petitioner's visit with Dr. Cobden document that she had a "2x2 centimeter area of warmth and tenderness in the deltoid insertion area left shoulder." Ex. 4 at 37. Further, the September 4, 2018 medical record from her visit with Dr. Csiba reveals temperature asymmetry of more than 2˚C between the vaccination site on her left arm and her asymptomatic right arm. Ex. 21 at 1. Dr. Csiba further documented that Petitioner's left deltoid was red; this color change is clearly visible in the photographs he took. *Id.* at 7.

These objective findings from Petitioner's treating physicians, which are consistent with Petitioner's theory that she experienced local inflammation at the vaccination site, lend further support to Petitioner's position that the Tdap vaccine injured her.

3. Location of Vaccine Administration

Petitioner described that her Tdap vaccine was administered too low, well below her deltoid muscle. First B.B. Affidavit at 1. She further averred that the vaccination site became sore within hours of vaccine administration. *Id.* Both Dr. Cobden's and Dr. Csiba's objective, documented, physical findings support Petitioner's claim that her vaccine was administered too low. Dr. Cobden noted an area of warmth and tenderness "in the deltoid insertion area" of the left shoulder. Ex. 4 at 37. This is the location where Petitioner describes that the vaccine was administered. Further, Dr. Csiba documented that "the vaccination site" was sore, warm, and red. Ex. 21 at 1. He included a picture which makes it clear that "the vaccination site" is in the area of the arm where the deltoid attaches to the humerus. *Id.* at 7. This evidence, when considered in conjunction with Petitioner's affidavit and her son's affidavit, preponderantly establishes that Petitioner's Tdap vaccine was administered in her lower deltoid area, where the deltoid attaches to the humerus.

4. Dr. Csiba's Opinion

Dr. Csiba, a neurologist, conducted a thorough exam of the Petitioner. He documented that the vaccination site was red and warm to the touch, measuring the skin temperature on both of Petitioner's arms and finding that the left side measured more than 2˚C warmer than the right. Ex. 21 at 1. Dr. Csiba noted hyperesthesia in Petitioner's left arm. *Id.* at 2-3. He further documented that Petitioner's left sided triceps and ulnar reflexes were slightly decreased. *Id.* at 3. He took photographs of Petitioner's arms, remarking that the vaccination site on Petitioner's left arm was red when compared with the other extremity. *Id.* at 1, 7. Dr. Csiba ultimately opined that "the previous and present complain[t]s have [a] causal relationship with the vaccination resulting in chronic complain[t]s." *Id.* at 4.

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. The views of treating doctors are often persuasive because the doctors have direct experience with the patient whom they are treating. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). I find the views of Dr. Csiba to be persuasive, and when considered in conjunction with Dr. Bodor's opinion, help Petitioner to establish that the vaccine "did cause" her condition.

The fact that Petitioner has established that vaccination can cause a deltoid tendinopathy and that the timing prong has been met (as discussed below) helps establish that she has also demonstrated that vaccination was a but-for cause of her condition. The Federal Circuit has provided guidance with respect to this issue.

> Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the "but-for" prong of the causation analysis. *See Capizzano,* 440 F.3d at 1326 (finding medical opinions that explain how a vaccine can cause the injury alleged coupled with evidence demonstrating a close temporal relationship "are quite probative" in proving actual causation).

Pafford, 451 F.3d at 1358. *See also Contreras* (finding that there is a "logical overlap between the three *Althen* prongs, and that evidence that goes to one prong may also be probative for another prong"). 107 Fed. Cl. at 295. I find that Petitioner has presented preponderant evidence in support of the second *Althen* prong.

In light of the evidence discussed above, I find that Petitioner has presented preponderant evidence in support of the second *Althen* prong.

D. *Althen* Prong Three

The timing prong contains two parts. First, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

I have determined that Petitioner's left arm and shoulder pain began the same day as her vaccination. This onset interval is medically appropriate and consistent with Petitioner's causal theory.

Although Petitioner's injury is not a SIRVA, the causal mechanism is analogous; here, the vaccine was administered into Petitioner's left deltoid tendon at its insertion onto the mid-humerus. The deposition of the vaccine components into unintended tissues then caused a local immune-mediated inflammatory reaction. Petitioner's medical literature supports an onset of pain on the day of vaccination, consistent with SIRVA cases. For example, in his five patient series, Dr. Bodor noted that each patient who developed vaccine-related shoulder dysfunction had an immediate or near immediate onset of pain. Bodor Article at 3-4, 6. Of the 16 patients studied in Hirsiger, 15 of them reported onset of shoulder pain within 24 hours of vaccination. Hirsiger at 1. Atanasoff et al. documented that 93% of patients studied reported onset of shoulder pain within 24 hours of vaccination. Atanasoff at 8050. Okur et al. noted that the onset of pain in its four patients ranged from immediate to two days. Okur at 1329.

Petitioner's onset of pain on the same day as her Tdap vaccination is consistent with her causal theory and is medically appropriate. Petitioner has presented preponderant evidence in support of the third *Althen* prong.

VIII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the affidavits, as well as the experts' opinions and medical literature, I conclude that Petitioner has established entitlement to compensation. An order regarding damages will issue shortly.

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master