# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

Filed: October 19, 2022

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| ROBERT INTROINI, | * | PUBLISHED |
| Petitioner, | * | No. 20-176V |
| v. | * | Special Master Nora Beth Dorsey |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | Entitlement; Tetanus-Diphtheria-Acellular Pertussis ("Tdap") Vaccine; Transverse Myelitis ("TM"). |
| Respondent. | * | |

Ronald Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.
Felicia Langel, U.S. Department of Justice, Washington, DC, for Respondent.

**RULING ON ENTITLEMENT**[1]

## I. INTRODUCTION

On February 20, 2020, Robert Introini ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleges that he developed transverse myelitis ("TM") as the result of a tetanus-diphtheria-acellular pertussis ("Tdap") vaccination administered on February 24, 2017. Amended ("Am.") Petition at 1 (ECF No. 42). Respondent argued

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (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, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

against compensation, stating that "this case is not appropriate for compensation under the terms of the Vaccine Act." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 33).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that Petitioner has provided preponderant evidence that his Tdap vaccine caused his TM, satisfying Petitioner's burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is entitled to compensation.

## II. ISSUES TO BE DECIDED

Diagnosis and causation are in dispute. Joint Submission, filed Feb. 15, 2022, at 1-2 (ECF No. 60). Petitioner argues his proper diagnosis is TM, while Respondent argues Petitioner has not provided preponderant evidence that he developed TM. Petitioner's Motion for a Ruling on the Record ("Pet. Mot."), filed Mar. 16, 2022, at 19-25 (ECF No. 65); Resp. Response to Pet. Mot. ("Resp. Response"), filed Apr. 14, 2022, at 15-21 (ECF No. 70). "Although both parties agree that [P]etitioner had cervical disc disease, [R]espondent also argues that [P]etitioner's neurological condition can be explained by his cervical disc disease." Resp. Response at 28; see also Resp. Response at 21-26; Pet. Mot. at 20-21. However, Petitioner maintains he "suffered both a vaccine-induced demyelinating disease and cervical disc disease," and "the two diagnoses . . . are not competing."[3] Pet. Mot. at 20 (emphasis omitted).

With regard to causation, Petitioner contends he has provided preponderant evidence that his Tdap vaccine caused his TM, satisfying all three Althen prongs. Pet. Mot. at 25-39. Assuming Petitioner is able to prove by preponderant evidence that he developed TM, Respondent argues Petitioner "failed to meet his burden of proof under each of the Althen prongs." Resp. Response at 29-36.

## III. BACKGROUND

### A. Medical Terminology

Transverse myelitis ("TM") is generally defined as "a neurological disorder causing acute spinal cord injury as a result of acute inflammation." Resp. Exhibit ("Ex.") A, Tab 1 at 1.[4] "[TM] can be acute or a slow subacute process," with symptoms "develop[ing] over several hours and then worsen[ing] over one to several days" or "over several weeks." Id. at 2. TM can "result[] in motor, sensory, and autonomic dysfunction." Resp. Ex. A, Tab 3 at 1.[5] Typically,

[3] Petitioner does not allege that his cervical disc disease is vaccine-related. See Pet. Mot.; Pet. Reply to Resp. Response ("Pet. Reply"), filed May 2, 2022 (ECF No. 71).

[4] Anupama Bhat et al., The Epidemiology of Transverse Myelitis, 9 Autoimmunity Revs. A395 (2010).

[5] Transverse Myelitis Consortium Working Grp., Proposed Diagnostic Criteria and Nosology of Acute Transverse Myelitis, 59 Neurology 499 (2002).

patients have bilateral weakness and sensory disturbance below the level of the lesion, but unilateral symptoms have also been described. Resp. Ex. A, Tab 1 at 2. "[Eighty] to 94% of patients have numbness, paresthesias, or band-like dysesthesias."[6] Resp. Ex. A, Tab 3 at 1. "Autonomic symptoms consist variably of increased urinary urgency, bowel or bladder incontinence, difficulty or inability to void, incomplete evacuation, or bowel constipation." Id.; see also Resp. Ex. A, Tab 1 at 2.

"TM is usually accompanied by [magnetic resonance imaging ("MRI")] signal abnormality in the spinal cord, [cerebral spinal fluid ("CSF")] pleocytosis,[7] or both." Resp. Ex. C, Tab 4 at 1.[8] The TM Consortium Working Group proposed uniform diagnostic criteria for idiopathic acute TM:

***Table 1*** *Criteria for idiopathic acute transverse myelitis*

| Inclusion criteria | Exclusion criteria |
|---|---|
| Development of sensory, motor, or autonomic dysfunction attributable to the spinal cord | History of previous radiation to the spine within the last 10 y |
| Bilateral signs and/or symptoms (though not necessarily symmetric) | Clear arterial distribution clinical deficit consistent with thrombosis of the anterior spinal artery |
| Clearly defined sensory level | Abnormal flow voids on the surface of the spinal cord c/w AVM |
| Exclusion of extra-axial compressive etiology by neuroimaging (MRI or myelography; CT of spine not adequate) | Serologic or clinical evidence of connective tissue disease (sarcoidosis, Behçet's disease, Sjögren's syndrome, SLE, mixed connective tissue disorder, etc.)* |
| Inflammation within the spinal cord demonstrated by CSF pleocytosis *or* elevated IgG index *or* gadolinium enhancement. If none of the inflammatory criteria is met at symptom onset, repeat MRI and lumbar puncture evaluation between 2 and 7 d following symptom onset meet criteria | CNS manifestations of syphilis, Lyme disease, HIV, HTLV-1, *Mycoplasma*, other viral infection (e.g. HSV-1, HSV-2, VZV, EBV, CMV, HHV-6, enteroviruses)* |
| Progression to nadir between 4 h and 21 d following the onset of symptoms (if patient awakens with symptoms, symptoms must become more pronounced from point of awakening) | Brain MRI abnormalities suggestive of MS* |
| | History of clinically apparent optic neuritis* |

*Do not exclude disease-associated acute transverse myelitis.

AVM = arteriovenous malformation; SLE = systemic lupus erythematosus; HTLV-1 = human T-cell lymphotropic virus-1; HSV = herpes simplex virus; VZV = varicella zoster virus; EBV = Epstein–Barr virus; CMV = cytomegalovirus; HHV = human herpes virus.

Resp. Ex. A, Tab 3 at 2 tbl.1. "A diagnosis of idiopathic [acute TM] should require that all of the inclusion criteria and none of the exclusion criteria are fulfilled." Id. at 2.

"The pathogenesis of TM is probably of an autoimmune nature, whether TM presents as an isolated disorder or as part of a systemic disease." Pet. Ex. 18 at 2.[9] TM has been associated

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[6] Dysesthesia is "an unpleasant abnormal sensation produced by normal stimuli." Dysesthesias, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15186 (last visited Sept. 29, 2022).

[7] Pleocytosis is the "presence of a greater than normal number of cells in the cerebrospinal fluid." Pleocytosis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=39556 (last visited Sept. 29, 2022).

[8] T.F. Scott et al., Evidence-Based Guideline: Clinical Evaluation and Treatment of Transverse Myelitis, 77 Neurology 2128 (2011).

[9] N. Agmon-Levin et al., Transverse Myelitis and Vaccines: A Multi-Analysis, 18 Lupus 1198 (2009).

with viral infections, autoimmune disorders, and vaccinations. Id. at 2-3; Resp. Ex. A, Tab 1 at 2-4; Resp. Ex. A, Tab 2 at 3.[10]

### B. Procedural History

On February 20, 2020, Petitioner filed his petition.[11] Petition (ECF No. 1). Petitioner filed medical records and an affidavit in June, August, and September 2020. Pet. Exs. 1-12. Respondent filed his Rule 4(c) Report, arguing against compensation, on December 14, 2020. Resp. Rept. at 2.

Petitioner filed an expert report from Dr. Salvatore Napoli on April 12, 2021. Pet. Ex. 13. The following day, on April 13, 2021, Petitioner filed an amended petition. Am. Petition. On July 26, 2021, Respondent filed expert reports from Dr. Olajumoke Fadugba and Dr. Eric Lancaster. Resp. Exs. A, C.

Thereafter, the undersigned held a Rule 5 status conference on October 26, 2021. Rule 5 Order dated Oct. 29, 2021 (ECF No. 51). The undersigned preliminarily "found that there was preponderant evidence that [P]etitioner's diagnosis was a demyelinating illness consistent with myelitis." Id. at 2. Additionally, the undersigned preliminarily found Petitioner's theory sound and that Petitioner's onset was appropriate given Petitioner's theory. Id. at 2-3. The undersigned ordered that the parties consider settlement negotiations, but by November 2021, Respondent indicated he was not interested in settlement. Id. at 3; Resp. Status Rept., filed Nov. 23, 2021 (ECF No. 54).

At a status conference on December 21, 2021, Petitioner indicated that he preferred to resolve this matter through a ruling on the record. Order dated Dec. 21, 2021 (ECF No. 55). On January 12, 2022, Respondent indicated that he was amenable to resolving this case through a ruling on the record. Resp. Status Rept., filed Jan. 12, 2022 (ECF No. 56).

Petitioner filed a motion for a ruling on the record on March 16, 2022. Pet. Mot. Respondent filed a response on April 14, 2022, and Petitioner filed a reply on May 2, 2022. Resp. Response; Pet. Reply to Resp. Response ("Pet. Reply"), filed May 2, 2022 (ECF No. 71).

This matter is now ripe for adjudication.

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[10] Roger Baxter et al., Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis, 63 Clinical Infectious Diseases 1456 (2016).

[11] Petitioner appeared pro se until March 23, 2020, when a consented motion to substitute attorney was filed.

### C. Factual History

#### 1. Medical History

On February 24, 2017, at 63 years of age, Petitioner presented to his primary care physician, Dr. James Hedde, for an annual physical. Pet. Ex. 2 at 18-20. Under review of systems, Dr. Hedde documented that Petitioner did not complain of weakness or numbness. Id. at 20. Physical examination was normal. Id. at 20-21. At this visit, Petitioner received a Tdap vaccine in his right deltoid. Id. at 21; Pet. Ex. 1 at 1. Prior to vaccination, Petitioner had no history of neurological issues. See Pet. Exs. 2-11; Resp. Rept. at 2; see also Pet. Ex. 13 at 1; Resp. Ex. A at 2.

Petitioner returned to Dr. Hedde on April 7, 2017. Pet. Ex. 2 at 16. Under chief complaint, Dr. Hedde wrote Petitioner was "having a lot of issues with right arm lately." Id. History of present illness documented Petitioner was experiencing numbness and tingling in his right arm and into the thumb that began on Thursday[12] while Petitioner was in Aruba. Id. Since then, he has had "trouble with moving [his] arm" with "shots down both sides," and "now starting to have weakness in right leg." Id. Dr. Hedde documented Petitioner received a Tdap vaccine one month prior. Id. Physical examination revealed Petitioner's Spurling's test[13] was positive. Id. at 18. Dr. Hedde ordered X-rays of Petitioner's thoracic and cervical spine. Id. Both X-rays showed "[e]xtensive degenerative changes" and no "signs of a post-traumatic spondylolisthesis[14] or spondylolysis."[15] Id. at 43-44. Assessment was displacement of cervical intervertebral disc without myelopathy. Id. at 18. He prescribed a Medrol dose pack and Valium and referred Petitioner to physical therapy for his neck. Id.

Petitioner returned to Dr. Hedde on July 20, 2017, complaining of continued neurological symptoms. Pet. Ex. 2 at 13-14. Petitioner reported that he continued to feel pins and needles in

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[12] Thursday was March 30, 2017. In Petitioner's declaration, he stated he "woke up with numbness and tingling in [his] right arm" on March 31, 2017. Pet. Ex. 11 at ¶ 3.

[13] A Spurling test indicates cervical radiculopathy when a patient exhibits "pain radiating into the upper limp ipsilateral to a rotation position of the head." Spurling Test, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=112983 (last visited Sept. 29, 2022).

[14] Spondylolisthesis is the "forward displacement (olisthy) of one vertebra over another, usually of the fifth lumbar over the body of the sacrum, or of the fourth lumbar over the fifth, usually due to a developmental defect in the pars interarticularis." Spondylolisthesis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=46742 (last visited Sept. 29, 2022).

[15] Spondylolysis is the "dissolution of a vertebra; a condition marked by platyspondylia, aplasia of the vertebral arch, and separation of the pars interarticularis." Spondylolysis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=46743 (last visited Sept. 29, 2022).

both his arms with the sensation extending to his thumbs and night spasms in his arms and legs. Id. at 14. Petitioner reported that the weakness in his arm had subsided; however, when extending his arm, he would experience a burning sensation. Id. Physical examination noted Petitioner had positive Spurling's bilaterally and full strength in his upper extremities. Id. at 15. Dr. Hedde noted Petitioner continued to have "persistent numbness" and that Petitioner completed over six weeks of physical therapy.[16] Id. Assessment was neuropathy and displacement of cervical intervertebral disc without myelopathy. Id. Dr. Hedde ordered an MRI of Petitioner's cervical spine and lab work and prescribed gabapentin.[17] Id.

The July 26, 2017 MRI revealed

> C4/5 mild anterolisthesis, spondylosis, and congenital spinal stenosis causes severe central canal stenosis, severe right foraminal stenosis, and moderate left foraminal stenosis. There is abnormal bilateral cervical hemicord signal at this level, likely due to gliosis.[18] Additional punctate T2 hyperintense signal of the left cervical hemicord at the C6/7 level is also likely due to gliosis.
>
> Additional levels of spondylosis and congenital spinal stenosis of the cervical spine cause moderate central stenosis at the C5/6 level, mild central stenosis at the C3/4 level, and multiple levels of significant foraminal stenosis as described.
>
> C3/C4 disc shows severe loss of height but with increased T2 weighted signal within the disc. This is likely due to degenerative disc signal rather than discitis. If there is any clinical concern for discitis, recommend repeat MRI imaging of the cervical spine, and possibly with IV contrast to evaluate for additional spinal infection.
>
> Mild levoscoliosis of the cervicothoracic spine.

Pet. Ex. 2 at 38 (emphasis omitted).

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[16] "[P]etitioner [] confirm[ed] that he did not participate in formal physical therapy, rather, he did at-home physical therapy exercises between his April 7, 2017 and July 26, 2017 visits with Dr. Hedde." Pet. Response to Resp. Medical Records Requests, filed Dec. 20, 2020, at 1-2 (ECF No. 35).

[17] Gabapentin is a medication given for "the management of postherpetic neuralgia" and other nerve pain. Gabapentin, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=19523 (last visited Sept. 29, 2022).

[18] Gliosis is "an excess of astroglia in damaged areas of the central nervous system." Gliosis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=20342 (last visited Sept. 29, 2022).

On August 31, 2017, Petitioner visited orthopedist Dr. Simon Chao, complaining of "several months of worsening neck pain" and "bilateral arm numbness." Pet. Ex. 10 at 3. Petitioner "describe[d] neck pain extending across middle portion of his neck as sharp, aching, [and] throbbing." Id. He also complained of "[n]umbness extend[ing] down both arms, into the hands," and "problems with balance, coordination, [and] dexterity." Id. He "denie[d] bowel/bladder dysfunction." Id. Physical examination revealed "limited range of motion to flexion, extension, rotation, and lateral side bends" in cervical spine; brisk deep tendon reflexes in the bilateral upper and lower extremities; positive Spurling's bilaterally; positive Hoffman's[19] bilaterally; and motor strength of 4/5 from C5-T1. Id. Petitioner also had good range of motion in his lumbar spine. Id. Dr. Chao agreed with the MRI findings. Id. Assessment was cervical myeloradiculopathy in the context of cord signal change and stenosis at C4-5. Id. Dr. Chao recommended anterior cervical discectomy and fusion ("ACDF") surgery at C4-5. Id. at 4.

On September 8, 2017, Petitioner saw Dr. Michael Geiger, a neurosurgeon, for a consultation. Pet. Ex. 9 at 16. Dr. Geiger noted that the onset of symptoms appeared in April 2017 after Petitioner received a "[Tdap] injection in [his] right arm in February." Id. Petitioner was not in pain but reported right arm muscle spasms, difficulty walking, numbness, and tingling or "pins and needles." Id. Physical examination revealed light touch symmetrical paresthesias in a C6 distribution in the upper extremities; brisk deep tendon reflexes (3+) in biceps, triceps, knees, and ankles; positive Hoffman's bilaterally; and positive Babinski bilaterally.[20] Id. at 18-19. Dr. Geiger diagnosed Petitioner with acute TM and a cervical disc disorder. Id. at 19. After reviewing the MRI, Dr. Geiger noted that Petitioner's injury appeared "consistent with a demyelination pattern or myelitis." Id. Dr. Geiger recommended ACDF surgery only if other neurological issues were ruled out. Id. He referred Petitioner for a neurological consultation. Id.

Petitioner presented to Dr. Salvatore Napoli, a neurologist, on September 20, 2017, for a consultation. Pet. Ex. 3 at 23. Dr. Napoli noted that after Petitioner's Tdap vaccine, "his right arm went dead" while in Aruba. Id. Petitioner "started getting weakness of the right leg" and night spasms in the right arm. Id. He complained of constant tingling in both arms and thumbs, but reported his strength returned. Id. Dr. Napoli mentioned Dr. Geiger attributed Petitioner's condition to three possible reasons: vaccination-induced myelitis, multiple sclerosis, or stenotic lesion.[21] Id. Dr. Napoli's physical examination revealed reflexes were 3 and symmetric, bilateral Babinski and Hoffman's, and plantar reflexes downgoing bilaterally. Id. at 24.

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[19] For more information on Hoffman's sign and central nervous system lesions, specifically lesions on the spinal cord, see Principles of Neurology 53-55 (Allan H. Ropper eds., 10th ed. 2014).

[20] The Babinski reflex is "dorsiflexion of the big toe on stimulating the sole of the foot" that is "a sign of a lesion in the central nervous system." Babinski Reflex, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=102809 (last visited Sept. 29, 2022).

[21] Although Dr. Napoli's medical records reference Dr. Geiger's three possible causes, Dr. Geiger's records do not include this information.

Dr. Napoli assessed Petitioner with myelitis, demyelinating disease of the central nervous system, and cervical disc disease. Pet. Ex. 3 at 25. Dr. Napoli noted "[t]here was some evidence of stenosis around the level of C4 but in discussion with Dr. Geiger he does not believe this is a compressive lesion and is wondering about possible vaccine and is [sic] myelitis."[22] Id. Dr. Napoli also wondered whether there was a downstream lesion as well, at the level of C6. Id. He ordered additional MRI scans "to assess for any lesions suggestive of demyelination or multiple sclerosis," and noted a possibility for spinal tap after assessment of the MRIs. Id. Dr. Napoli prescribed gabapentin and ordered Petitioner to follow up in 2-3 weeks. Id.

On October 10, 2017, Petitioner underwent brain and cervical spine MRIs. Pet. Ex. 3 at 38-43. Petitioner's brain MRI findings were interpreted by Dr. Brian Park as "represent[ing] the sequela of small vessel ischemic disease or demyelinating disease." Id. at 41 (emphasis omitted). Dr. Park, in an addendum, wrote "[t]here is no evidence of enhancing mass lesion or foci to indicate active disease."[23] Id. at 40. Petitioner's cervical spine MRI was interpreted by Dr. Samir Semine, who noted

> [c]ord signal abnormality most apparent at the C4-5 level where there is severe central stenosis. The smaller T2 hyperintense foci inferior to this are not associated with central stenosis and may be a reflection of primary demyelinating disease. When compared to the July 2017 study[,] the left C6-7 cord hyperintensity is unchanged. The right-sided lesion at the same level may be new or may be better seen due to slice selection. Right C7-T1 cord lesion is not visualized on the prior study, likely for the same reasons.

Id. at 39 (emphasis omitted). Petitioner's October 12, 2017 thoracic spine MRI, also interpreted by Dr. Semine, showed signs of "mild degenerative disc disease," but "no sign[s] of thoracic cord demyelination." Id. at 37 (emphasis omitted).

Petitioner followed-up with Dr. Napoli on October 13, 2017. Pet. Ex. 3 at 21-22. Dr. Napoli "suspect[ed] that [Petitioner] may have sustained a vaccine induced myelitis. [Petitioner] does have demyelinating lesion at C4-C5 as well as lesion at a level lower than that around C6-C7. Temporally it appears to be consistent with a vaccine induced issue." Id. at 22. He noted Petitioner's clinical symptoms appear to be "unchanged with the exception of bilateral hand tingling and spasticity particularly of the right upper extremity. Id. Dr. Napoli spoke "with [Petitioner's] neurosurgeon at previous visit [and] do[es] not suspect that this was a compressive disc." Id. Dr. Napoli increased Petitioner's gabapentin dose and prescribed Petitioner three days of IV Solumedrol, a steroid, which Petitioner received from October 17 to October 19. Id. at 16, 19-20, 22.

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[22] The "and is" of this quote appears to be a typographical error. In the context of Dr. Napoli's records, he may have meant "induced."

[23] Dr. Napoli agreed with Dr. Park's addendum. Pet. Ex. 13 at 4. Likewise, Dr. Lancaster agreed "there was no evidence of any involvement of the brain." Resp. Ex. C at 2.

Petitioner had another follow-up visit with Dr. Napoli on October 19, 2017. Pet. Ex. 3 at 17. Petitioner "state[d] that the steroids have helped the tingling[] [s]ensation and gabapentin has helped spasms as well." Id. Dr. Napoli again noted "[Petitioner] does appear to have vaccine induced myelitis . . . . [H]is symptoms appear to be consistent with a vaccine induced demyelination and he also had improvement." Id. He encouraged Petitioner to undergo further evaluation regarding Petitioner's cervical disc disease causing stenosis. Id. Petitioner was directed to follow up in one month. Id.

At a follow-up visit with Dr. Napoli on November 29, 2017, Petitioner reported "he is no better." Pet. Ex. 3 at 14. Petitioner reported "no problems with weakness," but continued to experience numbness in both hands and thumbs. Id. Dr. Napoli indicated "[Petitioner's] main issue at the current time involves bilateral numbness of the tips of the thumbs along with pain in the thumb area." Id. at 15. Dr. Napoli ordered a nerve conduction study ("NCS") to rule out carpal tunnel syndrome.[24] Id. He also considered referring Petitioner for a hand evaluation to rule out tenosynovitis.[25] Id. Dr. Napoli again noted Petitioner should see a neurosurgeon for evaluation of his disc, "which was considered severe radiologically." Id.

On November 30, 2017, Dr. Napoli performed an electromyography ("EMG")/NCS, which revealed "electrodiagnostic evidence suggestive of a mild right ulnar mononeuropathy possibly localized to the elbow based on slight reduction of velocity at the elbow segment" and "[s]igns of chronic reinnervation were seen in the right bicep and triceps which could be suggestive of a chronic right C6 radiculopathy." Pet. Ex. 3 at 12, 28-30.

Petitioner saw Dr. Geiger on December 14, 2017. Pet. Ex. 9 at 14-16. Dr. Geiger noted the EMG did not show significant carpal tunnel syndrome or radiculopathy. Id. at 14. He recorded Petitioner's TM diagnosis. Id. Petitioner continued to have "[p]ersistent thumb symptoms after steroid infusion. Id. Physical examination remained unchanged since his last examination. Id. at 15. Dr. Geiger's assessment was "[a]cute [TM] in demyelinating disease of central nervous system" and "[c]ervical disc disorder with myelopathy, mid-cervical region." Id. at 16. Dr. Geiger and Petitioner discussed ACDF surgery for decompression. Id. Petitioner was directed to follow up in two weeks. Id.

On December 22, 2017, Petitioner returned to Dr. Geiger. Pet. Ex. 9 at 11. Petitioner indicated he would like to proceed with decompression surgery. Id. Dr. Geiger indicated Dr. Napoli agreed after discussion. Id. Petitioner underwent ACDF surgery at the C4-C5 level on January 3, 2018. Pet. Ex. 5 at 90-91.

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[24] Carpal tunnel syndrome is "an entrapment neuropathy characterized by pain and burning or tingling paresthesias in the fingers and hand, sometimes extending to the elbow. Symptoms result from compression of the median nerve in the carpal tunnel." Carpal Tunnel Syndrome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110370 (last visited Sept. 29, 2022).

[25] Tenosynovitis is "inflammation of a tendon sheath." Tenosynovitis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=42914 (last visited Sept. 29, 2022).

Thereafter, he followed up with Dr. Geiger on January 12, 2018, February 2, 2018, and February 16, 2018. Pet. Ex. 9 at 4-11. At these visits, Petitioner continued to complain of "persistent hand symptoms of numbness, tingling, [and] pain," arm numbness, and mild neck pain (2/10). Id. at 5, 7, 9. Petitioner underwent an MRI of his cervical spine on February 14, 2018, which indicated cord decompression, cord hyperintense signals that remained, and several areas of stenosis. Id. at 6; Pet. Ex. 5 at 9-10.

At a fourth follow-up visit on April 12, 2018, Petitioner reported "everything [was] the same," with "[h]ands feel[ing] alternately hot and cold." Pet. Ex. 9 at 3. Dr. Geiger noted that Petitioner's condition was "likely due to the inciting post-injection reaction since both the area of the compression and the non-compressed area below are involved." Id. Petitioner also reported weakness in his right leg, muscle spasms in his right arm, difficulty walking, numbness, and tingling. Id. Neurologic examination revealed brisk bilateral deep tendon reflexes in biceps (3+, 4+), knees (3+), and ankles (3+), and positive Hoffman's and Babinski bilaterally. Id. at 4. Impression remained acute TM. Id. Dr. Geiger noted Petitioner was "[s]till symptomatic and myelopathic from the [TM] type syndrome following the injection. Cord compression [was] resolved." Id. He referred Petitioner to Dr. Napoli for "treatment of the nerve injury symptoms." Id.

On April 13, 2018, Petitioner presented to Dr. Hedde for an annual physical examination. Pet. Ex. 2 at 8-11. Dr. Hedde listed Tdap as an allergy, writing "? adverse reaction given [TM]." Id. at 9. Under history of present illness, Dr. Hedde noted Petitioner "[s]till [had] thumbs that are tingling and at times . . . painful," felt sensation of "hot and cold in his arms and sometimes in his back," had freezing hands, and "fe[lt] like his balance [was] off" when standing. Id. at 10. Petitioner reported weakness and numbness. Id. Physical examination was normal. Id. Dr. Hedde's assessment was neuropathy. Id. at 11. He noted Petitioner has "[TM] which is believed to be secondary to [the Tdap] vaccine but could be secondary to numerous etiologies." Id. Petitioner indicated he would forego future vaccinations. Id.

Petitioner returned to Dr. Napoli on May 9, 2018. Pet. Ex. 3 at 10-11. Petitioner found gabapentin was helping with his arm spasms, but reported continued hand and arm symptoms, including a "burning and cold sensation." Id. at 10 (emphasis omitted). Assessments were myelitis and demyelinating disease of the central nervous system. Id. at 11. Dr. Napoli stated "[Petitioner] has what we presume to be a post vaccine myelitis. [Petitioner] has residual symptoms of bilateral upper extremity spasticity as well as sensory symptoms of the hands." Id. Dr. Napoli reviewed Petitioner's February MRI and considered it unchanged. Id.

Petitioner followed up with Dr. Napoli on November 7, 2018. Pet. Ex. 3 at 8-9. Dr. Napoli noted Petitioner continued to have pain in his thumbs. Id. at 8. Assessments were myelitis and cervical disc disease. Id. at 9. Petitioner reported he felt "relatively stable with no new change." Id. Dr. Napoli again stated he believed that Petitioner's issue was "a post vaccine

issue." Id. Dr. Napoli referred Petitioner to a hand specialist[26] for his bilateral thumb symptoms. Id.

Petitioner saw Dr. Hedde next on July 18, 2019 for an annual wellness examination. Pet. Ex. 2 at 4-8. Dr. Hedde again noted that Petitioner believed the Tdap vaccine caused his TM. Id. at 6. Dr. Hedde indicated Petitioner was suffering from cervical radiculopathy for which he was to continue taking gabapentin as it was "providing benefit." Id. at 7.

On February 26, 2020, Petitioner followed up with Dr. Napoli. Pet. Ex. 3 at 5-6. Petitioner reported "that the pain that radiates through his thumbs [was] getting worse. Right thumb ha[d] started 'cracking.'" Id. at 5. His thumbs and fingertips were still numb, with sharp pains intensifying. Id. Dr. Napoli indicated that Petitioner had no improvement following ACDF surgery. Id. Assessments were demyelinating disease of central nervous system, cervical disc disease, myelitis, and tenosynovitis. Id. at 6. Dr. Napoli "suspect[ed] previous vaccine induced myelitis" and indicated Petitioner was now suffering from residual thumb numbness as a result. Id. He considered tenosynovitis, for which he referred Petitioner to Dr. Tracy Webber, and repeat brain and cervical MRIs to ensure there were no changes. Id.

On March 11, 2020, Petitioner presented to Dr. Webber for an evaluation of his hands, specifically "bilateral carpometacarpal ("CMC") arthritis, left worse than right[,] as well as numbness and tingling in the thumb and index finger of his bilateral hands consistent with carpal tunnel syndrome." Pet. Ex. 8 at 5-6. Dr. Webber wrote, "[Petitioner] has an interesting history where he had a Tdap vaccination performed around 3 years ago where he unfortunately developed a [TM] with significant weakness and numbness in his bilateral upper extremities." Id. at 6. Petitioner reported "he has had [an] incomplete return of the sensation in his fingertips as well as pain in the base of his bilateral thumbs." Id. "He state[d] his left thumb is more symptomatic than the right. It bothers him with pinching and twisting activities such as opening a jar or turning [a] key." Id. He reported no clicking or locking. Id. Dr. Webber also noted that Petitioner had been a United Postal Service ("UPS") driver for many years and was constantly utilizing his thumbs to make deliveries. Id. at 7.

Physical examination revealed Petitioner was tender to palpation over both CMC joints, had pain with axial load of the CMC but no pain with thumb extension or flexion, had decreased sensation in the thumbs and index fingers, and had positive Tinel's[27] of the bilateral wrists but negative Tinel's of the bilateral elbows. Pet. Ex. 8 at 7. Dr. Webber obtained X-rays of Petitioner's hands and found "Petitioner ha[d] moderate severe left-sided CMC arthritis as well as some early [scaphotrapeziotrapezoidal ("STT")] arthritis" and "mild right CMC arthritis." Id.

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[26] Petitioner confirmed he did not seek care from this hand specialist; rather, he ultimately sought care from hand specialist, Dr. Tracy Webber, in 2020. Pet. Response to Resp. Medical Records Requests at 2; see also Pet. Ex. 8.

[27] Tinel sign is "a tingling sensation in the distal end of a limb when percussion is made over the site of a divided nerve. It indicates a partial lesion or the beginning regeneration of the nerve." Tinel Sign, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=106510 (last visited Sept. 29, 2022).

Assessment was osteoarthrosis of the CMC joint of the thumb and bilateral carpal tunnel syndrome. Id. Petitioner received a left thumb CMC injection. Id. Dr. Webber noted that with regard to Petitioner's bilateral carpal tunnel syndrome, Petitioner's "picture is somewhat confusing as he just ha[d] numbness and tingling in the tips of his thumb and index finger," which she noted Petitioner believed was related to TM "as sometimes his symptoms do begin more proximally." Id. at 8. Petitioner's examination, however, showed "provocative symptoms consistent with carpal tunnel syndrome." Id. Dr. Webber ordered an EMG.[28] Id.

No additional medical records were provided.

**2. Petitioner's Declaration**[29]

In his declaration, Petitioner indicated that prior to his Tdap vaccination, "[he] was generally healthy and only sought care for annual physicals." Pet. Ex. 11 at ¶ 1. He was also fairly active, participating in a corn hole league in his free time. Id. In retirement, he worked for Boston College at sporting events and participated in local club activities. Id.

Petitioner received a Tdap vaccination in his right arm on February 24, 2017. Pet. Ex. 11 at ¶ 2. On March 31, 2017, Petitioner "woke up with numbness and tingling in [his] right arm." Id. at ¶ 3. Because he was on vacation in Aruba, he was not sure how to seek care for these symptoms. Id. He "remember[ed] having to eat with [his] left hand," which he found "particularly difficult." Id. After about three days, he was able to get some movement back in his right arm, but the numbness and tingling continued and went down to his thumb. Id. At this time, he also experienced weakness in his right leg. Id.

On April 5, 2017, Petitioner returned home from Aruba and made an appointment to see a physician. Pet. Ex. 11 at ¶ 4. Petitioner saw Dr. Hedde on April 7, and received X-rays that showed degenerative changes. Id. Petitioner was referred to an orthopedic surgeon, who wanted to operate immediately. Id. Petitioner requested a second opinion, and Dr. Hedde referred him to neurosurgeon, Dr. Geiger. Id. at ¶ 5. Dr. Geiger ordered a full body MRI. Id. "After examining the results, [Dr. Geiger] believed that [Petitioner] had [TM], which [Dr. Geiger] said can be caused by a Tdap vaccination." Id. Dr. Geiger referred Petitioner to a neurologist to confirm Petitioner's diagnosis. Id. Throughout this time, Petitioner "continued to experience numbness and tingling, as well as pain and muscle spasms." Id.

Petitioner saw neurologist, Dr. Napoli, "who agreed that [Petitioner] had a vaccine-induced myelitis." Pet. Ex. 11 at ¶ 6. Petitioner received two steroid infusions. Id. Petitioner "continued to experience pain running down [his] arms and pins and needles in both of [his] thumbs, as well as spasms in [his] arms and legs." Id. Nr. Napoli prescribed 300 mg of gabapentin, which Petitioner felt helped with spasms at night and aided in sleep. Id.

[28] From the medical records provided, it is unclear if Petitioner ever underwent this EMG.

[29] This exhibit is titled "Affidavit" but it is not notarized, and therefore, the undersigned references it as a declaration.

As of August 24, 2020, the day in which Petitioner executed his declaration, he "continue[d] to experience residual symptoms, including muscle spasms, pain, and right leg drag." Pet. Ex. 11 at ¶ 7. Petitioner indicated that these symptoms have affected his ability to work, hold a glass, and have even prevented him from picking up his grandson for fear of losing his balance. Id. Petitioner averred that "[p]rior to [his] Tdap vaccination, [he] was in good health, only [went] to [his] doctor for annual physicals, and rarely [missed] a day of work." Id. at ¶ 8. He concluded that "[t]his entire experience has negatively impacted every aspect of [his] life." Id.

### D. Expert Reports

#### 1. Petitioner's Expert, Dr. Salvatore Napoli[30]

##### a. Background and Qualifications

Dr. Napoli is a board-certified neurologist. Pet. Ex. 13 at 1; Pet. Ex. 14 at 1. Dr. Napoli received his M.D. from Albany Medical College, after which he completed an internship and neurology residency at Albany Medical Center Hospital, followed by multiple fellowships. Pet. Ex. 14 at 1. He is currently the Medical Director and President of the Neurology Center of New England. Id. Dr. Napoli has written numerous publications in the field of neurology and demyelinating diseases specifically, including articles relating to patients with TM. Pet. Ex. 13 at 1; Pet. Ex. 14 at 5. Furthermore, Dr. Napoli is Petitioner's treating neurologist and is well-acquainted with Petitioner's medical history and clinical course. Pet. Ex. 13 at 1.

##### b. Opinion

Dr. Napoli opined that more likely than not, Petitioner's February 24, 2017 Tdap vaccine caused him to develop TM through the mechanism of molecular mimicry. Pet. Ex. 13 at 4-6.

###### i. Diagnosis

Dr. Napoli opined Petitioner's injury "is consistent with a vaccine induced [TM]." Pet. Ex. 13 at 4. He added that Petitioner's "timeline and onset of his symptoms as well as the abruptness of his symptoms appear to be most consistent with a vaccine-induced myelitis," which is further supported by his imaging findings. Id. He considered Petitioner's diagnosis to be "a partial [TM], which can cause unilateral or asymmetric bilateral sensory and motor dysfunction." Id. Dr. Napoli noted Petitioner had hyperintense lesions on both the left and right

[30] Petitioner submitted one expert report from Dr. Napoli. Pet. Ex. 13.

C7-T1 distribution. Id. Dr. Napoli specifically ruled out multiple sclerosis, neuromyelitis optica ("NMO"),[31] and myelin oligodendrocyte glycoprotein ("MOG") antibody syndrome.[32] Id.

In addition to TM, Dr. Napoli agreed that Petitioner had degenerative disc disease. Pet. Ex. 13 at 4. He believed "[Petitioner] may have had [] severe stenotic lesion on a chronic basis and the time course [relevant to that condition] is usually progressive and non-inflammatory in nature. This can be seen as a natural process of aging as well." Id. Dr. Napoli found not all of Petitioner's symptoms could be explained by degenerative disease. Id. He noted the ACDF surgery was a preventative measure that was recommended to Petitioner, and he agreed with the recommendation. Id. at 4-5.

**ii. Althen Prong One**

Dr. Napoli posited that demyelinating diseases, such as NMO, Guillain-Barré Syndrome ("GBS"), and TM specifically, can be triggered by vaccination through molecular mimicry. Pet. Ex. 13 at 5-6; see, e.g., Pet. Ex. 23 at 3, 3 tbl.2 (noting antecedent flu vaccination in two of 23 (9%) monophasic cases of NMO);[33] Pet. Ex. 13 at 5 (opining that "[t]here is a proven model of molecular mimicry in human neurologic disease," specifically with "acute motor axonal neuropathy (AMAN), a form of [GBS] that can occur following infection with the bacterium *Campylobacter jejuni*," which he argued demonstrates that "molecular mimicry is a valid scientific method" (emphasis added)).

He further explained that the Tdap vaccine specifically can cause TM through molecular mimicry. Pet. Ex. 13 at 5. "If the antigen present on the vaccine shares any homologies with host antigen, then immune response will be directed at both the injected antigens and host antigen leading to an autoimmune response." Id. Additionally, Dr. Napoli asserted molecular mimicry "is a well-known response in immunology," and "[t]he theory of molecular mimicry relating to autoimmune diseases such as [TM] is well-published and supported in the medical community." Id. at 5-6. He cited studies that have linked autoimmune neurologic conditions,

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[31] Neuromyelitis optica is the "combined, but not usually clinically simultaneous, demyelination of the optic nerve and the spinal cord; it is marked by diminution of vision and possibly blindness, flaccid paralysis of the extremities, and sensory and genitourinary disturbances." Neuromyelitis Optica, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=92610 (last visited Sept. 29, 2022).

[32] "Myelin oligodendrocyte glycoprotein (MOG)-associated disease (MOGAD) is a rare, antibody-mediated inflammatory demyelinating disorder of the central nervous system (CNS) with various phenotypes starting from optic neuritis, via [TM] to acute demyelinating encephalomyelitis (ADEM) and cortical encephalitis." Wojciech Ambrosius et al., Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease: Current Insights into the Disease Pathophysiology, Diagnosis and Management, 22 Int'l J. Molecular Scis. 100 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7795410/.

[33] Dean M. Wingerchuk et al., The Clinical Course of Neuromyelitis Optica (Devic's Syndrome), 53 Neurology 1107 (1999).

including TM, to vaccinations through the mechanism of molecular mimicry. Id. at 5 (citing, e.g., Pet. Ex. 16;[34] Pet. Ex. 17;[35] Pet. Ex. 18).

For additional support of his posited theory, he cited Olsen et al.[36] and Agmon-Levin et al. Pet. Ex. 13 at 5-6. Olsen et al. described a virus-induced molecular mimicry model of multiple sclerosis in mice. Pet. Ex. 22 at 1. The authors stated "[m]olecular mimicry remains the major postulated mechanism by which infections may trigger autoimmune tissue damage." Id. They explained molecular mimicry occurs when there is "activation of autoreactive T cells secondary to an encounter with a pathogen by epitopes shared or cross-reactive with self antigens." Id.

Specific to TM, Agmon-Levin et al. noted "[t]he pathogenesis of [TM] is mostly of an autoimmune nature, triggered by various environmental factors, including vaccination." Pet. Ex. 18 at 1. Agmon-Levin et al. conducted a systematic review of journals published between 1970 and 2009 to analyze cases of TM following vaccination. Id. at 1-2. Their initial search revealed 43 cases, but six were excluded due to insufficient data. Id. at 2. Of the remaining 37 cases, four were reported after diphtheria-tetanus-pertussis ("DTP") or diphtheria and tetanus ("DT") vaccines, and one was reported after a multiple vaccine regimen that included DT. Id. at 2, 3 tbl.1. "In most of these cases[,] the temporal association was between several days and 3 months . . . ." Id. at 5. Twenty-seven of the 37 cases (73%) developed symptoms of TM within the first month after vaccination, three developed symptoms between one and two months after vaccination, and seven developed symptoms more than two months after vaccination. Id. at 2, 3 tbl.1. For the cases of TM after DTP and DT, onset was between three and 17 days. Id. at 3 tbl.1.

The authors discussed mechanisms by which vaccines may induce TM, and noted "molecular mimicry between infectious antigens and self antigens is the most common mechanism." Pet. Ex. 18 at 4 (emphasis omitted). They added that a "host's response to a vaccine, originally generated to produce protective immunity, is similar to its response to an infectious invasion." Id. The authors concluded that "the temporal association between [] vaccines and TM, and the possible mechanism associating these phenomena cannot be ignored. The rarity of TM makes it a difficult disease to study." Id. at 5.

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[34] R. Lahesmaa et al., Molecular Mimickry Between HLA B27 and *Yersinia*, *Salmonella*, *Shigella* and *Klebsiella* Within the Same Region of HLA $\alpha_1$-Helix, 86 Clinical & Experimental Immunology 399 (1991).

[35] Kai W. Wucherpfannig & Jack L. Strominger, Molecular Mimicry in T Cell-Mediated Autoimmunity: Viral Peptides Activate Human T Cell Clones Specific for Myelin Basic Protein, 80 Cell 695 (1995).

[36] Julie K. Olson et al., A Virus-Induced Molecular Mimicry Model of Multiple Sclerosis, 108 J. Clinical Investigation 311 (2001).

With the goal of examining the relationship between clinical characteristics and outcomes in patients with acute TM, Pidcock et al.[37] evaluated a cohort of acute TM patients under the age of 18 who were treated at Johns Hopkins TM Center over an interval of four years. Pet. Ex. 19 at 1-2. The authors identified 47 patients with acute onset TM, and 13 of the 47 cases (28%) had a confirmed immunization, including DTP, or allergy shot within 30 days of onset. Id. at 2-3. Even though the authors did not conduct this study to determine causality, the authors found "a potential causal link between vaccination and [acute TM]." Id. at 7. However, they noted that this association was "undermined" by "the large fraction of younger children affected, the current recommended vaccination schedule for children, and the lack of any single vaccine association within this group." Id.

Dr. Napoli also cited several case reports of individuals developing TM following vaccinations similar to Tdap. Pet. Ex. 13 at 5 (citing Pet. Ex. 27;[38] Pet. Ex. 28;[39] Pet. Ex. 29).[40] Read et al. discussed a case of a 50-year-old man received a tetanus toxoid booster vaccination after suffering a penetrating foot wound. Pet. Ex. 27 at 1. The patient was diagnosed with a viral illness about ten days later after complaining of myalgia, lethargy, fatigue, and mild bifrontal headache. Id. Twelve days after initial presentation, he was admitted to the hospital with "flaccid, areflexic paralysis of the legs, associated with sensory loss to T6, moderately severe midthoracic back pain, and urinary retention." Id. After diagnostic testing, he was diagnosed with acute TM. Id. at 2. The authors concluded that "[a]lthough it is possible that the myelopathy in [their] patient occurred independently of vaccination, the timing and absence of an alternative explanation may implicate tetanus toxoid." Id.

The second case report, authored by Whittle and Robertson, described the case of a seven-month-old girl who presented to the hospital with inability to move her legs. Pet. Ex. 28 at 1. Physical examination revealed complete flaccid paralysis of her legs and lower trunk, as well as absent abdominal reflexes. Id. The child received her first vaccination against DT, as well as her first oral polio immunization six days before onset. Id. She spent ten days in the hospital where some symptoms, such as use of her bladder, improved; however, the paraplegia did not improve with steroid treatment. Id. The child's condition was consistent with TM. Id. The authors noted that although her condition "may have occurred by chance," her onset occurred at the time when reactions to vaccines "are most frequently found." Id. Without other evidence, the authors were unable to determine which vaccine was "the most likely to have been responsible." Id.

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[37] F.S. Pidcock et al., Acute Transverse Myelitis in Childhood: Center-Based Analysis of 47 Cases, 68 Neurology 1474 (2007).

[38] Stephen J. Read et al., Acute Transverse Myelitis After Tetanus Toxoid Vaccination, 339 Lancet 1111 (1992).

[39] Eileen Whittle & N. R. C. Robertson, Transverse Myelitis After Diphtheria, Tetanus, and Polio Immunisation, 1 British Med. J. 1450 (1977).

[40] RMS Riel-Romero, Acute Transverse Myelitis in a 7-Month-Old Boy After Diphtheria-Tetanus-Pertussis Immunization, 44 Spinal Cord 688 (2006).

The third case report Dr. Napoli cited is from Riel-Romero. Pet. Ex. 29. Riel-Romero examined a seven-month-old boy who developed acute TM 17 days after a diphtheria-tetanus-acellular pertussis ("DTaP") vaccination. Id. at 1-2. The child received two prior doses of DTaP that were tolerated without adverse effect. Id. at 1. He had an upper respiratory tract infection two weeks prior to admission. Id. He developed flaccid paraplegia, urinary issues, and constipation. Id. at 1-2. "MRI of the spinal cord showed diffuse edema of and increased T2 signal within the spinal cord from the level of C3-T6." Id. at 2. "A repeat MRI of the spine done 3 months later showed resolution of cord edema and signal abnormality but reduction in cord caliber. At 10 months from initial presentation, he continued to have paraplegia and spasticity of the lower extremities." Id.

The authors hypothesized that (1) "[i]t is possible that [their] patient had a postinfectious or a postvaccination acute [TM] as his symptoms occurred about 2 weeks after an upper respiratory infection and 17 days after a DTaP vaccination," (2) "[i]t is [] possible that the concomitant exposure to these two antigens may have increased the risk of an abnormal immunologic response in a genetically susceptible individual," or (3) the occurrence was "simply coincidental." Pet. Ex. 29 at 3. The authors briefly discussed other reports[41] of acute TM after vaccination, including after DTP and DT vaccinations, and found "[r]eports of postvaccination acute [TM] suggest [] an immune-mediated process" to be at play. Id. Specifically, "the concept of molecular mimicry has been postulated whereby the offending agent triggers an autoimmune response to the myelin sheath of the central tracts of the spinal cord." Id.

### iii. Althen Prong Two

Dr. Napoli opined that "more likely than not, [] [Petitioner] suffered TM, and that his Tdap vaccination had a causal role in the development of his TM via the mechanism[] outlined above." Pet. Ex. 13 at 6.

As Petitioner's treating physician, Dr. Napoli specifically and contemporaneously described Petitioner's clinical course and identified Petitioner's injury as a myelitis as a result of his Tdap vaccination. Pet. Ex. 13 at 1-4. Dr. Napoli also indicated that some of Petitioner's other treating physicians also believed Petitioner's TM was caused by his Tdap vaccination. Id. For example, Dr. Hedde noted Petitioner's symptom onset began after Petitioner received a Tdap vaccine. Id. at 2 (citing Pet. Ex. 2 at 16). Dr. Geiger also noted Petitioner's condition was "likely due to the inciting post-injection reaction." Id. at 4 (quoting Pet. Ex. 9 at 3).

### iv. Althen Prong Three

Dr. Napoli opined Petitioner received a Tdap vaccine on February 24, 2017, and almost five weeks later (34 days), on or around March 30, 2017, Petitioner "developed symptoms

[41] The reports specific to DTP and DT vaccines include the Whittle and Robertson case report and an article authored by Kulenkampff et al. on a six-month-old who developed TM 17 days after a DTP vaccine. Pet. Ex. 29 at 3. This article was not filed in this case. See M. Kulenkampff et al., Neurological Complications of Pertussis Inoculation, 49 Archives Disease Childhood 46 (1974).

related to his [central nervous system] disorder." Pet. Ex. 13 at 6. He found this timing consistent with the medical literature. Id.

Dr. Napoli, relying on a 1994 Institute of Medicine ("IOM") (now the National Academy of Medicine) book,[42] opined "[t]here is an increased risk of autoimmunity primarily concentrated within the first six weeks after vaccination." Pet. Ex. 13 at 6 (citing Pet. Ex. 21 at 5). Dr. Napoli also cited Schonberger et al.,[43] who found an increased risk of GBS within the five weeks following flu vaccination. Id. (citing Pet. Ex. 20 at 1). Dr. Napoli noted an "increased incidence of demyelinating injury was seen up to 9 or 10 weeks following vaccination" in Schonberger et al. Id. (citing Pet. Ex. 20 at 1).

With regard to TM cases specifically, Agmon-Levin et al. noted that in "most of [their] cases[,] the temporal association was between several days and 3 months" Pet. Ex. 18 at 5. For the cases of TM after DTP and DT vaccines specifically, onset was between three to 17 days. Id. at 3 tbl.1. Likewise, Pidcock et al. analyzed 47 cases of acute TM and found 13 (28%) received a vaccine, including DTP, or allergy shot within 30 days of onset. Pet. Ex. 19 at 1, 3. Read et al. discussed a case of a 50-year-old man who received a tetanus toxoid booster vaccination three weeks prior to developing TM. Pet. Ex. 27 at 1. Whittle and Robertson described the case of a seven-month-old girl who developed TM six days after DT and oral polio vaccines. Pet. Ex. 28 at 1. And Riel-Romero examined a seven-month-old boy who developed acute TM 17 days after DTaP vaccination. Pet. Ex. 29 at 1-2.

### 2. Respondent's Expert, Dr. Olajumoke Fadugba[44]

#### a. Background and Qualifications

Dr. Fadugba is board certified in allergy and immunology and internal medicine. Resp. Ex. B at 1-2. She obtained her B.Sc. in Biochemistry from the University of Delaware in 2005 and her M.D. from Vanderbilt University School of Medicine in 2009. Id. at 1. Thereafter, she completed an internal medicine internship and residency at Washington University School of Medicine and an allergy and immunology fellowship at Vanderbilt University. Id. Dr. Fadugba is an Attending Clinic Allergist and Immunologist with the Allergy and Immunology Section at the University of Pennsylvania, "where [she] evaluate[s] and treat[s] vaccine response[s] from both the clinical and immunologic perspectives in addition to the spectrum of possible vaccine reactions that may be reported." Resp. Ex. A at 1. She also works as an Associate Professor of Clinical Medicine in the Allergy and Immunology Section at the University of Pennsylvania. Id.

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[42] Inst. of Med., Neurologic Disorders, in Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality 34, 46-47 (Kathleen Stratton et al. eds., 1994). Petitioner filed only two pages of this chapter; however, this text is well known to the undersigned.

[43] Lawrence B. Schonberger et al., Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977, 110 Am. J. Epidemiology 105 (1979).

[44] Respondent submitted one expert report from Dr. Fadugba. Resp. Ex. A.

She "ha[s] extensive experience in caring for adults with a variety of immunologic diseases including reactions to vaccines" and "ha[s] published, as first author, a study investigating the immune responses to pertussis antigens in infants and toddlers after immunization with multicomponent acellular pertussis vaccine." Id. Dr. Fadugba has also previously opined before this Court. Id. at 2. Although Dr. Fadugba notes allergy and immunology "involves assessment of complex dysregulated immune responses, [and thus] reaches into the field[] of neurology," she is not certified in neurology and her CV does not indicate any specialized training in neurology. Id. at 1; see Resp. Ex. B at 1-9.

**b. Opinion**

**i. Diagnosis**

Dr. Fadugba opined Petitioner did not suffer from TM due to confounding findings on testing and potential alternative causes. Resp. Ex. A at 9.

Dr. Fadugba defined acute TM as "a rare demyelinating condition that presents with acute onset of neurologic deficits due to spinal cord lesions. Patients typically develop bilateral weakness and sensory deficits below the level of the lesion over a period of several hours, and worsen over one to several days." Resp. Ex. A at 6 (citing Resp. Ex. A, Tab 1 at 2; Resp. Ex. A, Tab 2 at 2). Additionally, she listed conditions TM has been associated with, including infection, spinal cord infarction, autoimmune processes, and others. Id. She also noted 10-45% of TM cases are idiopathic. Id. (citing Resp. Ex. A, Tab 1 at 4).

Dr. Fadugba opined that to make a definite diagnosis of acute TM, the TM Consortium Working Group

> requires both the presence of spinal cord inflammation, as defined by CSF pleocytosis, elevated CSF [Immunoglobulin G ("IgG")] index, or gadolinium enhancement on a spinal MRI, and the absence of an identified [central nervous system] infection. The diagnosis also requires exclusion of acute myelopathy secondary to a known underlying disease and from compressive myelopathies (such as cervical stenosis).

Resp. Ex. A at 9 (emphasis omitted). Dr. Fadugba noted Petitioner's July 2017 cervical spine MRI revealed significant cervical spine stenosis at multiple levels. Id.

Next, Dr. Fadugba opined that Petitioner's treating physicians did not exhaust all diagnostic testing. Resp. Ex. A at 9. "Given that the patient had such significant compressive myelopathy on imaging (a potential confounder), it may have been prudent to obtain a lumbar puncture[45] in order to more definitely make a diagnosis of TM." Id. Additionally, she asserted that even though "up to 50% of patients have a preceding infection," Petitioner's medical records

[45] Petitioner's medical records indicate that a lumbar puncture for CSF analysis was considered, but ultimately never ordered by Dr. Napoli. Pet. Ex. 3 at 25.

do not indicate potential infectious causes were investigated via past medical history or laboratory testing. Id. at 6, 9.

Lastly, she opined Petitioner's medical records and imaging findings show Petitioner had findings that confound his diagnosis and provide alternative causes of his residual symptoms, which Dr. Fadugba believed Dr. Napoli did not address. Resp. Ex. A at 9. In August 2017, for example, orthopedist Dr. Chao assessed Petitioner with cervical myeloradiculopathy in the context of cord signal change and stenosis at C4-5 and recommended ACDF surgery at C4-C5. Id. (citing Pet. Ex. 10 at 3-4). Petitioner continued to have persistent symptoms in his thumbs even after receiving steroids and visited Dr. Webber in March 2020. Id. (citing Pet. Ex. 8). Dr. Webber's assessment was CMC arthritis and carpal tunnel syndrome, which Dr. Fadugba opined explains Petitioner's symptoms. Id. Lastly, due to his job at UPS for 27 years, she noted Petitioner would have been constantly using his thumbs. Id.

**ii. Althen Prong One**

Dr. Fadugba challenged Dr. Napoli's theory, opining "[t]here is no reliable evidence that the Tdap vaccine causes acute [TM] via molecular mimicry." Resp. Ex. A at 6-11.

First, Dr. Fadugba asserted that Dr. Napoli's literature on molecular mimicry relates to viral and bacterial infections, rather than vaccinations. Resp. Ex. A at 8. Dr. Fadugba argued "[i]nfection and vaccination are not analogous—the form, the route, and antigen quantity are fundamentally different. There is no evidence to support Dr. Napoli's inherent assumption that the vaccine and the live infection elicit [t]he same immunogenicity." Id. Dr. Fadugba, however, does not cite any literature or other evidence to show that antigens formed by infection and those formed after vaccination are different.

Next, Dr. Fadugba took issue with the fact that Dr. Napoli relied upon animal studies in support of his molecular mimicry mechanism. Resp. Ex. A at 8. Dr. Fadugba posited that such studies are "genetically restricted (and different from humans)." Id.

Dr. Fadugba, citing Peterson and Fujinami,[46] listed criteria that must be fulfilled to conclude molecular mimicry causes an autoimmune disease:

> (1) similarity between a host epitope and an epitope in a microorganism or environmental agent (Tdap vaccine in this case), (2) antibodies or T cells cross-reactive with both epitopes detected in patients with the autoimmune disease, (3) an epidemiological link between exposure to the environmental agent or microbe and the development of autoimmune disease[,] and (4) reproducibility of autoimmunity in an animal model following sensitization with the epitopes, infection with the microbe[,] or exposure to the environmental agent.

[46] Lisa K. Peterson & Robert S. Fujinami, Molecular Mimicry, in Autoantibodies 13 (Yehuda Shoenfeld et al. eds., 2nd ed. 2007).

Resp. Ex. A at 8 (citing Resp. Ex. A, Tab 8 at 1). She opined none of these criteria have been met to link Tdap with TM. Id. Additionally, she opined that given the high frequency of Tdap vaccinations administered[47] "and the supposed existence of purported cross-reactive peptides, one would expect a higher frequency of autoimmunity (and specifically TM) in populations that receive [] Tdap, if molecular mimicry were a plausible mechanism for development of TM." Id. at 9.

Dr. Fadugba next criticized Dr. Napoli's medical literature. Resp. Ex. A at 7. First, Dr. Fadugba noted that Pidcock et al. focused on children with TM rather than adults, and thus, the findings "cannot necessarily be translated into risk seen in adults." Id. Additionally, Dr. Fadugba maintained there would be a higher likelihood of occurrence of TM post-vaccination in young children due to the higher rates of vaccination in children. Id. The authors noted several different vaccines that were administered in their patients, which "suggests that a correlation between vaccine and TM is tenuous and not explained/linked by a single factor." Id. Lastly, eight of the 13 patients in Pidcock et al. had co-occurring illnesses that Dr. Fadugba found to be "critical confounder[s] since viral illness is well-known to be associated with onset of TM. Id.

Next, regarding Agmon-Levin et al., Dr. Fadugba argued there are limitations in the study preventing any conclusions to be reached about an association between vaccination and TM. Resp. Ex. A at 7. She indicated that of the 37 cases identified, many were associated with live vaccines, which Tdap is not. Id. "The risk of adverse immune activation is fundamentally different between live and inactivated vaccines," argued Dr. Fadugba. Id. However, she acknowledged other vaccines[48] have been found to be potential causes of TM. Id. (citing Resp. Ex. A, Tab 6).[49] Dr. Fadugba indicated that Agmon-Levin et al. identified four cases of TM following DTP or DT vaccination, which she believed was small given the rate of administration worldwide. Id. at 8. Also, three of the four cases occurred in children under the age of one. Id. She opined this finding cannot be generalized to adults. Id.

Lastly, Dr. Fadugba opined there is a lack of epidemiologic evidence to support an association between the Tdap vaccine and TM. Resp. Ex. A at 10. She argued Dr. Napoli relied on case reports and passive surveillance systems to support his opinions, both of which "are

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[47] For support, Dr. Fadugba provided documentation from the Centers for Disease Control and Prevention ("CDC") summarizing DTaP and Tdap vaccine recommendations across one's lifespan. See Resp. Ex. A, Tab 9 (Ctrs. for Disease Control & Prevention, Pertussis: Summary of Vaccine Recommendations, https://www.cdc.gov/vaccines/vpd/pertussis/recs-summary.html (last reviewed Jan. 22, 2020)). There is no evidence in this record as to how often the Tdap vaccine is actually given, particularly in adults.

[48] Dr. Fadugba stated, "[f]or example, poliovirus infection is a known cause of acute [] TM, and the oral polio virus vaccine was declared as a potential cause of TM." Resp. Ex. A at 7.

[49] Ctrs. for Disease Control & Prevention, Poliomyelitis Prevention in the United States: Introduction of a Sequential Vaccination Schedule of Inactivated Poliovirus Vaccine Followed by Oral Poliovirus Vaccine; Recommendations of the Advisory Committee on Immunization Practices (ACIP) (1997).

inherently flawed and cannot be used to draw conclusions about causality due to high potential for reporting bias, and causality cannot be inferred from an uncontrolled observation." Id. She added that "[a]n association does not equal cause-effect relationship, and an observation could be coincidence." Id. She argued that a case-series, risk-interval, or case-centered analysis would be more useful here, where the adverse event (TM) is "abrupt in onset, clearly defined, occur[s] relatively soon after vaccination, ha[s] a limited period of risk . . . , and [is] serious enough that people seek medical care." Id.

Relying on Baxter et al., Dr. Fadugba opined that the IOM has found evidence of a causal association between specific acute demyelinating events, including TM, and any vaccine to be "inconclusive." Resp. Ex. A at 10 (quoting Resp. Ex. A, Tab 2 at 1). The case-centered analysis conducted by Baxter et al. analyzed the association of vaccination and the subsequent development of TM or acute disseminated encephalomyelitis ("ADEM"). Resp. Ex. A, Tab 2 at 1. The study population included those who were enrolled in the Vaccine Safety Datalink and received one or more vaccines from 2007 through 2012.[50] Id. at 2. They identified 545 potential cases of TM; 184 were rejected for various reasons, 193 did not meet inclusion criteria according to a neurologist, and 87 had alternative diagnoses. Id. at 4. Eighty-one were accepted as new, acute-onset idiopathic TM cases according to the TM Consortium Working Group definition, and 67 of these cases received a vaccine within the nine months prior to onset.[51] Id. at 4-5. For TM, the authors found "no statistically significant increased risk of immunization in either the 5- to 28-day or the 2- to 42-day risk interval prior to onset."[52] Id. at 5.

### iii. Althen Prong Two

Dr. Fadugba opined Petitioner's Tdap vaccination did not cause his symptoms and that Petitioner did not suffer from TM. Resp. Ex. A at 8-11. Relying on the four criteria from Peterson and Fujinami, she opined there was (1) "no investigation or discovery of cross-reactive proteins in the administered vaccine and [P]etitioner's proteins;" (2) "no discovery of antibodies or T-cells in [P]etitioner's serum;" (3) "no epidemiological link between Tdap and TM;" and (4) "no evidence that vaccinating an animal with this specific Tdap vaccine induced TM in an animal." Id. at 8 (citing Resp. Ex. A, Tab 8 at 1).

Dr. Fadugba believed there were better explanations for Petitioner's symptoms. Resp. Ex. A at 9. As for alternative causes, Dr. Fadugba noted Dr. Chao diagnosed Petitioner with cervical myeloradiculopathy in the context of cord signal change and stenosis at C4-5 and recommended Petitioner undergo ACDF surgery at C4-C5. Id. (citing Pet. Ex. 10 at 3-4). Dr. Fadugba asserted that Petitioner's symptoms of bilateral thumb discomfort could be explained by

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[50] The authors "did not analyze combinations of vaccines." Resp. Ex. A, Tab 2 at 6.

[51] The timing of these vaccines within the nine-month interval is unclear, as the authors did not provide this data.

[52] For Tdap and ADEM (another central nervous system demyelinating illness), the authors found "a statistically significant increase in risk in the 5- to 28-day exposure interval," but not in the 2- to 42-day interval. Resp. Ex. A, Tab 2 at 5.

his diagnosis of CMC arthritis and carpal tunnel syndrome by Dr. Webber in 2020. Id. (citing Pet. Ex. 8). Lastly, she opined that Petitioner's 27 years at UPS likely required the extensive use of his thumbs, which could explain Petitioner's symptoms. Id.

#### iv. Althen Prong Three

Dr. Fadugba did not rebut Petitioner's expert's opinion that the temporal association between Petitioner's Tdap vaccine and the onset of his symptoms was appropriate. In her summary of Petitioner's medical history, she noted Petitioner's numbness and tingling of the right arm began the morning of March 31, 2017. Resp. Ex. A at 2.

### 3. Respondent's Expert, Dr. Eric Lancaster[53]

#### a. Background & Qualifications

Dr. Eric Lancaster received his M.D. and Ph.D. from the University of Maryland School of Medicine. Resp. Ex. C at 1. Thereafter, he completed his internship, neurology residency, neuromuscular fellowship, and neuromuscular research fellowship at the University of Pennsylvania. Resp. Ex. D at 1. Dr. Lancaster is board certified in neurology, neuromuscular medicine, and electrodiagnostic medicine. Id. at 2. Since 2013, he has been an Assistant Professor of Neurology at the University of Pennsylvania. Id. at 1. He has written over 30 peer-reviewed publications, with most of his recent publications focusing on autoimmune neurological disorders and their mechanisms. Resp. Ex. C at 1. He has also written about autoimmune encephalitis, paraneoplastic disorders, and neuronal autoantibodies. Id. "[His] lab is focused on detection of neuronal autoantibodies, particularly in the context of autoimmune encephalitis and paraneoplastic disorders," and "[his] clinic is currently focused on autoimmune neurological diseases." Id.

#### b. Opinion

##### i. Diagnosis

Dr. Lancaster opined Petitioner did not suffer from TM, but instead "most likely had [a] cervical spinal cord compression" that explains his symptoms. Resp. Ex. C at 2-4.

First, Dr. Lancaster opined Petitioner's "primary symptoms . . . are most likely due to cervical radiculopathies and compression of the cervical spinal cord at C4/5." Resp. Ex. C at 2. Dr. Lancaster believed Petitioner's "numbness, paresthesias[,] and pain extending from the neck down to the hands (especially the thumbs) are most likely due to involvement of the cervical nerve roots and cervical spinal cord." Id. Dr. Lancaster also believed Petitioner's "hyper-reflexia in the hands and lower extremities are most likely due to injury to the spinal cord at [the C4-C5] level." Id.

[53] Respondent submitted one expert report from Dr. Lancaster. Resp. Ex. C.

Dr. Lancaster next opined that the cord signal abnormality at C4/5 shown on MRI "is almost certainly due to cervical spinal stenosis" because it would be an "improbable coincidence" for Petitioner to have "severe cervical stenosis at this level and cord inflammation from another cause." Resp. Ex. C at 2. He believed that the spinal decompression surgery Petitioner received helped prevent future nerve damage. Id. He acknowledged the surgery did not resolve the abnormal spinal cord signal seen on MRI or the associated symptoms, but explained that this is a frequent outcome with this type of surgery. Id.; see Resp. Ex. C, Tab 5 at 4 ("The presence of an abnormal signal within the cervical cord or adjacent to the level of compression by spondylosis is considered a serious finding, which may signify a less satisfactory outcome with surgical decompression than would otherwise be expected.").[54] Additionally, he found the fact that both Petitioner's neurosurgeon and neurologist agreed to perform this surgery evidence of "the seriousness of [Petitioner's] stenosis." Id.

With regard to the signal abnormality seen on MRI at C6/7, Dr. Lancaster opined it "is of uncertain cause and it is also unclear how long this signal change may have been present." Resp. Ex. C at 2. Without further explanation or support, Dr. Lancaster opined the signal abnormality at C6/7 "is not . . . clear evidence of an inflammatory spinal cord process." Id.

Next, Dr. Lancaster opined Petitioner's thumb paresthesias "most likely reflect[s] involvement of the C6 nerve roots and associated areas of spinal cord from spinal stenosis and foraminal stenosis." Resp. Ex. C at 2. In support of his opinion, he relied upon Petitioner's EMG,[55] and found evidence of a C6 radiculopathy and "did not find evidence of the most likely alternative cause of hand numbness (carpal tunnel syndrome)." Id. at 2-3. Notably, Dr. Lancaster, unlike Dr. Fadugba, did not opine that Petitioner's carpel tunnel syndrome caused his thumb paresthesias.

Dr. Lancaster questioned the diagnosis of TM because Dr. Napoli treated Petitioner with steroids in October 2017, several months after Petitioner's symptom onset around March 30, 2017. Resp. Ex. C at 3. Dr. Lancaster explained, "[TM] should be a self-limited inflammatory process that terminates within several weeks (although damage may persist afterwards). Treating with high dose steroids many months later is therefore not logical if Petitioner had inflammatory [TM] in March 2017." Id. Dr. Lancaster did not provide literature or other evidence to support his opinion that treatment with steroids "many months" after onset of TM is "not logical." In fact, Scott et al.,[56] who provided recommendations for diagnostic testing and therapies for TM, found steroids are "typically the first treatment offered" to TM patients. Resp. Ex. C, Tab 4 at 4-5. They explained that despite the "insufficient evidence to determine the

[54] Nicholas Theodore, Degenerative Cervical Spondylosis, 383 New Eng. J. Med. 159 (2020). Although Respondent filed this article, Dr. Lancaster did not discuss or reference this article in his report.

[55] The November 2017 EMG revealed findings suggestive of "a mild right ulnar mononeuropathy" and "a chronic right C6 radiculopathy." Pet. Ex. 3 at 12, 28-30.

[56] Although Respondent filed this article, Dr. Lancaster did not discuss or reference this article in his report.

utility of corticosteroids in alleviating TM attacks[,] . . . administration of high-dose IV methylprednisolone (1 g[ram] daily for 3 to 7 days) is typically the first treatment offered to hasten recovery, reduce disease activity, and restore neurologic function." Id. The authors did not note whether there is a timeline during which steroids should be administered after onset, nor did they opine on an outside time frame after which administration of steroids would be too late.

Additionally, he argued that simply because Dr. Napoli found Petitioner benefitted from treatment with steroids, does not mean Petitioner had TM. Resp. Ex. C at 3. Dr. Lancaster noted "cord inflammation from compression can also get better with steroids, or with conservative treatment." Id.

Lastly, he found no "convincing data to support an inflammatory cause of [Petitioner's] symptoms." Resp. Ex. C at 3. Although "[m]any of these tests were not done," he opined no test showed "inflammation in the spinal fluid, oligoclonal bands, or specific antibodies associated with autoimmune myelitis." Id. He concluded an "[i]nflammatory [TM] is unlikely to have occurred." Id. at 4.

**ii. Althen Prong One**

Dr. Lancaster opined that there is no evidence to support Dr. Napoli's theory that the Tdap vaccine can cause TM via molecular mimicry. Resp. Ex. C at 3-4.

With regard to the mechanism of molecular mimicry posited by Dr. Napoli, Dr. Lancaster opined Dr. Napoli's argument is too broad and arbitrary, stating that "Dr. Napoli's standard could be applied [] to any autoimmune condition and any vaccine." Resp. Ex. C at 3. He added "there is no specific mimic proposed in the vaccine and no specific target antigen proposed in the human nervous system," and thus, this is not a reasonable standard for a theory of causation. Id. He found it would be unreasonable to accept Dr. Napoli's theory because "then we have to accept any vaccine—to a more likely than not standard—causes every autoimmune disease that occurs afterwards." Id. Instead, Dr. Lancaster opined specific antigens from the vaccine and specific antigens within the human body must be identified to substantiate the mechanism of molecular mimicry in this case. Id.

Dr. Lancaster opined that any discussion of different vaccines and disorders are not relevant to this case. Resp. Ex. C at 3. He found only the discussions pertaining to Tdap and TM to be relevant. Id.

Citing Baxter et al., an article also cited by Dr. Fadugba, Dr. Lancaster opined "it is not clear that there is any actual increased risk of [TM] after vaccination with [Tdap]." Resp. Ex. C at 3 (citing Resp. Ex. A, Tab 2). Dr. Lancaster opined Baxter et al. "found no correlation between [TM] and vaccination." Id. (citing Resp. Ex. A, Tab 2 at 1). But, as Baxter et al. and

Dr. Lancaster noted, in 2012, the IOM[57] found "[t]he evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and [TM]." Id. (quoting Resp. Ex. C, Tab 2 at 3); see also Resp. Ex. A, Tab 2 at 1.

Dr. Lancaster concluded "[t]here is no reliable evidence that [Tdap] vaccination causes [TM]" and "[t]here is no evidence that molecular mimicry actually occurs between [Tdap] vaccination and any antigen relevant to [TM]." Resp. Ex. C at 4.

### iii. Althen Prong Two

Dr. Lancaster opined there is no evidence that via molecular mimicry, Petitioner's Tdap vaccine caused him to develop TM. Resp. Ex. C at 3-4. He also opined that an "[i]nflammatory [TM] is unlikely to have occurred" here and that the Tdap vaccine is "unlikely to be the cause of Petitioner's injury." Id. at 4.

Dr. Lancaster maintained that Petitioner's symptoms are a result of Petitioner's cervical spinal stenosis for the reasons stated above in his diagnosis section. Resp. Ex. C at 3-4.

### iv. Althen Prong Three

Dr. Lancaster agreed that on approximately March 30, 2017, Petitioner developed new symptoms of neck pain, pain and parethesias radiating down both arms, and weakness of the right arm and leg. Resp. Ex. C at 2. Dr. Lancaster opined this onset is outside a reasonable time period for both cervical spinal cord stenosis and TM. Id. at 2-4.

For cervical spinal cord stenosis, Dr. Lancaster did not provide support or additional explanation to support his statement.

For TM, he noted Baxter et al. used a four-week onset as their "upper limit," which he found more reasonable than Dr. Napoli's up to nine- to ten-week window. Resp. Ex. C at 3 (citing Resp. Ex. A, Tab 2 at 1-2). Therefore, he opined Petitioner's onset does not fall within a reasonable time period based on Baxter et al. Id. However, Baxter et al. used two exposure windows: (1) 5-28 days and (2) 2-42 days. Resp. Ex. A, Tab 2 at 1-2. Thus, the authors examined cases of TM up to six weeks, or 42 days, post-vaccination. Id. As Dr. Lancaster explained, Petitioner's symptom onset was on or around March 30, 2017, which is five weeks post-vaccination, and within the six-week, or 42-day, exposure window used by Baxter et al. See Resp. Ex. C at 2; Resp. Ex. A, Tab 2 at 1-2.

[57] Inst. of Med., Diphtheria Toxoid-, Tetanus Toxoid-, and Acellular Pertussis-Containing Vaccines, in Adverse Effects of Vaccines: Evidence and Causality 525, 547-48 (Kathleen Stratton et al. eds., 2012). Respondent filed only two pages of this chapter; however, this text is well known to the undersigned.

## IV. DISCUSSION

### A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, Petitioner must prove 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, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

### B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records, "in general, warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting 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))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

There are situations in which compelling 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) ("[L]ike 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 v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[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 v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded to medical records, special masters are not rigidly bound by those records in determining onset of a petitioner's symptoms. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

### C. Causation

To receive compensation through the Program, a petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must

show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege he suffered a Table Injury, he must prove a vaccine he received caused his injury. To do so, Petitioner must establish, by preponderant evidence: "(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." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d. 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor).

"Expert medical testimony which merely expresses the possibility—not the probability—of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred." LaCour v. Sec'y of Health & Hum. Servs., No. 90-316V, 1991 WL 66579, at *5 (Fed. Cl. Spec. Mstr. Apr. 15, 1991); accord Burns v. Sec'y of Health & Hum. Servs., No. 90-953V, 1992 WL 365410, at *6 (Fed. Cl. Spec. Mstr. Nov. 6, 1992), aff'd, 3 F.3d 415. The Federal Circuit has likewise made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

## V. DIAGNOSIS ANALYSIS

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since "each prong of the Althen test is

decided relative to the injury[,]" determining facts relating to the claimed injury can be significant in a case like this, where Petitioner's diagnosis is at issue. Id. Thus, before determining if Petitioner has met each prong of Althen, the undersigned addresses whether Petitioner has established, by a preponderance of the evidence, that Petitioner suffers from TM.

The undersigned finds Petitioner suffers from TM. First, a brief review of Petitioner's medical records show Petitioner's treating physicians diagnosed him with TM, a demyelinating disease of the central nervous system.[58] On February 24, 2017, Petitioner received a Tdap vaccination. Petitioner first reported neurologic symptoms that began on March 30, 2017 to his primary care physician, Dr. Hedde, on April 7, 2017. The experts agree Petitioner had no neurologic symptoms prior to March 30, 2017.

Petitioner's July 2017 MRI revealed increased T2 weighted signal at C3/4, abnormal bilateral cervical hemicord signal at C4/5, and punctate T2 hyperintense signal of the left cervical hemicord at the C6/7.

On September 8, 2017, Petitioner saw neurosurgeon, Dr. Geiger. His physical examination found light touch symmetrical paresthesias in a C6 distribution in the upper extremities, positive Hoffman's bilaterally, and positive Babinski bilaterally. After reviewing the July 2017 MRI, Dr. Geiger opined that Petitioner's condition appeared "consistent with a demyelination pattern or myelitis." Pet. Ex. 9 at 19. Dr. Geiger assessed Petitioner with acute TM and a cervical disc disorder.

Petitioner then presented to neurologist Dr. Napoli on September 20, 2017. Dr. Napoli's physical examination revealed bilateral Babinski and Hoffman's and plantar reflexes downgoing bilaterally. Dr. Napoli diagnosed Petitioner with myelitis, demyelinating disease of the central nervous system, and cervical disc disease.

Additional MRIs were ordered. Dr. Samir Semine, a radiologist, interpreted Petitioner's October 10, 2017 cervical spine MRI as showing hyperintense foci, that "are not associated with central stenosis and may be a reflection of primary demyelinating disease." Pet. Ex. 3 at 39.

Thereafter, since October 2017, Petitioner's treating physicians' diagnosis remained TM, a demyelinating disease of the central nervous system, or myelitis. See Pet. Ex. 3 at 17, 22 (myelitis); Pet. Ex. 9 at 16 (acute TM in demyelinating disease of central nervous system); Pet. Ex. 9 at 3 ("[TM] type syndrome"); Pet. Ex. 2 at 11 (TM); Pet. Ex. 3 at 11 (myelitis and demyelinating disease of the central nervous system); Pet. Ex. 3 at 9 (myelitis); Pet. Ex. 3 at 6 (demyelinating disease of central nervous system and myelitis). Thus, three different specialists—Dr. Napoli (neurologist), Dr. Geiger (neurosurgeon), and Dr. Semine (radiologist)—all agreed that Petitioner had a demyelinating disease, myelitis, or TM. And Petitioner's medical records consistently reflect a diagnosis of TM.

[58] Petitioner's treating physicians also used "myelitis" at times. Myelitis is the "inflammation of the spinal cord, often part of a more specifically defined disease process." Myelitis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=32680 (last visited Sept. 29, 2022).

Although Petitioner's treating physicians also agreed Petitioner had degenerative cervical disc disease, the undersigned finds that diagnosis does not negate their opinions regarding TM. When assessing Petitioner, Petitioner's treating physicians considered whether Petitioner had a demyelinating myelitis and/or a degenerative cervical disc disease. Petitioner's treating physicians did not believe Petitioner's neurologic symptoms could be attributed solely to his cervical disc disease.

For example, on September 20, 2017, Dr. Napoli acknowledged "[t]here was some evidence of stenosis around the level of C4," but after discussion with Dr. Geiger, "he [did] not believe this [was] a compressive lesion and [] wonder[ed] about possible vaccine [induced] myelitis." Pet. Ex. 3 at 25. After reviewing additional MRIs done in October 2017, Dr. Napoli continued to suspect a "vaccine induced myelitis" due to "demyelinating lesion at C4-C5 as well as lesion at a level lower than that around C6-C7." Id. at 22. He spoke "with [Petitioner's] neurosurgeon at previous visit [and] d[id] not suspect that this was a compressive disc." Id. At a follow up on October 19, 2017, Dr. Napoli continued to attribute Petitioner's symptoms to "a vaccine induced demyelination," but also encouraged Petitioner to undergo further evaluation regarding Petitioner's cervical disc disease causing stenosis. Id. at 17. After Petitioner underwent ACDF surgery in January 2018, Dr. Geiger, in April 2018, noted that Petitioner's condition was "likely due to the inciting post-injection reaction since both the area of the compression and the non-compressed area below are involved." Pet. Ex. 9 at 3. He also stated Petitioner was "[s]till symptomatic and myelopathic from the [TM] type syndrome following the injection" and that the "[c]ord compression [was] resolved." Pet. Ex. 9 at 4.

Respondent's expert, Dr. Fadugba, opined Petitioner did not meet the TM Consortium Working Group's TM diagnosis because of his cervical stenosis. Additionally, Respondent's expert, Dr. Lancaster, attributed Petitioner's primary neurologic symptoms to his cervical disc compression. However, Dr. Fadugba and Dr. Lancaster failed to acknowledge that Petitioner's treating physicians understood that Petitioner had two distinct conditions: cervical disc disease and TM. Additionally they failed to acknowledge that after Petitioner underwent spinal surgery, his neurosurgeon, Dr. Geiger, opined Petitioner's cord compression was resolved. Petitioner, however, continued to suffer neurologic symptoms.

Further, the undersigned finds Dr. Fadugba's opinions less persuasive here, as she is not a neurologist or a neurosurgeon and has no neurology experience. In contrast, Dr. Geiger and Dr. Napoli were Petitioner's treating physicians and a neurosurgeon and neurologist, respectively.

Although Dr. Lancaster opined the cord signal abnormality at C4/5 shown on MRI "is almost certainly due to cervical spinal stenosis" because it would be an "improbable coincidence" for Petitioner to have "severe cervical stenosis at this level and cord inflammation from another cause," he did not provide evidence or other support as to why an adult with degenerative disc disease could not also have TM. Resp. Ex. C at 2. Nor did he explain the signal abnormality at C6/7. The undersigned does not find Dr. Lancaster's conclusory statements, without more, persuasive.

Even though Dr. Lancaster believes it "improbable" that Petitioner could have two illnesses, cervical disc disease (cervical stenosis) and a demyelinating myelitis, it also seems improbable that three different specialists (a neurosurgeon, a neurologist, and a radiologist) would review Petitioner's MRI studies and all conclude that he had a demyelinating lesion if the Petitioner's clinical course and images were not consistent with such findings.

Respondent's expert, Dr. Fadugba, opined TM is not the correct diagnosis because Petitioner's treating physicians did not exhaust all diagnostic testing. Again, Dr. Fadugba's opinion on this point is not persuasive as she is not a neurologist or neurosurgeon. The fact that a lumbar puncture for CSF analysis was not done does not negate the findings seen on MRI and the clinical course consistent with those findings.

Dr. Fadugba also opined Petitioner did not have TM because he exhibited confounding factors, such as persistent hand symptoms, leading to an ultimate diagnosis of carpal tunnel syndrome. Petitioner underwent an EMG/NCS in November 2017 that did not show significant carpal tunnel syndrome or radiculopathy. Petitioner was not diagnosed with carpal tunnel syndrome until 2020, after seeing hand specialist Dr. Webber,[59] almost three years after onset of his neurologic symptoms.

Moreover, in Theodore, an article filed by Respondent, the author noted that with a cervical degenerative myelopathy, inflammation and edema of the spinal cord "lead to slow, progressive deterioration of neurologic function" due to compression. Resp. Ex. C, Tab 5 at 3-4. By contrast, TM is an acute condition. Petitioner's clinical course was characterized by an acute onset. It is important to distinguish between a "slow, progressive deterioration of neurologic function" versus the sudden, acute onset of neurologic symptoms in this case.

For the reasons described above, the undersigned finds by preponderant evidence that Petitioner's diagnosis after vaccination was TM. He also had degenerative disc disease, but Petitioner is not claiming that condition is vaccine-related.

## VI. CAUSATION ANALYSIS

### A. Althen Prong One

Under Althen Prong One, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the

[59] An additional EMG was ordered in March 2020, but it is not clear whether Petitioner underwent this EMG.

offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

Regarding Althen prong one, the undersigned finds Petitioner has provided preponderant evidence that the Tdap vaccine can cause TM and that molecular mimicry is a sound and reliable causal theory. There are several reasons for this finding, including expert opinions, medical literature, and other reasoned decisions in the Program.

Petitioner's expert, Dr. Napoli, opined the Tdap vaccine can cause TM via molecular mimicry. Dr. Napoli asserted molecular mimicry "is a well-known response in immunology," and "[t]he theory of molecular mimicry relating to autoimmune diseases such as [TM] is well-published and supported in the medical community." Pet. Ex. 13 at 5-6. He explained, "If the antigen present on the vaccine shares any homologies with host antigen, then immune response will be directed at both the injected antigens and host antigen leading to an autoimmune response." Id. at 5. For additional support, he cited Olsen et al. and Agmon-Levin et al., who both described the mechanism of molecular mimicry and found it to be the "most common" or "postulated" mechanism by which infectious agents or vaccinations cause autoimmune diseases like TM. Pet. Ex. 18 at 4; Pet. Ex. 22 at 1.

Dr. Fadugba challenged Dr. Napoli's theory, asserting that "[i]nfection and vaccination are not analogous." Resp. Ex. A at 8. However, Dr. Fadugba provided no literature or other evidence to refute the Petitioner's proposition that antigens formed by infection and those formed by vaccination are similar with regard to the mechanism at play. As explained in Agmon-Levin et al., a "host's response to a vaccine, originally generated to produce protective immunity, is similar to its response to an infectious invasion." Pet. Ex. 18 at 4.

Additionally, Dr. Fadugba asserts that four criteria must be fulfilled in order to find molecular mimicry is the mechanism at play. The criteria include supportive epidemiology, identification of antibodies directed against human antigens, identification of the mimics of the target antigen, and reproduction in an animal model. Dr. Lancaster also opined that specific antigens from the vaccine and specific antigens within the human body must be identified to substantiate the mechanism of molecular mimicry in this case. However, Petitioner need not make a specific type of evidentiary showing with epidemiology. Capizzano, 440 F.3d at 1325. Given the state of current scientific knowledge, there is no way that a petitioner could satisfy these criteria. Further, fulfilment of these criteria would require scientific certainty, which is a bar too high. See Knudsen, 35 F.3d at 549 (explaining that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program").

Studies cited by Petitioner acknowledge that TM has been associated with vaccination. See, e.g., Pet. Ex. 18 at 1 ("The pathogenesis of [TM] is mostly of an autoimmune nature, triggered by various environmental factors, including vaccination."). Pidcock et al. examined 47 cases of acute TM and found 13 of the 47 cases received a vaccine, including the DTP vaccine,

or allergy shot within 30 days of onset. Similarly, Agmon-Levin et al. reviewed 37 cases of TM post-vaccination, including post-DTP and post-DT vaccination, and found 30 of the 37 cases developed symptoms of TM within two months after vaccination. Agmon-Levin et al. discussed mechanisms by which vaccines may induce TM, and noted molecular mimicry to be "the most common mechanism." Pet. Ex. 18 at 4.

Dr. Napoli cited case reports of TM associated with tetanus toxoid booster, DT, and DTaP. In Read et al., the patient received a tetanus toxoid booster. Ten days later, he was diagnosed with a viral illness, and 12 days after, he presented with neurologic symptoms and was diagnosed with TM. The authors concluded that the temporal association and lack of any other cause implicated the tetanus vaccination. Another case report, by Whittle and Robertson, described the case of patient who received DT and oral polio vaccines prior to TM onset.

And Riel-Romero described a case of a patient who developed TM 17 days after DTaP vaccination. The authors hypothesized that their patient's TM was caused by vaccination. They found an immune-mediated process to be at play, specifically noting molecular mimicry as a postulated mechanism.

Generally, case reports and literature reviews citing cases are insufficient to prove causation. However, in the context of rare conditions, where robust epidemiology studies are not available, they provide some evidence of causation. And here, where the medical literature reported TM cases associated with vaccines containing tetanus and/or diphtheria components, this evidence weighs in favor of causation.

Lastly, molecular mimicry has been accepted as a sound and reliable theory for many demyelinating conditions, including TM, in the Vaccine Program. See, e.g., Palattao v. Sec'y of Health & Hum. Servs., No. 13-591V, 2019 WL 989380, at *35-37 (Fed. Cl. Spec. Mstr. Feb. 4, 2019) (noting "many of the existing Program decisions in which TM has been found to be caused by a vaccine rely on a mechanism [of] []molecular mimicry"); Raymo v. Sec'y of Health & Hum. Servs., No. 11-0654V, 2014 WL 1092274, at *21 (Fed. Cl. Spec. Mstr. Feb. 24, 2014) (former Chief Special Master Denise Vowell concluding molecular mimicry explained how the tetanus vaccine can cause TM); Roberts v. Sec'y of Health & Hum. Servs., No. 09-427V, 2013 WL 5314698, at *6-7 (Fed. Cl. Spec. Mstr. Aug. 29, 2013) (finding the Petitioner entitled to compensation in a Tdap/TM case with the theory of molecular mimicry); see also Bowes v. Sec'y of Health & Hum. Servs., No. 01-481V, 2006 WL 2849816 (Fed. Cl. Spec. Mstr. Sept. 8, 2006). Compare Palattao, 2019 WL 989380, at *35-37 (Chief Special Master Corcoran denying entitlement in a TM case where the facts did not support application of molecular mimicry), with I.J. v. Sec'y of Health & Hum. Servs., No. 16-864V, 2022 WL 277555, at *4-7 (Fed. Cl. Spec. Mstr. Jan. 4, 2022) (Chief Special Master Corcoran finding Petitioner entitled to compensation on remand in a Tdap/TM case that relied upon the theory of molecular mimicry).

While the above cases are not binding here, the undersigned agrees with the reasoning of other special masters who have found molecular mimicry to be a sound and reliable mechanism to explain how the Tdap vaccine can cause TM.

Accordingly, for all of the reasons discussed above, the undersigned finds that Petitioner has satisfied his burden under Althen prong one.

### B. Althen Prong Two

Under Althen Prong Two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical 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 trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, Petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

With regard to the second Althen prong, the undersigned finds there is preponderant evidence in the record to support a logical sequence of cause-and-effect showing the February 24, 2017 Tdap vaccine to be the cause of Petitioner's TM. See Althen, 418 F.3d at 1278.

Here, the records show a clinical course consistent with the mechanism and time frame within which TM can occur following vaccination. To summarize, Petitioner received a Tdap vaccine on February 24, 2017 and reported to his primary care physician, Dr. Hedde, that he developed neurological symptoms on March 30, 2017. Dr. Hedde's assessment in July 2017 included neuropathy. On September 8, 2017, Petitioner first presented to neurosurgeon, Dr. Geiger, whose assessment was acute TM. Petitioner then presented to neurologist Dr. Napoli on September 20, 2017, where Petitioner was diagnosed with myelitis and demyelinating disease of the central nervous system. Petitioner's cervical spine MRI, conducted in October 2017, revealed abnormalities consistent with demyelinating disease.

Additionally, Petitioner's treating physicians related Petitioner's TM to his Tdap vaccine. For example, Dr. Napoli, as Petitioner's treating neurologist, found Petitioner "sustained a vaccine induced myelitis." Pet. Ex. 3 at 22; see also Pet. Ex. 3 at 25 (writing he "wonder[ed] about possible vaccine [induced] myelitis"); Pet. Ex. 3 at 17 ("[Petitioner] does appear to have vaccine induced myelitis . . . . [H]is symptoms appear to be consistent with a vaccine induced demyelination . . . ."); Pet. Ex. 3 at 11 ("[Petitioner] has what we presume to be a post vaccine myelitis."); Pet. Ex. 3 at 9 (stating he believed that Petitioner's issue was "a post vaccine issue"); Pet. Ex. 3 at 6 (indicating he "suspect[ed] previous vaccine induced myelitis"). Dr. Geiger, as

Petitioner's treating neurosurgeon, also related Petitioner's condition to vaccination. See Pet. Ex. 9 at 3-4 (noting Petitioner's "[TM] type syndrome" was "likely due to the inciting post-injection reaction"). Lastly, Dr. Hedde, Petitioner's primary care physician listed Tdap as an allergy, writing "? adverse reaction given [TM]." Pet. Ex. 2 at 9.

Petitioner's sudden and acute onset of symptoms is also consistent with the case reports cited by Dr. Napoli. In all three case reports, Read et al., Whittle and Robertson, and Riel-Romero, the patients developed symptoms of TM within two to three weeks of vaccination and the symptoms were consistent with sudden onset paralysis. While onset in these cases was closer in time to vaccination, the rate at which symptoms appeared is similar to Petitioner's presentation.

Lastly, there is no evidence of an alternative cause. Petitioner did not have any signs or symptoms of an infection around the time of onset. Nor was he diagnosed with any infection or any other autoimmune condition. There is evidence that Petitioner has degenerative disc disease. However, as described above in the diagnosis section, these diagnoses are two separate conditions. Dr. Geiger found his cord compression resolved, while Petitioner's neurological symptoms continued. Thus, Petitioner's cervical disc disease cannot explain his continued neurologic symptoms. Nor can a 2020 diagnosis of carpal tunnel syndrome explain Petitioner's neurologic symptoms that began in 2017.

Accordingly, the undersigned finds that Petitioner has satisfied his burden under Althen prong two.

### C. Althen Prong Three

Althen Prong Three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been defined as a "medically acceptable temporal relationship." Id. The Petitioner must offer "preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542; see Pafford, 451 F.3d at 1358.

Petitioner received his Tdap vaccination on February 24, 2017. In his declaration, Petitioner reported his neurological symptoms began the morning of March 31, 2017. The experts agree Petitioner's symptoms began on March 30 or March 31, 2017. Based on the most contemporaneous-in-time medical records, and consistent with the experts' opinions, the undersigned finds Petitioner's onset of TM to be on March 31, 2017, which is 35 days, or five weeks, post-vaccination.

This timing is within Dr. Napoli's six-week period, consistent with molecular mimicry. Dr. Napoli opined the IOM found "an increased risk of autoimmunity primarily concentrated within the first six weeks after vaccination." Pet. Ex. 13 at 6 (citing Pet. Ex. 21 at 5).

Schonberger et al. found an increased risk of GBS within five weeks following flu vaccination, and noted an "increased incidence of demyelinating injury was seen up to 9 or 10 weeks following vaccination." Id. (citing Pet. Ex. 20 at 1).

In Agmon-Levin et al., the authors found 30 of the 37 TM cases reported onset within the first two months after vaccination. And Pidcock et al. found 13 of the 47 acute TM cases received a vaccine or allergy shot within 30 days of onset.

Additionally, this timing is within the 42-day risk interval used in Baxter et al. Although the authors found "no statistically significant increased risk" of TM post-vaccination within the 2- to 42-day risk interval, the authors did find cases of TM that occurred within and outside of this interval.

While 35 days is five days outside the time frame of 30 days in Pidcock et al., it is exceedingly close, and within the two-month period in Agmon-Levin et al. and the 42-day interval in Baxter et al. See Paluck v. Sec'y of Health & Hum. Servs., 786 F.3d 1373, 1383-84 (Fed. Cir. 2015) (finding the "special master [] erred in setting a hard and fast deadline . . . between vaccination and [] onset"). Therefore, it reasonable and appropriate to find that the onset of Petitioner's TM is within the appropriate time frame given the mechanism of molecular mimicry.

Therefore, the undersigned finds the temporal association is appropriate given the mechanism of injury and Petitioner has satisfied the third Althen prong.

### D. Alternative Causation

Because the undersigned concludes that Petitioner has established a prima facie case, Petitioner is entitled to compensation unless Respondent can put forth preponderant evidence "that [Petitioner's] injury was in fact caused by factors unrelated to the vaccine." Whitecotton v. Sec'y of Health & Hum. Servs., 17 F.3d 374, 376 (Fed. Cir. 1994), rev'd on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007). As discussed above in the analysis related to Althen Prong Two, the undersigned found Respondent failed to show that Petitioner's TM was caused by a source other than vaccination. Specifically, the undersigned does not find that Petitioner's cervical disc disease was the cause of his TM. Thus, Respondent did not prove by a preponderance of evidence that Petitioner's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

## VII. CONCLUSION

For the reasons discussed above, the undersigned finds that Petitioner has established, by preponderant evidence, that his Tdap vaccine caused his TM. Therefore, Petitioner is entitled to compensation. A separate damages order will issue.

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**
Nora Beth Dorsey
Special Master