OFFICE OF SPECIAL MASTERS

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PUBLISH

PATRICIA ANN D. WALTHER, D.V.M., Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	No. 00-0426V Remand; Acute Disseminated Encephalomyelitis (ADEM); Causation

DECISION ON REMAND[1]

The case is before the special master on remand from the United States Court of Appeals for the Federal Circuit (Federal Circuit). *See Walther v. Secretary of HHS*, 485 F.3d 1146 (Fed. Cir. 2007). The Federal Circuit held that in his initial unpublished decision denying petitioner's claim under the National Vaccine Injury Compensation Program (Program),[2] issued on July 29, 2005, the special master "appeared to apply an incorrect legal standard," *Walther*, 485 F.3d at 1152, by requiring petitioner, Patricia Ann D. Walther, D.V.M. (Dr. Walther), to "eliminate alternative causes to carry her burden to establish a *prima facie* case." *Id.* at 1148. The Federal Circuit iterated that the "statutory text more naturally places the burden on" respondent "to establish that there is an alternative cause by a preponderance of the evidence." *Id.* at 1150, citing § 300aa-13(a)(1)(B); *see also Althen v. Secretary of HHS*, 418 F.3d 1274, 1281-82 (Fed. Cir. 2005); *Knudsen v. Secretary of*

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[1] As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" will be available to the public. *Id.*

[2] The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

HHS, 35 F.3d 543, 547 (Fed. Cir. 1994), citing *Whitecotton v. Secretary of HHS*, 17 F.3d 374, 376 (Fed. Cir. 1994). The Federal Circuit directed the special master to "reconsider the causation issue under the correct legal standard." *Walther*, 485 F.3d at 1153.

The Federal Circuit authorized "other proceedings not inconsistent with" the Federal Circuit's "opinion." *Walther*, 485 F.3d at 1153. The Federal Circuit noted that the special master did not address respondent's "main contention" regarding Dr. Walther's putative diagnosis in his July 29, 2005 decision. *Id.* Therefore, the special master solicited briefs on the medical characterization of Dr. Walther's condition. *See Walther v. Secretary of HHS*, No. 00-0426V, Order of the Special Master (Fed. Cl. Spec. Mstr. Aug. 9, 2007). In addition, the Federal Circuit stated that "on the question of *causation*," Dr. Walther "relied on" a "report" from Marcel Kinsbourne, M.D. (Dr. Kinsbourne).[3] *Walther*, 485 F.3d at 1147 (emphasis added). However, Dr. Walther did not present testimony on causation from Dr. Kinsbourne during a hearing on entitlement in May 2005. *See, e.g.*, Transcript (Tr.I), filed June 22, 2005, at 40, 44, 241-58.[4] Therefore, the special master convened a hearing in October 2007 to afford Dr. Walther the opportunity to adduce Dr. Kinsbourne's testimony on causation. *See generally* Transcript (Tr.II), filed November 29, 2007. Dr. Walther's primary medical expert, Vera Byers, M.D. (Dr. Byers),[5] and respondent's primary medical expert, Arthur Safran, M.D. (Dr. Safran),[6] testified at the second hearing, too. *See generally* Tr.II.

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[3] Dr. Kinsbourne received his medical degree from Oxford University in England. Petitioner's exhibit (Pet. ex.) 54 at 1. He is a Member of the Royal College of Physicians. *Id.* In addition, he is certified by the American Board of Pediatrics. *Id.* He belongs to the American Neurological Association and to the Child Neurology Society. *Id.* at 4.

[4] Dr. Walther retained Dr. Kinsbourne to render an opinion rebutting respondent's assertions questioning the diagnosis of Dr. Walther's condition. *See, e.g.*, *Walther v. Secretary of HHS*, No. 00-0426V, Order of the Special Master (Fed. Cl. Spec. Mstr. July 2, 2004); *Walther v. Secretary of HHS*, No. 00-0426V, Order of the Special Master (Fed. Cl. Spec. Mstr. Nov. 17, 2004); Pet. ex. 53; Petitioner's Pretrial Memorandum (P. Memo I), filed May 11, 2005, at 14; Tr.I at 39-40, 44, 194-95, 254.

[5] Dr. Byers received her medical degree from the University of California at San Francisco. Pet. ex. 48 at 5. She is certified by the American Board of Internal Medicine. *Id.* at 6. She completed a Fellowship in Clinical Immunology at the Department of Medicine, University of California at San Francisco. *Id.* at 5. She is a Fellow of the American Academy of Allergy and a member of the American Association of Immunologists. *Id.* at 6.

[6] Dr. Safran received his medical degree from New York University. Respondent's exhibit (R. ex.) C at 1. He is certified by the American Board of Internal Medicine and by the American Board of Psychiatry and Neurology. *Id.* He is a Fellow of the American Academy of Neurology. *Id.*

BACKGROUND

Dr. Walther was born on March 14, 1968. *See* Pet. ex. 1 at 1. Upon receiving a degree in veterinary medicine from The Ohio State University College of Veterinary Medicine in 1994, *see, e.g.*, Pet. ex. 30 at 15, Dr. Walther commenced military service in the United States Army Veterinary Corps. *See, e.g.*, Pet. ex. 30 at 2. While stationed at Travis Air Force Base, California, where she was Chief, Travis Branch Veterinary Treatment Facility, Dr. Walther received the Junior Veterinary Corps Officer of the Year award, as well as an Air Force Commendation Medal, in early 1997. *See, e.g.*, Pet. ex. 30 at 3-6.

In March 1997, a physician determined apparently that Dr. Walther exhibited "bilateral carpal tunnel syndrome." *See* Pet. ex. 41 at 83; *see also* Pet. ex. 39 at 50.[7]

In Spring 1997, Dr. Walther presented to Stuart Gherini, M.D. (Dr. Gherini), a "specialist of the ear," expressing concerns "about dizziness" and "light sensitivity" that "began in November" 1994 following a transfer "to California." Pet. ex. 41 at 88.[8] Dr. Walther recounted that she experienced "an in-and-out sensation throughout the day," as if she "were drifting as aboard a ship," approximately "three times a week." *Id.* Dr. Walther denied "double or blurred vision or blindness, numbness of the face or arms or legs, weakness of the arms or legs, clumsiness, confusion, dysphagia, or dysarthria." *Id.* According to Dr. Gherini, "[a]n M[agnetic]R[esonance] scan of the brain in December 1994 was reportedly normal," *id.*, excluding a "significant central pathology" for Dr. Walther's symptoms. *Id.* at 89. Dr. Gherini suspected that Dr. Walther suffered "a mild vestibulopathy," perhaps "allergy[-]related." *Id.* Dr. Gherini prescribed a medication for "allergic rhinitis." *Id.*

Based upon Dr. Walther's "[positive] PPD" in Spring 1997, a pulmonologist instituted isoniazid (INH) on June 4, 1997. Pet. ex. 4 at 1; *see also* Pet. ex. 41 at 11, 84. Approximately two weeks later, Dr. Walther felt "excessively tired," Pet. ex. 41 at 11, described as "insomnia," *id.* at 84, and "altered," *id.* at 11, described as "light-headedness and forgetfulness." *Id.* at 84. The pulmonologist attributed Dr. Walther's symptoms to INH. *See* Pet. ex. 41 at 11. The pulmonologist discontinued INH, instituting instead "Rifampin" on June 16, 1997. Pet. ex. 41 at 11; *see also id.* at 84.

On July 31, 1997, Dr. Walther reported for duty at South Atlanta Veterinary Services Support District, Fort Stewart, Georgia. *See* Pet. ex. 41 at 90. As part of her processing, Dr. Walther received yellow fever vaccine, typhoid vaccine, tetanus-diphtheria (Td) vaccine and meningococcal (MGC) vaccine on July 31, 1997. *See* Pet. ex. 3 at 4-5. In addition, Dr. Walther received rabies vaccine on August 5, 1997, on August 13, 1997, and, ostensibly, on August 26, 1997. *See* Pet. ex. 5 at 1.

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[7] No notes of the examination are available.

[8] No notes of examinations prompting a referral to Dr. Gherini are available. In addition, only typewritten correspondence summarizing Dr. Gherini's examination is available.

On September 19, 1997, Scott Ring, M.D. (Dr. Ring), evaluated Dr. Walther for "symptoms of carpal tunnel since "Mar[ch] [']97." Pet. ex. 39 at 50.[9] Dr. Ring offered a "provisional diagnosis" of "carpal tunnel bilateral." *Id.* Dr. Ring referred Dr. Walther for a "nerve conduction test - E[lectro]M[yo]G[raph." *Id.*

On October 16, 1997, R. Kandala, M.D. (Dr. Kandala), examined Dr. Walther before performing a nerve conduction study (NCS). *See* Pet. ex. 39 at 50-51. According to Dr. Kandala, Dr. Walther described "hand paresthesias," more pronounced on the "L[eft]" side than the "R[ight" side, that began in "March [']97." Pet. ex. 39 at 50. Dr. Walther indicated that her symptoms had worsened since August 15, 1997. *See id.* Dr. Walther related "problems [with] hand grip/fine movements" and "lightening[-]like sensations." *Id.* However, Dr. Walther denied "neck or shoulder pain." *Id.*; *see also* Pet. ex. 8 at 1.

Dr. Kandala "detected" a "[positive] Tinel's" on one of Dr. Walther's sides and "D[eep]T[endon]R[eflex]s" at "2+ (Brisk)," but "no Babinski." Pet. ex. 39 at 50. Dr. Kandala identified "no EMG/NCS evidence suggestive of bilateral median or ulnar neuropathies." *Id.*; *see also id.* at 51. Based upon Dr. Walther's "constellation of symptoms," Dr. Kandala recommended a "Neurology consult." Pet. ex. 39 at 50; *see also* Pet. ex. 8 at 1. In his consultation request, Dr. Kandala questioned a "central etiology or cerebellar etiology for" Dr. Walther's complaints. Pet. ex. 8 at 1.

On October 22, 1997, Seth Stankus, D.O. (Dr. Stankus), a neurologist, assessed Dr. Walther for "U[pper]E[xtremity] weakness." Pet. ex. 8 at 2. In his comprehensive history of Dr. Walther's condition, Dr. Stankus noted that Dr. Walther had received treatment "for presumed B[ilateral] C[arpal]T[unnel]S[yndrome]" after "she developed paresthesias" in her "hands." *Id.* Dr. Stankus understood that Dr. Walther's symptoms of carpal tunnel syndrome had "waxed [and] waned for [approximately] 3 months" until "mid-August [']97," when Dr. Walther experienced "hand weakness," accompanied by "[increased] hand paresthesias, [increased] numbness in [the] same dist[ribution] as [the] paresthesias," a "sharp, shooting pain" at times in the "L[eft] forearm," and "U[pper]E[xtremity] clumsiness." *Id.* According to Dr. Stankus, Dr. Walther described "weakness [at] [the] wrist also, but not [at] [the] elbow, shoulders or L[ower]E[xtremities]." *Id.* In addition, according to Dr. Stankus, Dr. Walther described "paresthesias" in the "bottom of both feet up to [the] calves," without "color [changes] of [the] digits." *Id.* Further, according to Dr. Stankus, Dr. Walther described "midthoracic back pain." *Id.* Finally, according to Dr. Stankus, Dr. Walther described "brief episodes of rotational vertigo [without] nausea." *Id.*

Dr. Stankus performed a physical examination that revealed "mild L[eft] hemiparesis [with] [decreased]P[in]P[rick]/Tem[perature]" sensation throughout portions of Dr. Walther's "L[eft] hand." Pet. ex. 8 at 1; *see also id.* at 2. Dr. Stankus commented that Dr. Walther's "reflexes" were "preserved." Pet. ex. 8 at 1. Citing "no evidence [of] myopathy" and certain negative "studies," Dr. Stankus depicted "[t]he localization of" Dr. Walther's "lesion" as "difficult." *Id.* Dr. Stankus

[9] Few notes of Dr. Ring's examination are available.

suggested that "[a]n isolated small fiber sensory neuropathy could have n[orma]l NCS findings." *Id.* Dr. Stankus advanced that Dr. Walther's condition "may represent an infectious, metabolic, or inflammatory condition [with] atypical asymmetric neuropathy." *Id.* Dr. Stankus did not believe apparently that Dr. Walther's symptoms were related to medication, specifically, Rifampin. *See, e.g.*, Pet. ex. 3 at 6. Dr. Stankus planned additional diagnostic studies. *See* Pet. ex. 8 at 1.

On October 29, 1997, Dr. Walther underwent a magnetic resonance imaging (MRI) of her thoracic spine, an MRI of her cervical spine and an MRI of her brain. *See* Pet. ex. 11 at 1. A radiologist interpreted the MRI of Dr. Walther's thoracic spine and the MRI of Dr. Walther's cervical spine as normal. *See* Pet. ex. 11 at 1-2. A radiologist interpreted the MRI of Dr. Walther's brain as abnormal. *See* Pet. ex. 11 at 2. The radiologist cited "a prolonged T2 in the incus and amygdaloid region on the right side," representing "most likely" an "infarct." Pet. ex. 11 at 2. In addition, the radiologist cited an "asymmetric, abnormal appearance to vascular structures." *Id.*

On November 3, 1997, Dr. Walther "discontinued" apparently Rifampin. Pet. ex. 37 at 45.

On November 5, 1997, Dr. Walther consulted by telephone with a neurologist regarding her MRI "results." Pet. ex. 41 at 16. After reviewing Dr. Walther's "films," the neurologist expressed doubt about the "findings" because he had "a difficult time correlating" the findings to Dr. Walther's clinical presentation. *Id.* The neurologist advised Dr. Walther to "speak to Dr. Stankus." *Id.*

On November 12, 1997, Dr. Walther underwent a second MRI of her thoracic spine and a second MRI of her cervical spine. *See* Pet. ex. 41 at 63-64. On November 13, 1997, Dr. Walther underwent a second MRI of her brain "w[ith] contrast." Pet. ex. 41 at 66. A radiologist interpreted the second MRI of Dr. Walther's thoracic spine as "unremarkable," except for "minimal leftward curvature of the thoracic spine." Pet. ex. 41 at 64. A radiologist determined that the second MRI of Dr. Walther's cervical spine suggested "a history of prior trauma or degenerative change at the C6 level." *Id.* The radiologist recommended "[f]urther evaluation," particularly for any concern regarding a "neural foraminal encroachment." *Id.* A radiologist interpreted the second MRI of Dr. Walther's brain as "normal," but "limited." *Id.* at 66.

On November 19, 1997, Dr. Stankus assessed apparently Dr. Walther again. *See* Pet. ex. 37 at 5; *see also* Pet. ex. 41 at 19.[10] Suspecting a "R[ight] temporal lobe lesion," Dr. Stankus referred Dr. Walther for an electoencephalogram (EEG). Pet. ex. 41 at 19. The EEG was "normal," showing "[n]o focal slowing." *Id.* at 20.

During a "telephone consultation" with Dr. Walther on November 20, 1997, Dr. Stankus proposed additional diagnostic testing "for further localization," including "S[omato]S[ensory]E[voked]P[otentials]." Pet. ex. 41 at 15.

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[10] Few notes from the date of examination are available.

Based upon her "recent onset [of] pain [at] c6-c7 [with] l[eft]u[pper]e[xtremity] c7 radicuolopathy," Dr. Walther underwent a "C-spine (obliques only)" radiographic series on November 21, 1997, "for eval[uation] [of] foraminal encroachment." Pet. ex. 41 at 22. According to the radiologist who interpreted the films, Dr. Walther's "neural foramen" was "patent." *Id.*

After discussing Dr. Walther's condition "with Dr. Ring" on November 26, 1997, Dr. Stankus determined "to admit [Dr. Walther] to D[wight]DE[isenhower]A[rmy]M[edical]C[enter] on Monday, 01DEC97, for expeditious evaluation." Pet. ex. 41 at 16. Dr. Walther entered DDEAMC, Fort Gordon, Georgia, on December 1, 1997, "for further evaluation and work up of her progressive left hemiparesis and paresthesias of her left hand [and] neck and back pain." Pet. ex. 37 at 44. A "team" of physicians attended to Dr. Walther during her hospitalization. Pet. ex. 12 at 2. Dr. Stankus "assisted" the team "in the management of" Dr. Walther's care. Pet. ex. 37 at 46.

In her comprehensive history of Dr. Walther's condition, Catherine Demastes, M.D. (Dr. Demastes), noted that Dr. Walther had received a diagnosis of "carpal tunnel in March 1997." Pet. ex. 37 at 44.[11] However, according to Dr. Demastes, Dr. Walther reported that "she was in her usual state of health until August 1997," when she sought treatment for "recurrent bilateral carpal tunnel syndrome." *Id.* Dr. Walther indicated that following use of "Daypro and bilateral splints in August 1997," she experienced relief only of "her right hand symptoms." *Id.* Dr. Walther recounted that "over several weeks," she developed a "gradual progression of symptoms" on her left side, including "weakness of her hand and arm" and "leg." *Id.* Then, Dr. Walther stated that she suffered "worsening pain in her neck and back," followed by "fatigue" that became eventually "profound." *Id.* at 45. Further, Dr. Walther described herself as "forgetful" and "less astute." *Id.*

Upon examining Dr. Walther, Dr. Demastes commented that Dr. Walther "was in no apparent distress." Pet. ex. 37 at 45. However, Dr. Demastes observed that Dr. Walther presented "with her left hand held in a claw[-]like position." *Id.* Dr. Demastes determined that Dr. Walther exhibited diminished "[m]uscle strength" in her "left upper and lower extremities." *Id.* at 46. In addition, Dr. Demastes determined that Dr. Walther exhibited "marked sensory deficits" on her "left" side. *Id.* at 45-46. Further, Dr. Demastes determined that Dr. Walther's "[b]ack and spine demonstrated tenderness, concentrated around T3 and extended from the cervical spine down to the lumbar region." *Id.* at 45. Finally, Dr. Demastes determined that Dr. Walther's "[d]eep tendon reflexes were present bilaterally," with "no Babinski signs." *Id.* at 46.

In his initial record during Dr. Walther's hospitalization, Dr. Stankus recounted that Dr. Walther had experienced "paresthesias" in portions of her upper extremities that were "presumed due to CTS." Pet. ex. 37 at 88. However, Dr. Stankus noted, Dr. Walther's "EMG/NCS were

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[11] For convenience, the special master quotes the typed discharge summary of Dr. Walther's December 1997 hospitalization, signed by John W. Collins, M.D. (Dr. Collins), *see* Pet. ex. 37 at 44-47, the "intern" on Dr. Walther's team of physicians. Pet. ex. 12 at 2. The discharge summary appears nearly verbatim to Dr. Demastes's handwritten notes, *see* Pet. ex. 37 at 50, 60, and to notes endorsed by Dr. Demastes. *See id.* at 70-75.

normal." *Id.* Then, according to Dr. Stankus, Dr. Walther "presented to" him in the "neurology clinic" on October 22, 1997, complaining of "a progressive weakness" in her "hands." *Id.* Dr. Stankus indicated that Dr. Walther's weakness "began in August [']97" and appeared "in [the] same distribution" as Dr. Walther's previous "paresthesias." *Id.* Dr. Stankus described the "onset of" other symptoms, including "L[eft] foot [and] leg weakness" and "low cervical/upper thoracic midline back pain." *Id.* While Dr. Stankus stated that many of Dr. Walther's symptoms became "stable" sometime between late October 1997 and early November 1997, he depicted Dr. Walther's "back pain" as "increasing." *Id.*

Dr. Stankus suspected a "lesion," probably "above [Dr. Walther's] brainstem on the R[ight]." Pet. ex. 37 at 89. Dr. Stankus "ordered" an "SSEP to help localize [a] lesion." *Id.* All aspects of the study were "normal." *Id.* at 94-95.

Between December 4, 1997, and December 5, 1997, Dr. Walther informed Dr. Stankus about her "multiple immunizations (including rabies) in July 1997." Pet. ex. 37 at 64.

On December 6, 1997, Dr. Stankus "reviewed" Dr. Walther's initial "brain [and] spine MRIs" with a "neuroradiologist" associated with the Medical College of Georgia (MCG). Pet. ex. 37 at 65. Dr. Stankus reported that the neuroradiologist considered "the R[ight] temp[oral] asymmetry" in Dr. Walther's initial brain MRI to be "a normal variant." *Id.* Dr. Stankus registered his impression that Dr. Walther exhibited "postvaccinal encephalomyelitis," despite the absence of "neurodiagnostic or electrodiagnostic" confirmation. *Id.* Dr. Stankus planned to seek a "2nd opinion" from a neurologist "[at] MCG." *Id.*

On December 10, 1997, William T. Garrett, M.D. (Dr. Garrett), a neurologist associated with the Medical College of Georgia School of Medicine, Department of Neurology, evaluated Dr. Walther at Dr. Stankus's request. *See* Pet. ex. 14 at 1-2; *see also* Pet. ex. 38 at 1-8. Dr. Garrett understood that Dr. Walther presented with "complaints of left upper and lower extremity weakness and numbness" characterized by Dr. Stankus as "possible post-vaccinational [sic] encephalomyelitis." Pet. ex. 14 at 1. Dr. Garrett interviewed Dr. Walther, obtaining Dr. Walther's medical history, including information that Dr. Walther received rabies vaccinations before attending veterinary school. *See, e.g.*, Pet. ex. 38 at 1-8. Dr. Garrett conducted a physical examination of Dr. Walther. *See, e.g.*, Pet. ex. 38 at 1-8.

Dr. Garrett depicted the onset of Dr. Walther's "left arm numbness and weakness" in August 1997 as "gradually progressive in a stepwise fashion" until late November 1997 or early December 1997, when Dr. Walther's "symptoms" appeared to "have stabilized." Pet. ex. 14 at 1. According to Dr. Garrett, Dr. Walther's "general physical exam" was "unremarkable," except for "paraspinal muscle spasm, especially on the left." *Id.* And, according to Dr. Garrett, Dr. Walther's "[m]otor exam" on the "right" was "normal." *Id.* However, according to Dr. Garrett, Dr. Walther's motor examination on the "left" was "complicated by give-away weakness and functional overlay." *Id.* Dr. Garrett cited specific "testing of arm extension." *Id.* Dr. Garrett detected "a glove distribution sensory loss in the left upper extremity and an inverse stocking decrease in pinprick in the left lower

extremity." *Id.* at 2. Dr. Garrett commented that in walking, Dr. Walther seemed "to favor her left leg." *Id.*

Although Dr. Garrett believed that the "functional overlay" present in Dr. Walther's "examination" represented possibly "a hysterical cause for [Dr. Walther's] complaints," he concluded still that Dr. Walther exhibited "[l]eft upper and lower extremity weakness and numbness." Pet. ex. 14 at 2. He labeled the "etiology" of Dr. Walther's condition as "unclear." *Id.* Regardless, he emphasized that Dr. Walther had "no upper motor neuron signs to suggest an encephalomyelitis." *Id.* Indeed, Dr. Garrett posited that "[i]f an organic cause exists for [Dr. Walther's] symptoms, it is most likely a peripheral nervous system lesion." *Id.* Based upon a "slightly elevated" result for "rheumatoid factor" of questionable "significance," Dr. Garrett suggested a "rheumatology consult." *Id.* Otherwise, Dr. Garrett recommended "Elavil" for Dr. Walther's "chronic pain," and "physical therapy." *Id.*

Dr. Stankus "appreciated" Dr. Garrett's "neurology consult." Pet. ex. 37 at 67. Indeed, Dr. Stankus agreed that "possible embellishment" clouded Dr. Walther's "exam." *Id.* Nevertheless, Dr. Stankus concluded that Dr. Walther demonstrated "real deficits." *Id.* Thus, Dr. Stankus maintained his view that Dr. Walther suffered "a postvaccinal encephalomyelitis." *Id.* Dr. Stankus identified four factors supporting his "opinion:" Dr. Walther's "pattern of deficit;" Dr. Walther's "[increased] DTRs on [the] L[eft];" the "temporal relationship" between Dr. Walther's condition and "vaccination;" and an "[increased] R[heumatoid]F[actor]" test result that decreased on subsequent testing, "indicative of autoimmune [disease]." *Id.*; *see also id.* at 46 (reciting similar factors, including "temporal relationship to vaccination with a rabies vaccine in July 1997"). Upon Dr. Walther's discharge from DDEAMC on December 12, 1997, *see, e.g.*, *id.* at 44-47, Dr. Stankus initiated "medical board" proceedings. *Id.* at 58.

On February 20, 1998, Dr. Stankus dictated a "narrative summary" of Dr. Walther's medical history. Pet. ex. 37 at 5. According to Dr. Stankus, he "based" his dictation on a November 19, 1997 "physical examination." *Id.*[12] Dr. Stankus reviewed Dr. Walther's "progressive" course of "left upper and lower extremity weakness and numbness" following "a battery of immunizations," including a "first Rabies immunization." *Id.* at 6. Dr. Stankus commented that although Dr. Walther's symptoms "appeared to stabilize" eventually, Dr. Walther exhibited residual "significant pyramidal distribution left hemiparesis with disabling upper thoracic back pain of unclear etiology." *Id.* at 4. Dr. Stankus affirmed his previous clinical impression that Dr. Walther sustained "[n]umbness and weakness, arm and leg, presumed secondary to a postvaccinal encephalomyelitis without neuroimaging or neurophysiological correlation." *Id.* at 5. In Dr. Stankus's view, Dr. Walther's impairments rendered Dr. Walther "unable to perform" the "duties" of her position as a military veterinarian; "unable to take or pass an Army physical fitness test;" and unable "to function in the field environment." *Id.* at 4. Dr. Stankus referred Dr. Walther "to the Physical Evaluation Board for determination of fitness for duty." *Id.* at 8.

[12] Few notes from the November 19, 1997 examination are available. *See* n.10, *supra*.

In mid-1998, Dr. Walther "retired from the military." Pet. ex. 39 at 86; *see also* Pet. ex. 19 at 1 (Dr. Walther "was medically[-]discharged from the Army" after being placed on the "T[emporary]D[isability]R[etirement]L[ist]."). While she was pending on the TDRL, Dr. Walther completed periodic medical evaluations of her condition. *See, e.g.*, Pet. ex. 19 at 1; Pet. ex. 39 at 83-84, 95-96; Pet. ex. 40 at 4; Pet. ex. 49 at 1-2. Many physicians who examined Dr. Walther repeated the chronology that in 1997, Dr. Walther experienced progressive symptoms coinciding with the administration of multiple vaccinations. *See, e.g.*, Pet. ex. 19 at 1-2 (TDRL evaluation report from February 2, 1999); Pet. ex. 35 at 1 (evaluation report from September 5, 2000), 8-10 (evaluation report from March 23, 2000); Pet. ex. 36 at 5-6 (evaluation report from July 25, 2000); Pet. ex. 39 at 30-33 (evaluation report dictated on March 24, 1999), 86-88 (evaluation report from August 18, 1998), 89-90 (evaluation report from August 19, 1998); Pet. ex. 40 at 3 (consultation report from June 1, 1999), 4 (evaluation report from March, 22, 2000), 5 (partial evaluation report from May 29, 2001); Pet. ex. 49 at 1-2 (evaluation report from December 12, 2002).

Some physicians who examined Dr. Walther directed additional diagnostic tests. For instance, in March 1999, Robin King-Thiele, D.O. (Dr. King-Thiele), obtained another MRI of Dr. Walther's brain. *See* Pet. ex. 39 at 36. Although Dr. King-Thiele indicated that the MRI revealed "multiple small abnormalities" that were "consistent with a demyelinating process," Pet. ex. 39 at 32; *see also* Pet. ex. 40 at 5 (5/29/2001: "MRI (99) multiple demyelinating lesions"); Pet. ex. 49 at 1 (12/12/2002: "Her last MRI was performed in 1999 which revealed multiple demyelinating lesions"), the radiologist who interpreted the MRI determined that the MRI was "negative." Pet. ex. 39 at 36. A radiologist who interpreted yet another MRI of Dr. Walther's brain performed on April 30, 1999, identified "[n]o abnormal signal intensity lesions." Pet. ex. 36 at 1. The radiologist concluded that the April 30, 1999 MRI was "within normal limits." *Id.*

Some physicians who examined Dr. Walther investigated a cause for her condition. For instance, Dr. King-Thiele pursued "an extensive literature search," documenting "cases of encephalomyelitis and demyelination in the central nervous system" following "rabies vaccine." Pet. ex. 39 at 32; *see also id.* at 65-81. According to Dr. King-Thiele, the results of the literature search "would explain [Dr. Walther's] unusual syndrome given the recent onset post multiple vaccination." *Id.* at 32. Likewise, Andreas M. Walchner, M.D. (Dr. Walchner), Chief, Allergy/Immunology Service, 74th Medical Group, Wright-Patterson Air Force Base, concluded that Dr. Walther's condition occurred "most likely as [a] result of rabies (HDCV) immunization." Pet. ex. 40 at 3. Dr. Walchner cautioned that "[f]urther live-virus vaccines" were "contraindicated." *Id.*

Many physicians who examined Dr. Walther adopted a diagnosis of postvaccinal encephalomyelitis or acute disseminated encephalomyelitis (ADEM) for her condition. *See, e.g.*, Pet. ex. 19 at 1-2 (2/4/1999: "acute disseminated encephalomyelitis, presumably secondary to vaccination"); Pet. ex. 39 at 30-33 (3/24/1999: "encephalomyelitis and demyelination in the central nervous system" with "onset post multiple vaccination"); 89-90 (8/19/1998: "probable post vaccinial encephalomyelitis" despite "some functional overlay"); Pet. ex. 40 at 3 (6/1/1999: "ADEM"), 4 (3/22/2000: deficits "[secondary] to ADEM, presumed [secondary] to vaccination"), 5 (5/29/2001: "ADEM," with onset "? post vaccination"). Yet, not every physician who examined Dr. Walther

defined her condition as postvaccinal encephalomyelitis or ADEM. In 2000, Sandra Kostyk, M.D. (Dr. Kostyk), assessed Dr. Walther several times. *See, e.g.*, Pet. ex. 35 at 1, 8-10. Dr. Kostyk understood that Dr. Walther presented with "[n]eurological problems reported since vaccination." Pet. ex. 35 at 1. Indeed, upon examining Dr. Walther, Dr. Kostyk observed "weakness" that was "[d]iffuse" on Dr. Walther's "[L]eft" side, "head tremor" and "facial grimacing," accompanied by "cognitive problems." Pet. ex. 35 at 10. Dr. Kostyk stated that "[n]eurological complications, including encephalomyelitis[,] have been reported associated [sic] with a variety of vaccines." *Id.* However, Dr. Kostyk found Dr. Walther's "[p]attern of behavior and deficits" to be "a little unusual." *Id.* at 1. And, Dr. Kostyk considered the "etiology of [Dr. Walther's] symptoms" to be "unclear." *Id.* at 10.

Also in 2000, Dr. Walther presented to Kottil Rammohan, M.D. (Dr. Rammohan), a neurologist associated with The Ohio State University Medical Center, "for an opinion regarding her neurological status, which has been thought to be related to immunizations she received while in the U.S. Army." Pet. ex. 36 at 5. Dr. Rammohan conducted a "[n]eurological evaluation." *Id.* According to Dr. Rammohan, Dr. Walther "did not manifest any definite evidence of pyramidal or extrapyramidal involvement" in her "left upper extremity." *Id.* Dr. Rammohan described Dr. Walther's "right upper extremity" as "normal and useful." *Id.* Based upon his view that "manual muscle testing scores in the lower extremities were unreliable because of poor effort," Dr. Rammohan concluded "[o]nce again" that there existed no "objective evidence of upper motor neuron involvement in the form of extrapyramidal or pyramidal involvement." *Id.* at 5-6. Dr. Rammohan determined that Dr. Walther's "[s]ensory testing" was normal. *Id.* at 6. Dr. Rammohan rated Dr. Walther's "[d]eep tendon reflexes" as "2+ and symmetrical." *Id.* Dr. Rammohan elicited "bilateral flexor responses" on "plantar stimulation." *Id.*

Dr. Rammohan reviewed Dr. Walther's MRIs from October 29, 1997, November 13, 1997, March 26, 1999, and April 30, 1999. *See* Pet. ex. 36 at 6. Dr. Rammohan commented that the "report" from Dr. Walther's October 29, 1997 brain MRI identified "an infarct in the medulla on the right side." Pet. ex. 36 at 6. Dr. Rammohan "was unable to appreciate the presence of any past or recent cerebrovascular accidents in the MRI." *Id.* Dr. Rammohan interpreted the other "studies" as "normal, without any evidence of high-signal white matter lesions indicative of post[-]vaccination demyelination." *Id.*

Like Dr. Garrett at MCG, Dr. Rammohan was "at a loss as to the nature of [Dr. Walther's] problems" because "abnormalities were not evident at the bedside or evident on [Dr. Walther's] MRI studies." Pet. ex. 36 at 6. Dr. Rammohan suggested "genetic testing" based upon Dr. Walther's report of a "family history" of "Huntington's disease." *Id.* However, Dr. Rammohan did not believe Dr. Walther's "course" was consistent with Huntington's disease. *Id.*

While she was pending on the TDRL, Dr. Walther underwent psychological testing once and neuropsychological testing several times, too. *See, e.g.*, Pet. ex. 24 at 1-5; Pet. ex. 39 at 48-49; Pet. ex. 43 at 1-5; Pet. ex. 50 at 1-4. In March 1999, a psychologist suggested that despite a "full scale IQ score" placing Dr. Walther "in the average range," Dr. Walther demonstrated "some cognitive

impairment possibly as a result of" her "postvaccinal encephalomyelitia [sic]." Pet. ex. 39 at 48. The psychologist reasoned that the IQ score that Dr. Walther achieved was "significantly lower than one would expect" for a person with Dr. Walther's "high level of educational attainment and vocational performance." *Id.* In March 2000, Dr. Walther achieved a "full scale IQ" score placing her "in the high average range." Pet. ex. 24 at 3. Nevertheless, based upon "significant deficits on measures of processing speed, verbal fluency, and tests of sustained and divided attention," a psychologist perceived "a decline" in Dr. Walther's "premorbid level of cognitive functioning." *Id.* at 4. In May 2001, a psychologist detected further deterioration in certain of Dr. Walther's cognitive skills. *See* Pet. ex. 43 at 1-4; *see also* Pet. ex. 50 at 1-4 (confirming that the comparison of a "March 2000 evaluation" and a "May 2001 evaluation" showed "a decline" in "results").

By the end of 2002, Dr. Walther's military physicians determined that Dr. Walther had reached maximum, but incomplete, recovery from her condition. *See, e.g,* Pet. ex. 24 at 1-5; Pet. ex. 40 at 4; Pet. ex. 43 at 1-5; Pet. ex. 49 at 1-2; Pet. ex. 50. The military physicians concluded that Dr. Walther could not return to active duty. *See, e.g.*, Pet. ex. 24 at 1-5; Pet. ex. 40 at 4; Pet. ex. 49 at 1-2; Pet. ex. 50 at 1-4. The military physicians recommended permanent retirement. *See, e.g.*, Pet. ex. 24 at 1-5; Pet. ex. 40 at 4; Pet. ex. 43 at 1-5; Pet. ex. 49 at 1-2; Pet. ex. 50 at 1-4.

Dr. Walther filed a petition for Program compensation. *See* Petition (Pet.). She maintained that she sustained ADEM from her July 31, 1997 Td vaccination. *See, e.g.*, P. Memo at 3. Respondent contested Dr. Walther's claim on three grounds. *See, e.g.*, Respondent's Witness List and Prehearing Memorandum (R. Memo), filed May 9, 2005. First, respondent disputed that Dr. Walther exhibits ADEM. *See* R. Memo at 7. Second, respondent contended that Dr. Walther had not adduced sufficient evidence demonstrating that Td vaccine causes encephalomyelitis. *See* R. Memo at 7. Third, respondent asserted that Dr. Walther had "not adequately eliminated" several "other" vaccines that she received in Summer 1997 as "causative agents" for her condition. R. Memo at 10.

The special master convened a hearing on entitlement. Dr. Byers testified during Dr. Walther's case-in-chief. Dr. Safran and Gregory Shoukimas, M.D., Ph.D. (Dr. Shoukimas),[13] testified during respondent's rebuttal case. Dr. Kinsbourne and Margaret Montana, M.D. (Dr. Montana),[14] testified during Dr. Walther's surrebuttal case.

In a brief decision, the special master held that Dr. Walther was not entitled to Program compensation. *See Walther v. Secretary of HHS*, No. 00-0426V, Decision (Fed. Cl. Spec. Mstr. July

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[13] Dr. Shoukimas received his medical degree from Tufts University. R. ex. F at 1. He is certified by the American Board of Radiology. *Id.* He is a senior member of the American Society of Neuroradiology. *Id.* at 2.

[14] Dr. Montana received her medical degree from Washington University, St. Louis. Pet. ex. 46 at 1. She is certified by the American Board of Radiology. *Id.* at 2. She is a member of the American College of Radiology. *Id.* at 5.

29, 2005). The special master determined that Dr. Walther relied "predominantly upon Dr. Byers's opinion to establish her claim." *Walther v. Secretary of HHS*, No. 00-0426V, Decision at 4 (Fed. Cl. Spec. Mstr. July 29, 2005). Yet, based upon his "significant concerns regarding the quality and the substance of Dr. Byers's testimony," the special master accorded Dr. Byers's testimony no weight. In one part of his analysis of Dr. Byers's testimony, the special master explained his impression that Dr. Byers had not advanced "a viable proposition that Dr. Walther's [Td] vaccination, rather than one of Dr. Walther's other vaccinations, caused more likely than not Dr. Walther's condition." *Id.* at 5.

Dr. Walther moved for review of the special master's decision. *See* Motion for Review, filed August 29, 2005. Dr. Walther argued that the special master "applied a legally erroneous standard to reject [Dr. Walther's] proof of causation." Memorandum of Objections (Objections), filed August 29, 2005, at 13 (emphasis omitted). A judge of the United States Court of Federal Claims affirmed the special master's decision, ruling that "the special master denied [Dr. Walther] relief because he rejected Dr. Byers'[s] opinion testimony and not because he applied the wrong legal standard." *Walther v. Secretary of HHS*, 69 Fed. Cl. 123, 127 (2005). The clerk of court entered judgment dismissing the petition. *See Walther v. Secretary of HHS*, No. 00–0426V, Judgment (Fed. Cl. Dec. 8, 2005).

Dr. Walther appealed the judgment to the Federal Circuit. *See* Petition for Review/Notice of Appeal, filed February 3, 2006. Dr. Walther renewed her argument "that the special master applied an incorrect standard" to her "*prima facie* case of causation." *Walther*, 485 F.3d at 1148. The Federal Circuit decided that "the special master's decision, to the extent that it did place a requirement on [Dr. Walther] to establish a lack of alternative causation, was erroneous." *Id.* at 1149. The Federal Circuit "vacated and remanded." *Id.* at 1153.

DISCUSSION

The special master divides his discussion into two distinct sections. In the first section, the special master addresses respondent's defense that Dr. Walther does not exhibit ADEM. *See* R. Memo at 7. The exceptionally complex factual issue requires the special master to weigh evidence contained in Dr. Walther's voluminous medical records from a plethora of providers, as well as Dr. Safran's testimony and Dr. Kinsbourne's testimony.[15] In the second section, the special master addresses evidence of causation "under the correct legal standard." *Walther*, 485 F.3d at 1153. In particular, adhering to the Federal Circuit's construct of respondent's burden in this case, the special master will examine whether respondent has established by the preponderance of the evidence that Dr. Walther's July 31, 1997 Td vaccination "did not cause" Dr. Walther's "harm." *Id.* at 1151.

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[15] Dr. Safran reviewed personally Dr. Walther's MRIs. Tr.I at 164-65. So, most of Dr. Shoukimas's testimony duplicated aspects of Dr. Safran's testimony. *See generally* Tr.I at 131-50. Dr. Kinsbourne advanced that physicians do not need radiographic evidence to diagnose ADEM. *See* Tr.I at 249. So, Dr. Montana's testimony was essentially superfluous.

I

Recognizing the unique relationship between a physician and a patient, the Federal Circuit instructs that "medical records" constitute "favored" evidence in Program cases. *Capizzano v. Secretary of HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), citing *Althen*, 418 F.3d at 1280 and § 300aa-13(a)(1); *see also Cucuras v. Secretary of HHS*, 993 F.2d 1525, 1528 (1993)(explaining that "[m]edical records, in general, warrant consideration as trustworthy evidence"). Indeed, the Vaccine Act commands a special master to "consider. . . any diagnosis, conclusion, [or] medical judgment. . . which is contained in the record regarding the nature, [or] causation. . . of the petitioner's illness, disability, injury, [or] condition" and "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1). Yet, the Vaccine Act provides specifically that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master." *Id.* Thus, Congress intended obviously special masters to plumb the reliability of statements in a petitioner's medical records, abrogating any common law or administrative "treating physician" rule–a principle according great deference to a treating physician's opinion. *See, e.g.*, BLACK'S LAW DICTIONARY 1507 (7th ed. 1999).

Nevertheless, the special master realizes absolutely the inherent dangers posed by subjecting treating physicians' clinical conclusions to full analysis anew in the context of litigation. Therefore, the special master does not brook well unsupported challenges to a petitioner's recorded diagnoses. Yet, in this case, Dr. Kinsbourne concedes clearly that Dr. Walther's records reflect "puzzling variability" regarding Dr. Walther's "subjective and objective symptoms." Tr.I at 245; *see also* Tr.I at 247. Indeed, while Dr. Kinsbourne urges that the majority of Dr. Walther's doctors documented manifestations of a central nervous system process, he acknowledges–as he must–at least "two notable exceptions:" Dr. Garrett and Dr. Rammohan. Tr. at 247; *see also* Tr. at 251. As a consequence, the special master is constrained to judge respondent's position that Dr. Walther does not suffer ADEM.

Dr. Safran did not dispute that Dr. Walther is "having difficulties." Tr.I at 180. In fact, Dr. Safran stated, "Dr. Walther had a neurologic condition before she ever got the inoculations in question." Tr.I at 157; *see also* Tr.I at 159-60, 196, 230. Dr. Safran remarked that Dr. Walther experienced "numbness in her arms for several months" preceding July 1997. Tr.I at 157; *see also* Tr.I at 160, 196, 230. And, Dr. Safran remarked that Dr. Walther exhibited "dizziness" preceding July 1997. Tr.I at 160; *see also* Tr. at 159.

Regardless, Dr. Safran insisted that Dr. Walther's neurologic condition does not fulfil criteria for ADEM. *See* Tr.I at 157, 180, 182, 191, 199, 201, 217, 221, 224, 228. Dr. Safran described ADEM as "usually a fairly abrupt illness." Tr.I at 190. Dr. Safran estimated that the course of ADEM "generally reaches its maximum in a few days," or perhaps "somewhat longer." *Id.* In addition, Dr. Safran described ADEM as "usually a devastating illness." *Id.* According to Dr. Safran, the majority of people who suffer ADEM "are in a hospital, comatose, and very, very sick." *Id.*

Dr. Safran reviewed general bases for his opinion that Dr. Walther does not exhibit ADEM. Although Dr. Safran granted that some of Dr. Walther's symptoms appear in ADEM, *see, e.g.*, Tr.I at 209-11, 215, 238, -39, Dr. Safran asserted that Dr. Walther's medical records portray consistently the onset of Dr. Walther's condition as "progressive." Tr.I at 160-64; *see also* Tr.I at 176, 182, 196, 235-36. Moreover, Dr. Safran asserted that if results from Dr. Walther's neuropsychological testing in 2000 and in 2001 are accurate, Dr. Walther "was getting worse" more than "two years after" Dr. Stankus advanced that Dr. Walther had suffered ADEM. Tr.I at 218-21; *see also* Tr.I at 164. Dr. Safran stated plainly that ADEM "is not a progressive disorder." Tr.I at 160; *see also* Tr.I at 164, 196. In addition, Dr. Safran commented that Dr. Walther reported "forearm pain," among her initial symptoms. Tr.I at 169; *see also* Tr.I at 163, 225-26. Again, Dr. Safran stated plainly that Dr. Walther's type of "pain is not" a clinical manifestation of ADEM. Tr.I at 163; *see also* Tr.I at 169, 172, 225-26.

Dr. Safran reviewed specific bases for his opinion that Dr. Walther does not suffer ADEM. Dr. Safran said that "a neurologic examination consists of five parts." Tr.I at 169. At the outset, Dr. Safran maintained that recorded data regarding certain parts of Dr. Walther's neurological examinations are not consistent with ADEM. Dr. Safran cited a particular kind of "sensory loss" described by both Dr. Stankus and by Dr. Garrett. Tr.I at 169-71. Dr. Safran stated that ADEM "does not cause" the type of "sensory loss." *Id.* In addition, Dr. Safran cited the repeated absence of "an abnormal reflex" known as the "Babinsky reflex." Tr.I at 173. According to Dr. Safran, the Babinsky reflex is "the classic sign of upper motor neuron weakness." *Id.* Thus, Dr. Safran stated, "someone with a [hemi]paresis" from ADEM should produce the Babinsky reflex upon testing. *Id.* Further, Dr. Safran cited a certain motor examination result "eliminating a structural basis" for Dr. Walther's condition. Tr.I at 178-79. Then, Dr. Safran maintained that "a variety of tests" and other procedures, including MRI, SSEP, EMG and EEG, "never" revealed "objective clinical abnormalities" correlating with structural damage attributable to ADEM. Tr.I at 162; *see also* Tr.I at 164-68, 180-82, 221, 228.

Dr. Kinsbourne agreed that "Dr. Safran made some good points." Tr.I at 245. Dr. Kinsbourne concurred that "pain is not an element of ADEM." *Id.* Likewise, Dr. Kinsbourne concurred that "sensory symptoms," as described by Dr. Walther's physicians, are "not prominent in" ADEM. Tr.I at 246. And, Dr. Kinsbourne concurred that "the absence of" a Babinsky reflex "would not be typical" in someone with left hemiparesis from ADEM. Tr.I at 247.

Nevertheless, Dr. Kinsbourne testified that "ADEM is an umbrella term for a wide range of demyelinating insults to the brain." Tr.I at 243. According to Dr. Kinsbourne, the conditions labeled as ADEM vary in "manifestations," from "explosive" to "milder." *Id.* In addition, according to Dr. Kinsbourne, the conditions labeled as ADEM vary in "time course," from rapid to slow. *Id.* Dr. Kinsbourne asserted that radiographic evidence of brain abnormalities is not required for the diagnosis of ADEM. Tr.I at 249. Indeed, Dr. Kinsbourne offered, "a high proportion of" the "milder examples" of ADEM "do not exhibit abnormalities on a head MRI." Tr.I at 243.

Dr. Kinsbourne opined that Dr. Walther's condition represents a "milder form of ADEM." Tr.I at 243. In Dr. Kinsbourne's view, Dr. Walther "suffered from a monophasic neurological disease

that began subacutely, reached a plateau and receded, leaving permanent disability." Pet. ex. 53 at 1. Dr. Kinsbourne identified the "salient features" of Dr. Walther's ADEM as "tremor, ataxia, paresthesias and weakness with left hemiparesis and hemisensory loss near the peak of the disorder." *Id.*

When a petitioner does not allege that a vaccination caused a significant aggravation of a preexisting condition–the situation in this case–the petitioner has to "show that no evidence of the injury appeared before the vaccination." *Shalala v. Whitecotton*, 514 U.S. 268, 274 (1995). Dr. Safran's testimony highlights extremely troublesome issues regarding Dr. Walther's condition preceding Dr. Walther's vaccinations in Summer 1997. *See, e.g.*, Tr.I at 157, 159-60, 196, 230. Dr. Walther's medical records reveal that in November 1994, Dr. Walther began to experience persistent "dizziness and light sensitivity." Pet. ex. 41 at 88. Dr. Walther's medical records reveal also that as early as December 1994, Dr. Walther's physicians were concerned about a "central pathology" for the symptoms. *See* Pet. ex. 41 at 88-89 (noting "[a]n MR scan of the brain in December 1994"). The symptoms did not resolve apparently following Dr. Walther's consultation with Dr. Gherini in Spring 1997 because Dr. Walther told Dr. Stankus on October 22, 1997, that she experienced "brief episodes of rotational vertigo." Pet. ex. 8 at 2. Likewise, Dr. Walther's medical records reveal that in March 1997, Dr. Walther began to experience symptoms described as "paresthesias" in her hands that several physicians presumed to represent bilateral carpal tunnel syndrome. Pet. ex. 39 at 50; *see also* Pet. ex. 8 at 2. The "hand paresthesias" were present still on October 16, 1997, when electrodiagnostic testing failed to demonstrate "bilateral median or ulnar neuropathies." Pet. ex. 39 at 50. And, Dr. Stankus reflected that "paresthesias" were a prominent feature of Dr. Walther's clinical presentation on October 22, 1997. Pet. ex. 8 at 2.

In turn, Dr. Walther's medical history preceding Dr. Walther's vaccinations in Summer 1997 highlights an extremely troublesome issue regarding Dr. Stankus's diagnosis of ADEM in December 1997. *See, e.g.*, Pet. ex. 37 at 46, 65, 67. Dr. Stankus knew clearly when he evaluated Dr. Walther on October 22, 1997, that Dr. Walther complained first of "[increasing] hand paresthesias," followed by "numbness in the same dist[ribution] as [the] paresthesias." Pet. ex. 8 at 2; *see also* Pet. ex. 37 at 88. In addition, Dr. Stankus knew clearly that Dr. Walther's hand paresthesias had "waxed [and] waned" over "[approximately] 3 months" before October 22, 1997, a period that would have predated Dr. Walther's vaccinations in Summer 1997. The special master appreciates that a physician's records will not "distill" necessarily all factors that a physician has considered in rendering a diagnosis. Tr.I at 247. However, the special master cannot discern from Dr. Stankus's records how, or even, if, Dr. Stankus accounted for Dr. Walther's paresthesias that existed before vaccination when he advanced his impression of "postvaccinal encephalomyelitis" in December 1997. Pet. ex. 37 at 65; *see also id.* at 67. Therefore, the special master is not persuaded that Dr. Stankus's medical conclusion regarding ADEM is sound. *See, e.g.*, *Perreira v. Secretary of HHS*, 33 F.3d 1375, 1377 n. 6 (Fed. Cir. 1994), citing *Fehrs v. United States*, 620 F.2d 255, 265 (Ct.Cl. 1980). Subsequent physicians who endorsed Dr. Stankus's diagnosis of ADEM do not appear to have been aware of Dr. Walther's complete medical history.

Dr. Safran characterizes Dr. Walther's dizziness, present from 1994, and Dr. Walther's hand paresthesias, present by Spring 1997, as "neurologic." Tr.I at 157; *see also* Tr.I at 159-60, 196, 230. Dr. Kinsbourne did not rebut Dr. Safran's testimony. Indeed, according to Dr. Kinsbourne, "paresthesias" were among the "salient features" of Dr. Walther's "ADEM." Pet. ex. 53 at 1. Yet, as the special master has discussed, Dr. Walther's paresthesias were manifest before Dr. Walther's vaccinations in Summer 1997. Given Dr. Walther's medical history before July 1997; the "puzzling variability" of Dr. Walther's "subjective and objective symptoms" from Fall 1997 through late 2002, Tr.I at 245; *see also* Tr.I at 247; and Dr. Safran's cogent, substantive testimony, the special master concludes that Dr. Walther has not established by the preponderance of the evidence that she sustained ADEM.

II

Dr. Walther concedes that the special master's factual determination that Dr. Walther has not established by a preponderance of the evidence that she sustained ADEM is dispositive. *See* P. Memo at 3. Nevertheless, the special master is compelled by the Federal Circuit's decision remanding the case to review evidence of causation. *Walther*, 485 F.3d at 1153. For purposes of discussion only, the special master assumes that Dr. Walther exhibits ADEM.

The Federal Circuit endorses the Restatement (Second) of Torts as a "uniform approach" to resolving actual causation issues in Program cases. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1351 (Fed. Cir. 1999). Thus, to prevail, a petitioner must demonstrate by the preponderance of the evidence that (1) "but for" the administration of a vaccine listed on the Vaccine Injury Table (Table), petitioner would not have been injured, and (2) a vaccine listed on the Table was "a 'substantial factor' in bringing about" petitioner's injury. *Id.* at 1352, citing Restatement (Second) of Torts § 431. The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See In re Winship,* 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring) (quoting F. JAMES, CIVIL PROCEDURE 250-51 (1965)). Mere conjecture or speculation will not meet the preponderance of evidence standard. *See Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612, 624 (1995), *aff'd*, 73 F.3d 381 (1995).

The simple temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove actual causation. *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148-50 (Fed. Cir. 1992). Rather, long-standing, well-established Federal Circuit precedent instructs that a petitioner establishes a *prima facie* actual causation case by adducing "preponderant evidence" of: "(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; *see also Capizzano*, 440 F.3d 1317; *Knudsen*, 35 F.3d 543, 548, citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993); *Grant*, 956 F.2d at 1148. The "*prima facie* case" is "a party's production of enough evidence to allow the fact-finder to infer the fact at issue and rule in the party's favor." BLACK'S LAW DICTIONARY 1228 (8th ed. 2004).

However, a petitioner does not gain Program compensation upon proving successfully the merits of the petitioner's *prima facie* actual causation case. *See Grant*, 956 F.2d at 1149. The Vaccine Act requires specifically the special master to "also determine that 'there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine,'" or "alternative etiologies." *Grant*, 956 F.2d at 1149, citing § 300aa-13(a)(1). The Federal Circuit has decreed that the burden of proving alternative actual causation rests squarely with respondent. *See, e.g.*, *Knudsen*, 35 F.3d at 547, citing *Whitecotton v. Secretary of HHS*, 17 F.3d 374, 376 (Fed. Cir. 1994); *Althen*, 418 F.3d at 1281-82; *Walther*, 485 F.3d at 1150. In addition, the Federal Circuit has decreed that "the standards that apply to a petitioner's proof of actual causation in fact" are "the same as those that apply to the government's proof of alternative actual causation in fact." *Knudsen*, 35 F.3d at 549. Thus, respondent establishes a *prima facie* alternative actual causation case by adducing "preponderant evidence" of: "(1) a medical theory causally connecting the [factor unrelated to the administration of the vaccine] and the injury; (2) a logical sequence of cause and effect showing that the [factor unrelated to the administration of the vaccine] was the reason for the injury; and (3) a showing of a proximate temporal relationship between [the factor unrelated to the administration of the vaccine] and injury." *Althen*, 418 F.3d at 1278; *see also Capizzano*, 440 F.3d 1317; *Knudsen*, 35 F.3d 543; *Grant*, 956 F.2d at 1148.

On remand, the case is in an unusual posture. The special master perceives that the Federal Circuit has held that if Dr. Walther suffered ADEM in 1997, she has prevailed upon her *prima facie* claim, as respondent "conceded that the Td vaccine was a biologically[-]plausible cause of [Dr.] Walther's ADEM and her symptoms appeared within a medically-acceptable time period." *Walther*, 485 F.3d at 1148, citing Tr.I at 26, 35; *see also* Tr.I at 191, 228-29 (Dr. Safran agreeing that Td vaccine can cause ADEM and that the interval is appropriate). In this context, the burden shifts to respondent to establish actual alternative causation. *See Walther*, 485 F.3d at 1150. The Federal Circuit has clarified that, under the Restatement (Second) of Torts § 433B(3), "when there are multiple independent potential causes, [respondent] has the burden to prove that the covered vaccine did not cause the harm." *Id.* at 1151.

Based upon the hypothetical that Dr. Walther sustained a "vaccine-related" ADEM, Dr. Safran identified "[c]ertainly" Dr. Walther's rabies vaccination as a "more likely candidate" than Dr. Walther's Td vaccination for the condition. Tr.I at 200, 229; *see also* Tr.II at 47, 61, 63. Even so, Dr. Safran admitted candidly the difficulty in distinguishing "one of" Dr. Walther's vaccinations from "another" of Dr. Walther's vaccinations. Tr.I at 201; *see also* Tr.I at 200, 229; Tr.II at 47, 60-63. Yet, the Vaccine Act provides that respondent's burden on "factors unrelated to the administration of the vaccine," or alternative etiologies, may be "documented by the petitioner's evidence." § 300aa-13(a)(2)(B). According to Dr. Walther's medical records, Dr. Walther received a series of rabies vaccine before entering veterinary school. *See, e.g.*, Pet. ex. 38 at 1-2. Dr. Walther commenced another series of rabies vaccine on August 5, 1997. *See* Pet. ex. 5 at 1. Contrary to untested affidavit statements placing the onset of Dr. Walther's symptoms on August 8, 1997, *see* Affidavit of Petitioner, filed July 20, 2000, ¶ 6, or "[a]bout a week or so after [Dr.] Walther arrived" at her new duty post in Fort Stewart, Georgia, Affidavit of Sgt. Robyn Borkowski, filed July 20, 2000, at 2, Dr. Walther's medical records show that in October 1997, Dr. Walther reported to two different

physicians the onset of increased hand paresthesias on August 15, 1997, *see* Pet. ex. 39 at 50, or in "mid-August [']97." Pet. ex. 8 at 2. The Federal Circuit credits highly the evidentiary value of medical records that are "generally contemporaneous to the medical events" because "[t]he records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528. In contrast, the Federal Circuit cautions that "oral testimony in conflict with contemporaneous documentary evidence deserves little weight." *Id.*, citing *United States v. United States Gypsum, Co.*, 333 U.S. 364, 396 (1947). Thus, the interval established by Dr. Walther's medical records between Dr. Walther's August 5, 1997 rabies vaccination and Dr. Walther's complaints of increased hand paresthesias arising on August 15, 1997, or in mid-August 1997, is appropriate for causation related to Dr. Walther's August 5, 1997 rabies vaccination. *See, e.g.*, Tr.I at 244 (Dr. Kinsbourne testifying that a period of "seven days would be classical for such a reaction"). Dr. Walther argues strenuously that the special master should defer to those treating physicians who have determined that Dr. Walther's condition represents ADEM. *See, e.g.* P. Memo; Petitioner's Memorandum on ADEM, filed September 17, 2007. If true, then Dr. Walther must accept that no fewer than three treating physicians–Dr. Stankus, Dr. King-Thiele and Dr. Walchner–attributed Dr. Walther's condition specifically to rabies vaccine, while no treating physician ever implicated the July 31, 1997 Td vaccination as the cause of Dr. Walther's condition. *See, e.g.*, Pet. ex. 37 at 46; Pet. ex. 39 at 32, 65-81; Pet. ex. 40 at 3. Thus, if Dr. Walther's treating physicians are correct that Dr. Walther sustained a vaccine-related ADEM, those physicians' conclusions that Dr. Walther's rabies vaccine caused the ADEM constitute powerful, substantial evidence. As the Federal Circuit has proclaimed, "treating physicians are likely to be in the best position to determine whether "'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano*, 440 F.3d at 1326, citing *Althen*, 418 F.3d at 1280, and § 300aa-13(a)(1). As a consequence, the special master "finds on the record as a whole" that there exists "a preponderance of the evidence" establishing that Dr. Walther's condition, defined as ADEM for purposes of this section, "is due to factors unrelated to the administration of" Dr. Walther's July 31, 1997 Td vaccination. § 300aa-13(a)(1).

CONCLUSION

The special master finds as a matter of fact, based upon the record as a whole, that Dr. Walther has not established by the preponderance of the evidence that she suffers ADEM. In the alternative, the special master finds as a matter of fact, based upon the record as a whole, that if Dr. Walther suffers ADEM, the preponderance of the evidence establishes that Dr. Walther's rabies vaccine, and not Dr. Walther's Td vaccine, is the cause of Dr. Walther's ADEM. Both rulings dictate that Dr. Walther is not entitled to Program compensation. Therefore, in the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

The clerk of court shall send Dr. Walther's copy of this decision on remand to Dr. Walther by overnight express delivery.

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John F. Edwards
Special Master