In the United States Court of Federal Claims

No. 16-185
(Filed Under Seal: May 27, 2020)
Reissued: June 17, 2020[1]

CHRISTIE KIRBY, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	Vaccine Case; Motion for Review; Influenza Vaccine; Radial Nerve Injury; Radial Neuritis; Injection Injury; *Althen*; Burden of Proof; Causation; Severity Requirement.

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.

Daniel Anthony Principato, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

OPINION

***SMITH*, Senior Judge**

Respondent, Secretary of the Department of Health and Human Services, seeks review of a decision issued by Special Master Daniel T. Horner awarding the petitioner, Christie Kirby, damages for vaccine injury compensation. Petitioner brought this action pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10 to -34 (2012) ("Vaccine Act"), alleging that the influenza ("flu") vaccine that she received on October 8, 2013, caused her pain and numbness in her right arm. On November 1, 2019, the Special Master issued a ruling on entitlement in favor of the petitioner, finding that the petitioner suffered a right radial nerve injury that was caused-in-fact by the injection of her flu vaccination. *Kirby v. Sec'y of Health and Human Servs.*, No. 16-185, 2019 WL 6336026 (Fed. Cl. Spec. Mstr. Nov. 1, 2019) (hereinafter "*Kirby*"). On December 30, 2019, respondent filed a proffer on award of compensation, to which petitioner agreed. *See generally* Proffer, ECF No. 67. That same day, the Special Master awarded the petitioner compensation pursuant to the terms of that proffer. *See generally* Decision of the Special Master, ECF No. 68. Respondent now moves the Court to review the Special Master's November 1, 2019 decision on entitlement. For the reasons that follow, the Court **GRANTS** respondent's Motion for Review and **REVERSES** the Ruling on Entitlement by the Special Master.

[1] An unredacted version of this opinion was issued under seal on May 27, 2020. The parties were given an opportunity to propose redactions, but no such proposals were made.

I. Background

A brief recitation of the facts provides necessary context.[2]

Petitioner's prior medical history is unremarkable with respect to symptoms or conditions potentially related to petitioner's alleged vaccine injury, which she claims occurred on October 8, 2013. Additionally, the Special Master's decision does not note any pre-existing conditions or injuries related to petitioner's right arm prior to the alleged vaccine injury. Rather, petitioner's medical records indicate that, in 2007, Ms. Kirby injured her left ankle and fractured her left wrist during a fall, the latter of which was treated with a fiberglass cast. Beginning in 2009, petitioner sought treatment for her left ankle, including a surgical procedure to treat that injury in March of 2009. Though subsequent treatment failed to alleviate her pain, petitioner continued to seek treatment for her ankle up to and after the alleged vaccine injury occurred in October of 2013, which is reflected in her medical records.

On October 8, 2013, Ms. Kirby received a seasonal flu vaccination in her right deltoid muscle at the Department of Corrections, her place of employment. One week later, on October 15, 2013, petitioner saw Jennifer Chandler, Nurse Practitioner ("NP"), at Pike Bowling Green Clinic. At that appointment, Ms. Kirby complained of persistent right arm numbness and tingling that she began experiencing one week prior. NP Chandler reviewed and examined petitioner's musculoskeletal system[3] and noted the presence of myalgia.[4] Based on that physical

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[2] As the basic facts here have not changed significantly, the Court's recitation of the background facts herein draws from the Special Master's earlier decision in *Kirby v. Secretary of Health and Human Services*, No. 16-185, 2019 WL 6336026 (Fed. Cl. Spec. Mstr. Nov. 1, 2019), including the exhibits cited therein.

[3] The musculoskeletal system is "the muscles (muscular system) and the bones and joints (skeletal system) of the body, considered as one unit." *Musculoskeletal system, Dorland's Medical Dictionary* (hereinafter "*Dorland's*"), https://www.dorlandsonline.com/dorland/definition?id=111871 (last visited May 14, 2020).

[4] Myalgia is defined as "pain in a muscle or muscles." *Myalgia, Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=32592 (last visited May 14, 2020).

examination, NP Chandler diagnosed petitioner as having right arm paresthesia[5] and prescribed a Depo-Medrol-Methylprednisolone acetate[6] injection, prednisone[7] packet, and ibuprofen.

Between October 16, 2013, and November 7, 2013, petitioner saw Dr. Gregory L. Henry, D.O., at the Hannibal Regional Medical Group Occupational Medicine on three separate occasions, complaining of moderate, persistent pain and numbness in her upper right arm that radiated[8] into the right side of her neck and down to her right hand and fingers. During the first visit, Dr. Henry noted "decreased radial nerve distribution regarding light touch and reduced muscle strength in petitioner's right upper extremity." Dr. Henry ordered a routine muscle test[9] and a limited electromyography[10] ("EMG") with nerve conduction study[11] to test for a radial[12]

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[5] Paresthesia is "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." *Paresthesia, Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=37052 (last visited May 14, 2020).

[6] Depo-Medrol is the "trademark for preparations of methylprednisolone acetate." *Depo-Medrol, Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=13281&searchterm=Depo-Medrol (last visited May 14, 2020). Methylprednisolone acetate is "the 21-acetate ester of methylprednisolone, administered topically as an antiinflammatory, by intramuscular injection in replacement therapy for adrenocortical insufficiency, and by intra-articular, intramuscular, intralesional, or soft-tissue injection as an antiinflammatory and immunosuppressant in a wide variety of disorders." *Methylprednisolone acetate, Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=89217 (last visited May 14, 2020).

[7] Prednisone is "a synthetic glucocorticoid derived from cortisone, administered orally as an antiinflammatory and immunosuppressant in a wide variety of disorders." *Prednisone, Dorland's,* https://www.dorlandsonline.com/dorland/definition?id=40742 (last visited May 14, 2020).

[8] To radiate is "to diverge or spread from a common point." *Radiate*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=42722 (last visited May 14, 2020).

[9] A muscle test, or "manual muscle test" is when a "therapist manually puts the patient's body part through a range of motion and records the extent of function and limitations." *Manual Muscle Test*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=112750 (last visited May 14, 2020).

[10] Electromyography is defined as "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation performed using any of a variety of surface electrodes, needle electrodes, and devices for amplifying, transmitting, and recording the signals." *Electromyography*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited May 14, 2020).

[11] A nerve conduction study (electroneurography) is "the measurement of the conduction velocity and latency of peripheral nerves." *Electroneurography*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=15860 (last visited May 14, 2020).

[12] Radial is defined as "pertaining to the radius" *Radial*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=42718 (last visited May 14, 2020).

nerve injury. Dr. Henry also noted that petitioner may require Magnetic Resonance Imaging[13] studies of the right brachium[14] for possible abscess[15] formation and of the neck for petitioner's radicular[16] pain. Based on his examination of Ms. Kirby, Dr. Henry diagnosed petitioner as "having a complication due to vaccination, infection following immunization, and radial neuritis."

On October 23, 2013, during a second visit, Dr. Henry again examined petitioner, who complained of a persistent pattern of pain over the prior fifteen days, which she described as mild to moderate and characterized as throbbing, aching, and feeling weak. Upon examining the petitioner, Dr. Henry noted that, while Ms. Kirby's strength had improved in her right arm, her right thumb was numb and she had a knot at the injection site. Dr. Henry found normal strength and tone in petitioner's right wrist and "normal grip strength and range of motion in her hand."

During petitioner's November 7, 2013 doctor's visit, she reported experiencing a persistent pattern of mild to moderate pain in her upper right arm over the prior thirty days and stated that she had numbness in her right thumb. During that visit, petitioner informed Dr. Henry that she had returned to working regular duties despite her hand and wrist feeling very weak, and that she could not write for long periods of time. Upon examining Ms. Kirby, Dr. Henry found decreased sensation in the dorsum[17] of her right thumb and mild tenderness over the spiral groove. Dr. Henry prescribed a routine physical therapy evaluation and treatment for post vaccination radial neuritis,[18] a routine limited EMG with nerve conduction study, and a routine EMG one-limb muscle test for radial neuropathy post-vaccination.

The radius is "the bone on the outer or thumb side of the forearm." *Radius*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=42874 (last visited May 14, 2020).

[13] Magnetic resonance imaging ("MRI") is "a method of visualizing soft tissues of the body by applying an external magnetic field that makes it possible to distinguish between hydrogen atoms in different environments." *Magnetic resonance imaging*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=81954 (last visited May 14, 2020).

[14] Brachium is defined as the "arm: the part of the upper limb from shoulder to elbow." *Brachium*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=6767 (last visited May 14, 2020).

[15] Abscess is "a localized collection of pus within tissues, organs, or confined spaces." *Abscess*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=185 (last visited May 14, 2020).

[16] Radicular means "of or pertaining to a root or radicle." *Radicular*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=42733 (last visited May 18, 2020).

[17] Dorsum refers to "1. the back. 2. the aspect of an anatomic part or structure corresponding in position to the back; posterior, in the human neck, trunk, and limbs." *Dorsum*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=14818&searchterm=dorsum (last visited May 18, 2020).

[18] Neuritis is defined as "inflammation of a nerve, with pain and tenderness, anesthesia and parasthesias, paralysis, wasting, and disappearance of the reflexes." *Neuritis*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=33645&searchterm=neuritis (last visited May 14, 2020).

On November 12, 2013, per Dr. Henry's referral, petitioner met with Brock Mitchell, a physical therapist at Advance Physical and Sports Medicine, for an initial evaluation. There, petitioner reported having no prior injury, but she noted having a lot of arm pain and hand weakness two days after she received the flu shot. The physical therapist noted that petitioner would require physical therapy in conjunction with a home exercise program in order to address her problems and achieve the goals discussed during their visit. He also stated that the expected length of therapy required to treat Ms. Kirby's condition would be one month.

Between November 13, 2013, and December 10, 2013, Ms. Kirby completed eleven physical therapy sessions. By the end of the sixth session, she was able to complete treatment without complaints of pain or difficulty and was on schedule to achieve her recovery goals. On December 10, 2013, Ms. Kirby was discharged from rehabilitative therapy, having largely met all her goals. Except for a 4/5 score on her right thumb extension muscle testing, Ms. Kirby scored 5/5 on all muscle testing, having previously scored 4/5 during her initial assessment in November of 2013. Upon discharge, the physical therapist recorded Ms. Kirby's pain as a 0/10 rating, although she still reported numbness.

On November 14, 2013, amid attending physical therapy sessions, petitioner visited Dr. Boris Khariton, M.D., P.C., for a motor nerve study. Dr. Khariton noted that petitioner had right arm pain as well as right thumb numbness and tingling since October of 2013. Upon examining the petitioner, Dr. Khariton concluded that Ms. Kirby had normal manual motor testing, decreased sensation in her right thumb compared with the left side, and mild pain during palpation[19] of her right lateral[20] arm.

On November 21, 2013, Ms. Kirby returned to Dr. Henry for a follow-up visit, reporting pain in an intermittent pattern over the previous forty-three days. At this appointment, Dr. Henry interpreted Ms. Kirby's EMG as negative, and his physical examination revealed that Ms. Kirby regained normal sensation and normal muscle strength. Ms. Kirby visited Dr. Henry again on December 12, 2013, complaining of mild pain in the morning that would fade as the day went on, and occasional tingling down her right arm over the previous sixty-four days. During that visit, Ms. Kirby's physical exams were normal in all aspects, including sensation, coordination, strength, and tone. According to Dr. Henry, "petitioner had reached maximum medical improvement ('MMI') with no impairment," and therefore concluded that she could resume regular duties. After that appointment, "petitioner's medical records do not address her right arm

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[19] Palpation is "the act of feeling with the hand; the application of the fingers with light pressure to the surface of the body for the purpose of determining the consistency of the parts beneath in physical diagnosis." *Palpation*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=36456&searchterm=palpation (last visited May 18, 2020).

[20] Lateral denotes "a position farther from the median plane or midline of the body or of a structure. 2. pertaining to a side." *Lateral*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=27702&searchterm=lateral (last visited May 18, 2020).

pain again until nearly two years later," though, in the interim, petitioner "had a number of medical appointments unrelated to her arm pain."

On January 16, 2014, petitioner returned to Pike Bowling Green Clinic for a general adult physical exam and to complete certain Family and Medical Leave Act paperwork related to her prior ankle injury. At that appointment, NP Chandler noted that the petitioner had joint pain associated with her ankle. On October 28, 2014, petitioner again visited NP Chandler, complaining of a foot problem without any associated injury. The medical report detailed pain and swelling in her legs and ankles and noted that weight bearing, walking, or standing exacerbated her symptoms. Petitioner's medical records from that visit noted the absence of muscle pain, tingling, and numbness.

Petitioner returned for three additional follow-up visits with NP Chandler between October of 2014 and July of 2015. On petitioner's February 3, 2015 visit, NP Chandler noted neuropathy[21] as "Not Present." The medical report from petitioner's March 19, 2015 visit described shooting pains in petitioner's left leg for the preceding two weeks and documented the absence of joint and muscle pain. The medical report from petitioner's July 21, 2015 visit noted that "patient feels well with no complaints," that petitioner had "[p]ain in feet and Muscle Pain (chronic foot pain)," and once more indicated the absence of neuropathy.

On October 13, 2015, petitioner visited NP Chandler once more, complaining of pain in her right arm that had been gradually and intermittently occurring since she received the flu vaccine. NP Chandler documented that Ms. Kirby was experiencing neuropathic pain of the upper extremity, but no treatment plan was recorded. Petitioner's medical records documented petitioner's complaint of ongoing symptoms, including muscle pain and nerve pain in her right arm, and the records linked petitioner's symptoms and pain to the influenza vaccine that she received three years prior.[22] Petitioner's records from that visit further indicated that she did not have any physical limitations stemming from the pain.

A. Procedural History

Petitioner filed her Petition with the Office of Special Masters on February 8, 2016. *See generally* Petition, ECF No. 1. On February 20, 2017, petitioner filed the expert report of neurologist Dr. Marcel Kinsbourne, B.M., B.Ch., M.D.[23] On June 30, 2017, respondent filed the

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[21] Neuropathy is defined as "a functional disturbance or pathologic change in the peripheral nervous system limited to noninflammatory lesions as opposed to those of neuritis; the etiology may be known or unknown." *Neuropathy*, *Dorland's*, https://www.dorlandsonline.com/dorland/definition?id=33813 (last visited May 21, 2020).

[22] The Special Master concluded that the petitioner actually received the vaccine two years prior, not three years prior. *Kirby*, at *19 n.25.

[23] Dr. Kinsbourne obtained his B.M. and B.Ch. from Oxford Medical School in 1955 and his M.D. from the State of North Carolina in 1967. *See Kirby*, at *8; *see also* Petitioner's Expert Report, ECF No. 27 (hereinafter "Pet'r's Expert Rep.") Ex. 3, at 1. Dr. Kinsbourne has served as a senior fellow at the Center for the Study of Aging and Human Development at Duke University since 1974, an adjunct professor of Neurology at Boston University School of Medicine since

expert report of neurologist Dr. Peter Donofrio, M.D.[24] On September 8, 2017, petitioner filed a supplemental expert report in which Dr. Kinsbourne revised his assessment of the onset of petitioner's symptoms following her vaccination and provided an alternative theory that petitioner suffered direct nerve trauma from an injection needle. Respondent filed a supplemental expert report from Dr. Donofrio on November 14, 2019, responding to Dr. Kinsbourne's alternate theory. An entitlement hearing was held July 22, 2019. On November 1, 2019, Special Master Horner found that petitioner was entitled to compensation, finding "preponderant evidence that petitioner experienced residual effects of her radial nerve injury for more than six months." *Kirby*, at *1, *20. Respondent filed its Motion for Review and Memorandum of Objections on January 1, 2020. *See generally* Respondent's Motion for Review, ECF No. 71; Respondent's Memorandum of Objections, ECF No. 72 (hereinafter "Resp't's Mem."). On February 21, 2020, petitioner filed her Response to respondent's Motion for Review and Memorandum of Objections. *See generally* Petitioner's Memorandum in Response to Respondent's Motion for Review, ECF No. 74 (hereinafter "Pet'r's Mem."). Respondent's Motion is fully briefed and ripe for review.

II. Standard of Review

Under the Vaccine Act, this Court may review a Special Master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)–(2) (2018). In reviewing such a request, this Court may:

> (A) uphold the findings of fact and conclusions of law . . . , (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or, (C) remand the

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1987, a research professor at the Center for Cognitive Studies at Tufts University since 1992, and a professor of psychology at New School University since 1995. *See Id.*; *see also* Pet'r's Expert Report Ex. 3, at 1–2. Dr. Kinsbourne testified that although he has retired from hospital-based clinical practice, he still occasionally sees patients, primarily regarding pediatric neurology. *See* Transcript (hereinafter "Tr.") at 71:5–12, 109:15–111:11.

[24] Dr. Donofrio obtained his B.S. from the University of Notre Dame in 1972 and obtained his M.D. from Ohio State University School of Medicine in 1975. *See* Respondent's Expert Report, ECF No. 34 (hereinafter "Resp't's Expert Report") Ex. 4, at 2. Dr. Donofrio is a professor of neurology at Vanderbilt University Medical Center, Director of Vanderbilt's Neuromuscular Section, Director of the Muscular Dystrophy Association Clinic and Amyotrophic Lateral Sclerosis Clinic, and member of the Medical Advisory Committee of the Guillan-Barré Syndrome/Chronic Inflammatory Demyelinating Polyneuropathy (GBS/CIPD) International Foundation. *Kirby*, at *10; *see* Resp't's Expert Report Ex. 4, at 4–9. He is board certified in neurology, internal medicine, EMG, and neuromuscular disorders and has treated patients with Multiple Sclerosis (MS), Acute Disseminated Encephalomyelitis (ADEM), Transverse Myelitis (TM), and brachial neuritis. *Id.*; Resp't's Expert Report Ex. 4, at 3. He is published in Guillan-Barré Syndrome (GBS), Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), and other neuropathies, including his textbook on peripheral neuropathy. *Id.*; *see generally* Resp't's Expert Report Ex. 4, at 19–31.

petition to the Special Master for further action in accordance with the court's direction.

Id. § 300aa-12(e)(2)(A)–(C). Findings of fact and discretionary rulings are reviewed under the arbitrary and capricious standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec'y of Dep't of Health and Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

This Court cannot "substitute its judgment for that of the special master merely because it might have reached a different conclusion." *Snyder v. Sec'y of Health and Human Servs.*, 88 Fed. Cl. 706, 718 (2009). Rather, "[r]eversal is appropriate only when the special master's decision is arbitrary, capricious, an abuse of discretion, or not in accordance with the law." *Id.* Under this "highly deferential" standard, a Special Master's decision need only "articulate a rational connection between the facts found and the choice made" in order to be upheld. *Cucuras v. Sec'y of Dep't of Health and Human Servs.*, 26 Cl. Ct. 537, 541 (1992) (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993)). As such, if the Special Master "has considered the relevant evidence of record, drawn plausible inferences[,] and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Id.* at 541–42; (quoting *Hines ex rel. Sevior v. Sec'y of Dep't of Health and Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

III. Discussion

Althen v. Secretary of Health and Human Services provides the evidentiary burden for petitioners to establish a prima facie case on causation in order to succeed in a vaccine petition. 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also Pafford v. Sec'y of Health and Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Boley v. Sec'y of Health and Human Servs.*, 86 Fed. Cl. 294, 302 (2009). A petitioner can prove causation by either showing that the injury falls under the Vaccine Injury Table, which provides a presumption of causation, or by proving causation in fact for an injury not listed on the Vaccine Injury Table. *Nunez v. Sec'y of Health and Human Servs.*, 144 Fed. Cl. 540, 544 (2019). As the injury in the case at bar is not listed on the Vaccine Injury Table, to prove causation in fact, the petitioner must "show by preponderant evidence that the vaccination brought about [petitioner's] injury by providing" the following: "(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. To succeed on the claim, a petitioner must provide a "reputable medical or scientific explanation" for their claim. *Id*. Additionally, the petitioner must satisfy the "severity requirement" under the Vaccine Act, 42 U.S.C. § 300aa-11(c)(1)(D)(i), which, as a threshold matter, requires that the petitioner "show that the injury from the vaccine persisted for at least six months." *Boley*, 86 Fed. Cl. at 302 (citing 42 U.S.C. § 300aa-11(c)(1)(D)(i)); *see also Cloer v. Sec'y of Health and Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011).

Within this framework, respondent makes three numbered objections to the Special Master's November 1, 2019 decision. *See* Resp't's Mem. at 9, 11–12, 13. First, respondent asserts that the Special Master erred by applying an erroneous legal standard under the guise of a credibility determination. *Id*. at 9. Second, respondent argues that the Special Master applied an

impermissibly low burden of proof in analyzing the first two prongs of *Althen*. *Id*. at 11–12. Finally, respondent asserts that the Special Master engaged in arbitrary and capricious fact-finding and applied an incorrect legal standard in evaluating whether the petitioner satisfied the Vaccine Act's severity requirement. *Id*. at 13.

A. Severity Requirement of the Vaccine Act

In its third numbered objection, respondent argues that it was arbitrary and capricious for the Special Master to find that the petitioner satisfied the Vaccine Act's severity requirement given petitioner's testimony and the evidence in the record. Resp't's Mem. at 13–14. Specifically, respondent asserts that the Special Master erred in relying on petitioner's testimony alone to conclude that the petitioner established that she suffered residual symptoms for at least six months. *Id*. at 14–15. Respondent argues that the Special Master erred in relying on petitioner's testimony, as petitioner's testimony conflicted with "presumptively accurate contemporaneous medical records." *Id*. at 15. Respondent cites to case law from this Court to support its claim that, when a Special Master bases a finding on lay testimony, there must also be corroborating evidence, medical or otherwise, to support petitioner's claim and testimony; respondent contends that there is no such corroborating evidence in the case at bar. *Id*. at 14 (citing *Epstein v. Sec'y of Dep't of Health and Human Servs.*, 35 Fed. Cl. 467, 478 (1996)). Further, respondent argues that medical records created contemporaneously with the events they describe are presumed to be accurate and complete. *Id*. at 13. *See Cucuras*, 993 F.2d at 1528; *see also Robi v. Sec'y of Health and Human Servs.*, No. 12-352, 2014 WL 1677116, at *1 (Fed. Cl. Spec. Mstr. Apr. 4, 2014). In support of its argument, respondent asserts that petitioner's medical records show that she was treated for her condition for approximately three months, and that by January 16, 2014, petitioner was "feeling fine" and reported no symptoms related to her shoulder. Resp't's Mem. at 14 (citing Medical Records, ECF No. 9 (hereinafter "Medical Records") Ex. 3, at 25). Respondent further argues that the medical records between January of 2014 and July of 2015 reflect multiple medical visits with NP Chandler, during which petitioner did not report "shoulder pain, arm pain, weakness, or thumb numbness." *Id*. (citing Medical Records Ex. 4, at 29–44).

In response, petitioner asserts that any "[d]iscrepancies between the testimony and records or gaps in the medical records are not in and of themselves decisive; clear, cogent, and consistent testimony can overcome such missing or contradictory medical records." Pet'r's Mem. at 14 (quoting *Stevens v. Sec'y of Dep't of Health and Human Servs.*, No. 90-221, 1990 WL 608693, at *3 (Cl. Ct. 1990)). Petitioner additionally argues that "[o]ther records and Ms. Kirby's testimony presented clear, cogent and consistent evidence that Ms. Kirby's symptoms did, in fact, continue for at least six months." *Id*. at 15.

As relevant to the case at bar, the severity requirement under the Vaccine Act states that a petitioner seeking "compensation under the Program for a vaccine-related injury" must include with such petition "an affidavit, and supporting documentation, demonstrating that the person who suffered such injury . . . suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine . . . ." 42 U.S.C. § 300aa-11(c)(1)(D)(i). The Vaccine Act further provides that "a special master or court may not make a finding [that petitioner met the requirements under 42

U.S.C. § 300aa-11] based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion." 42 U.S.C. § 300aa-13(a)(1). Rather, a petitioner must demonstrate that she satisfied the requirements under 42 U.S.C. § 300aa-11(c)(1) by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1)(A); *see also D'Tiole v. Sec'y of Health and Human Servs.*, 726 F. Appx. 809, 810 (Fed. Cir. 2018).

The Special Master accorded substantial weight to petitioner's testimony claiming that she experienced continuous symptoms past the requisite six-month period after receiving the vaccine. Thus, despite petitioner reporting that she was "feeling fine" at her January 16, 2014 appointment, the Special Master concluded that such statement "is relatively vague and does not rule out the possibility of ongoing, but less significant, symptoms related to petitioner's radial nerve injury." *Kirby*, at *19. The Special Master made this determination despite petitioner's medical records not corroborating that testimony, as he accorded substantial weight to the credibility of testimony and a discrete excerpt from records of an October 13, 2015 doctor's office visit in concluding that petitioner's symptoms persisted after the December 12, 2013 doctor's visit. *Id.* at *13, *19. Specifically, the Special Master found that the statement "Patient complains today that nerve pain is still present but has decreased tremendously from when the injury occurred" from the October 13, 2015 report demonstrated that the petitioner experienced persistent symptoms from December 12, 2013, to October 13, 2015, thereby satisfying the six-month severity requirement under the Vaccine Act. *Id*. at *19. Special Master Horner did, however note that after petitioner's December 12, 2013 visit to the doctor's office, "petitioner's medical records do not address her right arm pain again until nearly two years later," and that, "[i]n the interim, petitioner had a number of medical appointments unrelated to her arm pain." *Id.* at *6. Nevertheless, Special Master Horner was "not persuaded by respondent's contention that petitioner's condition does not meet the severity requirements of the Vaccine Act," concluding that "there is preponderant evidence that petitioner's condition lasted for at least six months." *Id*. at *17

This Court has explained that, where testimony conflicts with contemporaneous medical records, "the Special Master generally should afford contemporaneous medical records greater weight than conflicting testimony offered after the fact." *Caron v. Sec'y of Health and Human Servs.*, 136 Fed. Cl. 360, 377 (2018) (citing *Murphy v. Sec'y of Health and Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed Cir. 1992)). That standard exists because "medical records created contemporaneously with the events they describe are presumed to be accurate and complete." *Id.* (citing *Cucuras*, 993 F.2d at 1528 ("Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events."). However, a Special Master may also consider oral testimony in reaching a decision, and "there are situations when oral testimony may be more persuasive than written records," such as when medical records are inaccurate or incomplete. *See id*. (citing *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006)). Where oral testimony is inconsistent with medical records, "discrepancies between the testimony and records or gaps in the medical records are not in and of themselves decisive; clear, cogent, and consistent testimony can overcome such missing or contradictory medical records." *Stevens*, 1990 WL 608693, at *3; *see also Caron*, 136 Fed. Cl.

at 377–78 (*quoting Camery v. United States*, 42 Fed. Cl. 381, 391 (1998) ("'Oral testimony that is inconsistent with medical records must be consistent, clear, cogent and compelling to outweigh the medical records prepared for the purpose of diagnosis and treatment.'")).

Petitioner's testimony and medical records evidence that the petitioner received treatment for her vaccine injury from October 15, 2013, to December 13, 2013, a two-month period of time. *See generally* Medical Records Ex. 3, Ex. 4, at 1–28. Petitioner's medical records from January of 2014 through October of 2015, however, lack sufficient documentation to establish that the petitioner experienced continuous symptoms in her arm related to her vaccine during that period of time. Instead, petitioner's medical records reflect that between January of 2014 and October of 2015, the petitioner visited NP Chandler four times, exclusively seeking treatment for her ankle. *See* Medical Records Ex. 4, at 29–44. Petitioner's testimony likewise fails to demonstrate that the petitioner's symptoms were consistent and present from January of 2014 through October of 2015. *See* Tr. 24:10–38:12. The Special Master acknowledged that, at trial, "petitioner could not recall any significant detail when her injury resolved," and thus "a precise date for the resolution of her injury is difficult, if not impossible, to ascertain." *Kirby*, at *17. Though the petitioner testified to telling NP Chandler of her recurring symptoms, petitioner's testimony failed to identify on what date she mentioned those recurring symptoms. *See id*. The Court therefore concludes that petitioner's medical records do not establish that she experienced symptoms related to her alleged vaccine injury for at least six months, and that petitioner's medical records also do not corroborate her testimony in which she stated that she experienced recurring symptoms after her December 12, 2013 visit with Dr. Henry. *See* Medical Records Ex. 4, at 29–44. As such, the Court determines that it was arbitrary and capricious for the Special Master to conclude that the petitioner's medical records and testimony establish that the petitioner experienced symptoms stemming from her vaccine injury over a six-month period of time, as required by 42 U.S.C. § 300aa-11(c)(1)(D)(i).

Dr. Kinsbourne's testimony before the Special Master likewise fails to establish or corroborate petitioner's claim that she experienced vaccine-related symptoms for longer than six-months. In *Epstein v. Secretary of Health and Human Services*, this Court held that, "in cases in which a court has based a finding on lay testimony, there must be corroborating evidence, either medical or other to support the claim." 35 Fed. Cl. at 478. The *Epstein* Court further held that expert testimony based solely on medical records does not corroborate lay testimony that seeks to establish a medical timeline where the expert had not physically examined the petitioner during the period in question. *Id*. at 476. This Court reached that conclusion because "neither of the[] physicians could offer contemporaneous, first-hand knowledge based on personal observation, about the period of time [in question]." *Id.* Instead, examples of corroborating evidence that adequately support lay testimony can include a lay-person's personal calendar, a billing statement for medical services, hospital records, and testimony from the petitioner's regular treating physician who also administered the vaccination at issue. *Id.* at 478; *see also Brown v. Sec'y of Dep't of Health and Human Servs.*, 18 Cl. Ct. 834, 840 (1989), *rev'd on other grounds*, 920 F.2d 918 (Fed. Cir. 1990); *Berry v. Sec'y of Dep't of Health and Human Servs.*, No. 90-339, 1990 WL 293448, at *3 (Cl. Ct. Spec. Mstr. Nov. 15 1990); *Alger v. Sec'y of Dep't of Health and Human Servs.*, No. 89-31, 1990 WL 293408, at *7 (Cl. Ct. Spec. Mstr. Mar. 14, 1990).

During the hearing before the Special Master, petitioner's expert Dr. Kinsbourne stated that, prior to the hearing, he had never met the petitioner, and that he had never physically examined her. Tr. at 114:21–115:10. Dr. Kinsbourne further testified that he had never spoken directly with any of Ms. Kirby's treating medical providers, and that he based his opinion entirely on the petitioner's medical records. *Id*. at 115:5–10. On this basis, the Court finds that it was arbitrary and capricious for the Special Master to rely on Dr. Kinsbourne's testimony or to use such testimony in order to corroborate petitioner's testimony in which she claims to have experienced pain and numbness in her arm during the period between January 2014 and October 2015.

This Court has routinely held that "[r]eversal is appropriate only when the special master's decision is arbitrary, capricious, an abuse of discretion, or not in accordance with the law." *Snyder*, 88 Fed. Cl. at 718. Here, the Court finds that the Special Master's acceptance of petitioner's lay testimony, without the support of contemporaneous corroborating medical records or evidence, to be arbitrary and capricious. As such, the Court concludes that the petitioner failed to satisfy a fundamental prerequisite for establishing a claim under the Vaccine Act, as the petitioner has not demonstrated that she suffered residual effects or complications of her injury for at least six months after the administration of the vaccine. The Court therefore reverses the Special Master's decision on entitlement.

B. Expert Credibility Determination and *Althen* Prongs

In its Motion for Review and Memorandum of Objections, respondent also alleges that the Special Master "erred by cloaking the application of an erroneous legal standard in the guise of a credibility determination." Resp't's Mem. at 9 (citing *Andreu v. Sec'y of Dep't of Health and Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009)). Respondent contends that the Special Master inappropriately rejected the opinions of Dr. Donofrio, "the far-better-credentialed expert," in favor of those of Dr. Kinsbourne by framing that rejection as a credibility determination. *Id*. at 10. In response, petitioner argues that the Special Master did not arbitrarily evaluate the credibility of Dr. Donofrio's opinions, alleging that, in actuality, Special Master Horner found Dr. Donofrio's opinions to be unpersuasive. Pet'r's Mem. at 10–11. Petitioner further claims that "the Special Master determined both experts were qualified to opine in the case" and that it therefore "was not Dr. Donofrio's credibility as an expert that was an issue for the Special Master." *Id*. at 11.

In its second numbered objection, respondent alleges that the Special Master applied "an incorrect standard in evaluating petitioner's evidence of causation in violation of *Althen v. Secretary of Health and Human Services*. Resp't's Mem. at 1. As to the analysis of the first prong, respondent alleges that the Special Master erred in his treatment of Dr. Donofrio's concession that Dr. Kinsbourne's theory is possible, arguing "[a] concession that a theory is possible *is not* a concession that the theory is reputable, sound and reliable." *Id*. at 12 (emphasis in original); *see Boatmon v. Sec'y of Health and Human Servs.*, 941 F.3d, 1351, 1359 (Fed. Cir. 1996). In response, petitioner argues that a petitioner's theory "need only be 'legally probable, not medically or scientifically certain.'" Pet'r's Mem. at 12 (quoting *Knudsen v. Sec'y of Dep't of Health and Human Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)). Petitioner further contends that the word "possible" in this context means "can happen," and that both Dr. Kinsbourne and

Dr. Donofrio "testified it is medically, anatomically possible for a syringe to impact the radial nerve." *Id*.

Regarding the second prong, respondent argues that the Special Master's analysis was flawed when he interpreted Dr. Donofrio's acknowledgement that petitioner could conceivably have had mild radial neuritis undetected by an EMG, despite "petitioner's right arm study [being] better than her left." Resp't's Mem. at 12–13. Respondent further claims that in finding the petitioner had radial neuritis, based in part on expert opinions, the Special Master applied an inappropriately low burden of proof. *Id*. at 13. In response, petitioner asserts that "arguments based on statistical probabilities are deemed irrelevant" and that "bare statistical facts have no bearing on whether an injury in a particular case is vaccine related." Pet'r's Mem. at 13 (citing *Knudsen*, 35 F.3d at 550).

As the Court found the Special Master's determination that the petitioner met the six-month severity requirement to be arbitrary and capricious, the Court will not review in detail the government's remaining two objections to the Special Master's treatment of the expert opinions or his analysis of the *Althen* prongs. The Court does, however, think the government's arguments are well-founded.

III. Conclusion

For the foregoing reasons, the Court holds the Special Master's decision finding that the petitioner satisfied the severity requirement of the Vaccine Act to be arbitrary and capricious and not in accordance with law. Accordingly, the Court hereby **GRANTS** respondent's MOTION for review, **REVERSES** the Special Master's November 1, 2019 ruling on entitlement, and **VACATES** the decision of the Special Master. The Clerk is directed to dismiss the Petition and enter judgment for respondent.

IT IS SO ORDERED.

s/ *Loren A. Smith*
Loren A. Smith,
Senior Judge