In the United States Court of Federal Claims

No. 16-930V
(Filed: June 4, 2021)[1]
(Re-filed: July 12, 2021)

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KIRA HUGHES,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

National Childhood Vaccine Injury Act, 42 U.S.C. §§300aa-1 to -34 (2018); Motion for review; HPV vaccine; Off-table injury; Injury in-fact; Dismissal without a hearing; CRPS; POTS.

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Braden Blumenstiel, Dublin, OH, for petitioner.

Kyle E. Pozza, Trial Attorney, Torts Branch, Civil Division, Department of Justice, Washington, DC, with whom were *Brian M. Boynton*, Acting Assistant Attorney General, *C. Salvatore D'Alessio*, Acting Director, *Heather L. Pearlman*, Acting Deputy Director, and *Alexis B. Babcock*, Assistant Director, for respondent.

OPINION

BRUGGINK, *Judge*.

In this action, brought pursuant to the National Childhood Vaccine Injury Act, petitioner alleges that she suffers from pain and a heart condition caused by vaccines she received on August 15, 2013. The case is before the court on petitioner's motion for review of the January 4, 2021 entitlement

[1] This Opinion was held for fourteen days during which the parties were permitted to propose to chambers any appropriate redactions. They did not do so, and thus we reissue the decision without redactions.

decision denying compensation. *Hughes v. Sec'y of Health & Human Servs.*, No. 16-930V, 2021 WL 839092 (Fed. Cl. Spec. Mstr. Jan. 4, 2021). The motion is fully briefed, and oral argument is unnecessary. The Special Master's conclusion that the petitioner has not established that she suffers from the injuries alleged was neither arbitrary nor capricious. We therefore deny the motion for review.

BACKGROUND

I. Factual History

Petitioner's relevant medical history begins on November 27, 2012, when she visited the Wheeling Hospital in Wheeling, WV, complaining of breathing problems, elevated heart rate, and dizziness. Two weeks later, Ms. Hughes visited a community health center for headaches, heavy menstrual period and again dizziness. Blood tests were normal, and the physician's assistant thought that the dizziness might have been the result of ear or optical problems. On January 4, 2013, petitioner presented again at the health center with knee pain and posterior bruising after falling down the stairs. Cardiovascular and lung examinations were normal. The physician's assistant referred petitioner to physical therapy. On August 15, 2013, Ms. Hughes visited the community health center again for immunizations. The records of that visit state that she had a history of migraines. Petitioner received the Meningococcal, Tdap, and HPV vaccines at that time.[2]

A week later, petitioner returned to the health center, complaining a urinary tract infection, abdominal pain, and nausea. The treating doctor recorded that the examination revealed no pain in petitioner's legs. Pet.'s Ex. 1 at 4 (ECF No. 6-1). Nor were skin rashes observed. A urine culture came back negative. On August 23, 2013, Ms. Hughes visited an OBGYN specialist, Dr. Walsh, again for pain in her abdomen. This visit included an ultrasound to check for cysts, but none were found. The notes from that visit also indicate that petitioner had by then complained twice of belly pain during her menses. The following month, in September 2013, Dr. Walsh proscribed oral contraceptives after Ms. Hughes again presented with lower abdominal pain during her period.

[2] "Tdap" is short for tetanus diphtheria-acellular-pertussis and "HPV" is short for human papillomavirus.

On October 16, 2013, petitioner returned to Dr. Walsh, reporting leg pain in both legs. The record of that visit shows that petitioner said that the pain had begun three days prior. Pet.'s Ex. 24 at 3 (ECF No. 24-1). An ultrasound examination of her legs was ordered and performed. It revealed, however, nothing regarding the root of the pain. *Id.* at 5. Two days later, Ms. Hughes went to the emergency room at the Monongalia General Hospital in Morgantown, WV, for leg cramping, which she reported began three days earlier, as well as for headaches, and back pain. The treating doctor at the hospital conducted a physical exam, and then ordered blood testing and an x-ray of petitioner's legs. Nothing remarkable was found. The records of that visit indicate no neurological deficits or other motor or sensory problems. The doctor's differential diagnoses included sciatica, spinal stenosis, scoliosis, Guillian Barre syndrome, or a viral syndrome. Pet.'s Ex. 7B at 17 (ECF No. 7-5).

Petitioner's complaints of leg pain continued. On October 22, 2013, Ms. Hughes visited Dr. Joseph Li, M.D., for leg pain that she reported had been ongoing for 10 days. Consistent with the hospital notes, she reported no neurological or sensory problems other than an occasional limp in the morning. She also told Dr. Li that she had stopped taking birth control pills. Dr. Li's examination revealed tenderness in her legs. A blood test showed slightly elevated muscular enzymes, but she was negative for Lyme disease and rheumatoid disorders. Pet.'s Ex. 3 at 8 (ECF No. 6-3); Pet.'s Ex. 7B at 7-11 (ECF No. 7-5). Dr. Li's diagnosis was "myalgia," and he prescribed a muscle relaxant. Pet.'s Ex. 3 at 9.

One week later, petitioner was admitted to the West Virginia University Hospital due to complaints of continued pain in her abdomen, back, and legs. She stated that her pain level was a seven on a ten-point scale. Pet.'s Ex. 6A at 16 (ECF No. 7-1). The examiners, and the treating doctor, Dr. Jeffrey Lancaster, M.D., found no evidence of inflammatory disorders. *Id.* at 15. Dr. Lancaster noted that fibromyalgia fit the vague description of symptoms, but that it was unlikely given Ms. Hughes' youth. Records from that visit indicate that Ms. Hughes or her family asked about the possibility that the Gardasil vaccine (HPV) could have caused the pain. Pet.'s Ex. 6B at 25 (ECF No. 7-2). Ms. Moczek, petitioner's mother, requested a toxin screen to check for an adverse reaction, but the notes from Dr. Lancaster indicate that he and other treaters looked into the components of the vaccine and concluded that it was very unlikely to be the source of the pain. Pet.'s Ex. 6A at 19. The hospital suggested an MRI to look for multiple sclerosis, but petitioner's family declined.

On October 31, 2021, petitioner was seen by a neurologist, Dr. Jodi Lindsey, M.D. Dr. Lindsey found "giveaway weakness" in petitioner's left leg and overactive reflexes in both legs. *Id.* at 29. Dr. Lindsey's finding was that Ms. Hughes did not present a real weakness and that most of the symptoms might be explained by chronic constipation. *Id.* at 32. This time, an MRI was performed on petitioner, but it showed nothing extraordinary, the same result as the previous lab tests. Petitioner was discharged the next day. Dr. Lancaster wrote that there was no clear cause of Ms. Hughes' pain and that, given the extensive nature of her examinations and testing, anxiety might be to blame. *Id.* at 36.

On November 4, 2013, petitioner underwent a brain and spine MRI. Nothing remarkable was discovered other than a "subtle loss of height of disc space at the L4-5 level." Ex. 3 at 11 (ECF No. 6-3). On November 6, 2013, petitioner went to Dr. Li for a follow-up visit. Dr. Li's notes indicate that, after reviewing all available records and lab reports, including the MRI results, there was a consensus among the treating physicians that no physical etiology of petitioner's pain had been found. Notable was the observation by Dr. Li that, despite his light touch causing her pain during examination, Ms. Hughes was able to take on and off "skin tight jeans" without pain. Pet.'s Ex. 3 at 13. He also recorded that, although petitioner complained of pain in the mornings, to the point where she could not walk to school, in the afternoon, in his office, she was walking normally, and her movements were fluid. *Id.* at 11. The notes also reveal that Ms. Hughes was upset and cried when discussing returning to school although she stated that she did want to return. *Id.* at 13. Upon leaving Dr. Li's office, Ms. Hughes' gait became unsteady and her legs stiff.

Ms. Moczek again proposed that the HPV vaccine might be to blame, but Dr. Li's notes indicate that her daughter's symptoms were not consistent with the side effects recorded for Gardasil in the medical literature. *Id.* at 16. Petitioner cried when Dr. Li suggested that the pain might be mental in origin. His notes from the visit include that the "active problems" were "myalgia and myositis" and "somatization." *Id.* at 12. Dr. Li suggested counseling. The record of the visit also indicates that Dr. Lancaster had agreed that petitioner could try alternative medicine, and Dr. Li provided a referral to a practitioner.

Early the next year, petitioner followed up with the neurologist, Dr. Lindsey, at an outpatient visit. The notes of that visit indicate that the leg

pain continued and that severe headaches had begun since the hospital stay in 2013. Petitioner also reported continued constipation and poor sleep. Petitioner "den[ied] any clear noted social stressors." Pet.'s Ex. 6C at 30 (ECF No. 7-3). Petitioner and her mother reiterated their vaccine-induced pain theory, this time including additional detail regarding an "inflammatory process." Dr. Lindsey concluded otherwise, however, noting neither evidence of an inflammatory issue after repeated blood testing nor any neurological problems. *Id.* at 32. The doctor recommended "Cognitive Behavioral Therapy" to deal with stress and pain somatization. *Id.*

Also around this time, petitioner began to consult with Dr. Phillip DeMio, one of petitioner's experts in this case. The intake forms for Dr. DeMio's practice, located in Worthington, OH, indicated pain, headaches, and constipation. *See* Pet.'s Ex. 10A at 2-3 (ECF No. 7-7). Some of petitioner's relevant medical history was also provided, including the administration of the HPV vaccine. Those forms also state that petitioner presented an "uneven smile," which Dr. DeMio indicated might be indicative of bell palsy. *Id.* at 4. In the box labeled "Adverse reactions and allergies to drugs, supplements, foods, anything else," "Gardasil-adverse reaction" was listed. *Id.* at 3.

Dr. DeMio's records are very difficult to read as they are often handwritten and dates or frequently missing or are indecipherable. He continued to treat Ms. Hughes through 2016. A chronological recital is both impossible and unnecessary. Over his several years of involvement with petitioner, he recommended, which were performed, a host of blood tests for various diseases, genetic conditions, and hormonal levels. He prescribed an extensive list of homeopathic remedies, vitamins, and minerals. *See id.* at 11-23. Antiviral medications were also recommended. Most of the tests were negative or unremarkable other than one set of antibodies indicative of a viral infection from the herpes family.

On March 19, 2014, Ms. Hughes returned to Dr. Li with the same pain complaints, reporting that her myalgia began in October 2013. Petitioner's mother informed Dr. Li that Dr. DeMio had thought that Lyme disease might be to blame. Dr. Li explained that petitioner had already tested negative for Lyme disease. Dr. Li again recorded the difference between the pain reported and petitioner's demeanor and reactions during the exam. Pet.'s Ex. 3 at 22. He advised that Dr. DeMio's testing was unnecessary and again proposed somatization as the likely diagnosis. Petitioner requested a rheumatoid referral, which Dr. Li agreed to provide.

On March 31, 2014, petitioner went to a clinic at the West Virginia University Hospital for her chronic pain, headaches, fatigue, and sleep problems. The treating physician, Dr. Ahmad Al-Huniti, M.D., noted the lack of a clear etiology and thus concluded a potential "psychogenic" root and/ or "complex regional pain syndrome, chronic fatigue syndrome, Ehler's Danlos/POTS."[3] Pet.'s Ex. 6C at 211.

Ms. Hughes had a rheumatology examination at the Nationwide Children's Hospital in Columbus, OH, on April 22, 2014. The records of that visit indicate that petitioner's mother explained that her daughter's pain began in August 2013, two months earlier than previously reported. Pet.'s Ex. 5 at 6 (ECF No. 6-5). The treaters at the Children's Hospital noted hypermobility and excessive pain and fatigue. Psychological causes were also proposed as potential etiology and anxiety treatment recommended. *Id.* at 67-68.

The next month, petitioner visited a genetics clinic back at the West Virginia University Hospital. Following examination, Dr. Tara Narumanchi, M.D., did not recommend genetic testing. She did recommend hydrotherapy and a cardiology evaluation with a "tilt table test" due to "concern of POTS."[4] Ex. 6C at 225.

In June 2014, Ms. Hughes visited Dr. Freeda Flynn, M.D., in Saint Clairsville, Ohio for "HPV Complications." Pet.'s Ex. 23 at 18 (ECF No. 22-1). The printed record of that visit indicates a 15-minute office visit and an electrocardiogram. *Id.* at 19. The diagnoses listed on the two-page printed record were an unspecified mycoplasma infection and a heart murmur. *Id.* Dr. Flynn's handwritten notes on the next page also indicate a viral infection and "possible Gardasil reaction." *Id.* at 20.

Dr. Flynn continued to see and order tests on petitioner through 2016. These included a cortisol serum test in August 2014, chest x-rays and an EKG in September 2014, and spinal x-rays in August 2016. *See id.* at 21-26. Dr.

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[3] "POTS" is short for postural orthostatic tachycardia syndrome.

[4] The Special Master noted that it was not clear why Dr. Narumanchi included POTS as an issue during the genetics consultation other than the fact that petitioner's mother had previously brought it up to other treating physicians and Dr. Al-Huniti's notations in March 2014. 2021 WL 839092 at *7.

Flynn authored a general letter, dated September 11, 2014, stating that petitioner was in her care for "Gardesil [sic] Syndrome" and a bacterial infection. *Id.* at 27. The letter stated that it was in Ms. Hughes' best interest to "remain home bound" until December 19, 2014. *Id.*

Also in September 2014, petitioner again saw Dr. DeMio, who prescribed pain medication, but records indicate that she did not take the medicine for fear of nausea. Pet.'s Ex. 17 at 9 (ECF No. 8-7). Dr. DeMio saw Ms. Hughes again that month and opined that Ms. Hughes might have Lyme disease and recommended a slate of treatments consisting of antivirals, antibiotics, and various nutritional supplements. *Id.* at 17. After attending and dancing at a wedding in mid-September, Ms. Hughes presented to the emergency room at the Wheeling Hospital for heart palpitations. An EKG and chest x-ray were unremarkable, however. Pet.'s Ex. 18 at 14-15 (ECF No. 12-1).

In January 2015, Dr. DeMio issued a letter similar to Dr. Flynn's. In it, he stated that he was treating petitioner for several diseases and disorders, among which were Lyme disease, autoimmune problems, and metabolic disorder. Pet.'s Ex. 10A at 44 (ECF No. 7-7). His recommendation was a limited school schedule.

After filing the lawsuit, petitioner also submitted a two-page record from the Cleveland Clinic Neurology Department, dated August 15, 2019. That document states that petitioner was referred by a Certified Nurse Practitioner for back pain and sciatica. The document indicates "associated diagnos[e]s" of POTS and insomnia. Pet.'s Ex. 47 (ECF No. 76-1). The Special Master found the probative value of that document to be limited, however, due to the lack of explanation or other corroborative testing. 2021 WL 839092 at *8.

II. Procedural History

On August 3, 2016, petitioner's mother, on behalf of her then-minor daughter,[5] timely filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§300aa-1 to -34 (2018) ("Vaccine Act"). Shortly thereafter, petitioner filed the medical records discussed above and other records as they became available. Petitioner also

[5] Ms. Hughes was eventually substituted as the petitioner when she reached the age of majority.

initially filed expert reports from Dr. DeMio and and Dr. James Lyons-Weiler. The Special Master stated in his opinion that he reviewed the reports and instructed petitioner to provide a third expert report due to misgivings he had about the experts based on his prior experience with them and the substance of their reports. 2021 WL 839092 at *17. A minute order entered on July 31, 2017, directed such by September 8, 2017. It is not clear from the opinion below nor the docket entries if the Special Master's substantive doubts were communicated nor how petitioner knew what the third expert report was to address.

Although petitioner did eventually submit several reports from a third expert, Dr. Michael Miller, M.D., on September 29, 2017, the Special Master dismissed the petition for failure to prosecute due to repeated failures to file documents on time. ECF No. 38. He denied reconsideration on February 16, 2018. ECF No. 58. Petitioner then filed a motion for review, which we denied. ECF No. 63. Those decisions were reversed, however, by the Federal Circuit in 2019. *Moczek v. Sec'y of Health & Human Servs.*, 776 F. App'x 671 (Fed. Cir. 2019) (holding that dismissal for failure to prosecute was an abuse of discretion due to the nature of the Vaccine Act's intent to create a less formal litigation process).

After remand, respondent moved for an order to show cause why the case should not be dismissed on the basis that the petition, records, and expert reports were insufficient to meet the Vaccine Act's causation standard. Petitioner opposed on the basis that the motion was a thinly veiled attempt at summary judgment and that it was inappropriate to grant on the record already established. The Special Master agreed and denied the motion on February 19, 2020. ECF No. 77. The Special Master advised, however, that the government could revisit the issue by moving for a ruling on the record. *Id.* at 4. The Special Master reiterated that he found petitioner's case particularly unpersuasive and that he was unlikely to ultimately order compensation.

Respondent moved for a ruling on the record in May 2020. Petitioner opposed and submitted a final expert report from Dr. Miller. Respondent submitted neither expert opinion nor any other form of evidence for the Special Master to consider.

III. Petitioner's Experts

Petitioner presented reports from three experts. The first, Dr. DeMio, as summarized above, also examined Ms. Hughes during her complained of symptoms prior to the action at bar.

A. Dr. DeMio

Dr. DeMio has an M.D. from Case Western Reserve University and completed residencies in pathology and emergency medicine. He now primarily treats Lyme disease and autism spectrum disorders but does see patients with chronic pain, such as Ms. Hughes. He has authored several papers on chronic conditions such as arthritis, gout, and general inflammatory problems. He has spoken at conferences about spinal injuries and Lyme disease. Pet.'s Ex. 49 at 3 (ECF No. 76-8) (DeMio CV).

His report in this case describes petitioner's health as generally "very good" prior to her immunizations in 2013. He details that, at his initial examination, he found tender areas in her legs, differences in her tendon reflexes, mottled skin, and an otherwise unexplained "emotional liability." Pet.'s Ex. 11 at 1 (ECF No. 8-1). After testing, he treated Ms. Hughes for immune problems and "metabolic dysfunction." *Id.* at 2. He believes that petitioner's health rapidly declined after the vaccines and that she has now been rendered permanently disabled. He draws a causal link between them.

His report states that the vaccines administered to Ms. Hughes contained elements which elicited an "intense long-lasting reaction[] in the body." *Id.* These adjuvants, microbial DNA, and microbial proteins, in his view, can and did create a "pathologic response" damaging end organs by way of cellular damage in those tissues, opines Dr. DeMio. *Id.* He cites an article from the Journal of Investigative Medicine High Impact Case Report from 2014.[6] This article appears in the record as Pet.'s Ex. 36 (ECF No. 48-2). Dr. DeMio rules out other causes based on petitioner's test results. He further singles out the HPV vaccine as the likely perpetrator based on his opinion that it was insufficiently tested and its relationship to other pediatric cases. Pet.'s Ex. 11 at 2. The report concludes that a psychological

[6] Tomljienovic, et al., *Postural Orthostatic Tachycardia with Chronic Fatigue After HPV Vaccination as Part of the "Autoimmune/Auto-inflammatory Syndrome Induced by Adjuvants": Case Report and Literature Review*, J. of Investigative Med. High Impact Case Rep. 1–8 (2014).

explanation for petitioner's pain was unlikely because symptoms, such as muscle wasting, would not be explained by somatization. *Id.*

The Special Master, in his background section of the entitlement decision, prefaces his detailed summary of Dr. DeMio's report with the conclusion that the expert was unqualified to offer his opinion on the vaccine's causation. The Special Master cites four other instances in which special masters have reached similar conclusions contrary to Dr. DeMio's. 2021 WL 839092 at *9.

B. Dr. Lyons-Weiler, PHD

Dr. Lyons-Weiler has a Master's degree in Zoology from Ohio State University and a PHD in ecology, evolution, and conservation biology from the University of Nevada in Reno. His resume lists his current position as the CEO and Director of The Institute for Pure and Applied Knowledge, a nonprofit aimed at reducing human pain and suffering through biomedical research. Pet.'s Ex. 21 at 1 (ECF No. 15-4); *see also* 2021 WL 839092 at *10(citing http://ipaknowledge.org/ (last visited October 21, 2020)). After examining Dr. Lyons-Weiler's website, the Special Master concluded that, although Dr. Lyons-Weiler had a personal and professional interest in vaccine safety and molecular processes involved, his training left him "ill-equipped to offer the opinion he fashioned for this matter." 2021 WL 839092 at *10.

The opinion offered by Dr. Lyons-Weiler centers on his investigation of the safety of the HPV vaccine in general, especially as it involves its manufacture. The report also states the general proposition that vaccines can trigger autoimmune disorders, which the opinion below accepted as generally recognized among Special Masters. Pet.'s Ex. 20 at 14 (ECF No. 15-3). Dr. Lyons-Weiler went on to state that studies to the contrary involving the HPV vaccine were flawed. *See, e.g., id.* at 14-15. He also discusses several case studies purportedly drawing the link between HPV vaccines and "adverse neurological and immune reactions." *Id.* at 1. As the Special Master noted, however, those studies involve arthritis, lupus, neuropathy, and somatoform disorders. *Id.* at 2. The *Palmieri* article[7] proposes a theory of autoimmune inflammatory syndrome brought on by

[7] B. Palmieri et al., *Severe Somatoform and Dysautonomic Syndromes after HPV Vaccination: Case Series and Review of Literature*, Immunol. Res. (2016), filed as Pet.'s Ex. 82 (ECF No. 93-3).

vaccine adjuvants, which the Special Master noted in his background discussion had been routinely rejected by him and his colleagues at the court. A list of Special Master decisions was then included. 2021 WL 839092 at *11 n.16.

Other cited literature in Dr. Lyons-Weiler's report was dismissed as similarly untrustworthy, previously having been found unconvincing by other Special Masters. *Id.*[8] The report then goes on to describe a process of injury to petitioner caused primarily by similarity between vaccine molecules intended to induce an autoimmune response and Ms. Hughes' own tissues whereby the antigens produced by her body attacked her own cellular structures due to their similarity to the vaccine's structures. Pet.'s Ex. 20 at 3. This process, states Dr. Lyons-Weiler, would have been made worse by the HPV vaccine's aluminum adjuvants, especially since multiple vaccines were administered at the same time. *Id.* at 4.

Dr. Lyons-Weiler focused on one result from an October 2013 blood test of petitioner which showed one heightened inflammatory marker. This Bun/Creatine ratio was evidence to Dr. Lyons-Weiler of "vaccine-induced spondylosis." *Id.* at 6-7. He also found significant the timing of the onset of symptoms after the immunizations. This "long onset" after vaccination was, according to Dr. Lyons-Weiler "established in the medical literature." *Id.* at 4. He cites a study in which six individuals suffered a variety of symptoms, some nonspecific and others more concrete, indicating Lupus disease after the HPV vaccine. *Id.* (citing M. Gatto, *Human Papillomavirus Vaccine and Systemic Lupus Erythematosus*, 32 Clin. Rheumatol. 1301–1307 (2013)). That case study was not in evidence, however. As the Special Master noted, Dr. Lyons-Weiler's report does not explicitly draw the link between the Gatto study and the two-month gap between vaccination and onset in this case. It is also unclear how a diagnosis of spondylosis supports petitioner's theories.

C. Dr. Miller

Dr. Miller is a professor of pediatrics at Northwestern University and a staff member at the Children's Hospital of Chicago. Pet.'s Ex. 27 (1st Miller Rep.) (ECF No. 41-2). He prepared and petitioner submitted three

[8] *E.g.*, Brinth et al., *Suspected Side Effects to the Quadrivalent Human Papilloma Vaccine*, 62(4) Dan. Med. J. A5064, filed as Pet.'s Ex. 61 (ECF No. 91-2).

reports in this matter. To summarize all three, he diagnosed Ms. Hughes with complex regional pain syndrome ("CRPS"), although he noted she also suffered from POTS since vaccination. His first report explains that Dr. Miller has treated children with CRPS and has evaluated in his practice whether it and other autoimmune diseases were causally related to vaccines. *Id.* at 3.

Dr. Miller's first report states his general opinion that the onset of symptoms and subsequent course of events "is diagnostic for post-vaccine Adverse Event," although he recognizes that other causes for CRPS are possible. *Id.* at 1. His opinion, however, is that only the vaccines could have caused this injury to petitioner given the fact that the testing administered since the vaccine "excluded all other possible causes." *Id.* He goes on to describe CRPS as a neuropathy (nerve damage) and states that Gardasil "has been associated with neuropathy and related neurological side effects" in medical journals. *Id.* at 2. He recognizes that the precise biological mechanism has not been identified but postulates that the HPV vaccine "causes an immune response in which . . . [white blood cells] mount an antibody response directed against viral antigens . . . and [adjuvants] in the vaccine." *Id.* These white blood cells "experience a case of mistaken identity" which causes them to attack "parts of their own body." *Id.* This, in turn causes swelling and even scarring (fibrosis) of these nerve tissues. *Id.* This caused untreatable pain, according to Dr. Miller, because the scarring is not treatable with anti-inflammatories. *Id.* The third of four pages in his report discusses four case studies in medical literature in which patients experienced neurologic pain or encephalomyelitis after HPV vaccination.

Dr. Miller's second report, submitted in response to the motion to show cause, attempted to support his earlier opinions by including some additional literature support for the idea that Gardasil can cause CRPS. *See* Ozawa et al., *Suspected Adverse Effects After Human Papillomavirus Vaccination: A Temporal Relationship Between Vaccine Administration and the Appearance of Symptoms in Japan,* 40 Drug Saf. 1219–29 (2017), filed as Pet.'s Ex. 48C (ECF No. 76-5). Dr. Miller also further opined that petitioner's symptoms supported a diagnosis of POTS as well, which he deemed a second adverse reaction to the vaccine. He supported this assertion with a European study which followed six young women who developed POTS within two months following HPV immunization. *See* S. Blitshteyn, *Postural Tachycardia Syndrome Following Human Papillomavirus Vaccination,* 21 European J. of Neurology 135–139, filed Pet.'s Ex. 48D

(ECF No. 76-6). That article stated that investigation into a causal relationship was warranted. *Id.* at 138.

Dr. Miller's second report also took issue with the somatization diagnoses in petitioner's contemporary records by opining that Ms. Hughes did not experience the persistently high level of anxiety required for such a diagnosis. Pet.'s Ex. 48 at 2 (ECF No. 76-2). He also concluded that petitioner's medical records precluded a diagnosis of CRPS prior to administration of Gardasil, which he also found indicative of the casual relationship between the two. *Id.* at 1.

Dr. Miller's third report, Pet.'s Ex. 50 (ECF No. 87-1), submitted in August 2020, is his most robust and is responsive to respondent's motion for a ruling on the record. The seven-page report begins with the statement that Dr. Miller has diagnosed Ms. Hughes with both CRPS and POTS caused by the HPV vaccine. He then details the symptoms associated with CRPS, which he states is well recognized "to be triggered by autoimmune diseases." Pet.'s Ex. 50 at 1. He then lists the diagnostic criteria known as the "Budapest criteria." *Id.* at 1-2. These include disproportionate pain to any inciting event and at least one symptom that is sensory, vasomotor, edema, or motor, and must include "a sign in two or more of the following categories: (1) Sensory . . . (2) Vasomotor . . . (3) Edema . . . (4) motor." *Id.* Finally, "no other diagnosis . . . better explains the patient's signs and symptoms" according to Dr. Miller. *Id.* at 2.

Dr. Miller continues that CRPS is the appropriate diagnosis because Ms. Hughes experienced continuing pain disproportionate to the administration of the vaccine, hyperalgesia and hypoesthesia (sensory symptoms), abnormal skin coloration (vasomotor), sweating (edema), and changes to her hair, skin, and nails along with moto deficits. *Id.* The next page goes through the same rubric for POTS, which he offers is also an autoimmune disorder. The report states that petitioner's diagnosis of POTS by the Cleveland Clinic and her display of a variety of symptoms associated with POTS establish, in his view, the correctness of a diagnosis with the syndrome. *Id.* at 2-3.

Dr. Miller also again offers that somatization is inapposite as a diagnosis because petitioner does not fit the diagnostic criteria of "excessive thoughts, feelings, or behaviors related to the somatic symptoms" which manifest as either "disproportionate and persistent thoughts about the seriousness of one's symptoms," high levels of persistent anxiety about them,

or "excessive time and energy "devoted to these symptoms or health concerns." *Id.* at 4. The diagnostic criteria for somatization were also filed as Pet.'s Ex. 50E (ECF No. 87-6). This state is persistent, more than six months in duration. *Id.* Dr. Miller rejects somatization because no competent psychologist or psychiatrist diagnosed petitioner, and he found no evidence that Ms. Hughes' reports of her symptoms were disproportionate or excessive to the point of anxiety. *Id.*

Dr. Miller concluded his report by explaining that the other diagnoses by petitioner's treating physicians were inaccurate because neither Drs. Lancaster nor Li are immunologists, neurologists, nor rheumatologists. *Id.* at 6. Thus, as pediatric and internal medicine practitioners, they were out of their proverbial wheelhouses when dismissing the vaccines as a causal agent of Ms. Hughes' ailments, according to Dr. Miller.

IV. The Special Master's Decision

By the time the case was ripe for adjudication on the merits, petitioner's theory had become one of Gardasil-caused immune reaction by molecular mimicry causing CRPS and POTS. According to her experts, not only was the HPV vaccine dangerous and causal here, but her symptoms were consistent with those diagnoses, and the onset of pain and associated issues was consistent with the diagnosis. The Special Master disagreed on all points.

The Special Master exhaustively detailed the medical records, expert opinions, and medical literature presented by petitioner. Although prior rejections of similar theories were cited in the background discussion of these materials, each aspect of petitioner's case was treated on its own as well as weighed collectively and compared with petitioner's medical records and examined under the *Daubert* factors for indicators of reliability. *E.g.*, 2021 WL 839092 at *22 (stating that the Special Master would apply *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)). As the Special Master explained, in this court, the *Daubert* analysis is used, not as a gatekeeping tool, but instead as an analytical lens for testing the reliability of expert testimony and opinion. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010).

The opinion below also explains the Special Master's consideration and citation to prior vaccine decisions involving the same experts or similar theories of causation. These are, he states, cited to "establish common

themes as well as demonstrate how such prior determinations impact my thinking on the present case." 2021 WL 839092 at *23. Although not controlling and leaving room for the possibility of a different result here, the Special Master states that he would be remiss to ignore prior cases and their reasoning given that Special Masters draw upon their experience in deciding these matters. "It defies reason and logic to obligate special masters to 'reinvent the wheel', so to speak, in each new case before them, paying no heed at all to how their colleagues past and present have addressed similar causation theories or fact patterns." *Id.*

The opinion goes on to also explain that the Special Master's job includes the rejection of expert opinion outside of the expert's subject matter expertise. A circumstance that the Special Master found himself in in this case. *Id.* at *24-25. And, given the discussion above, he states that it would hardly be "arbitrary" to point out when such a determination had been made about an expert previously. *Id.* at *25.

The analysis of the evidence begins with a significant review of HPV vaccine-caused theories made to the Special Masters. *Id.* at *25-26. He explains that, while not controlling, he "referenced them to emphasize [his] great familiarity with the arguments about the HPV vaccine commonly made . . . ." *Id.* at 25. The more familiar the Special Master became with these theories, he explains, the less necessary a hearing on entitlement in similar cases has appeared to him. *Id.* One was unnecessary here, he concluded, given the Special Master's own experience previously rejecting Dr. DeMio's "Gardasil Syndrome" theory. *Id.* (citing *McKown v. Sec' y of Health & Human Servs.*, No. 15-1451V, 2019 WL 4072113, at *7 (Fed. Cl. Spec. Mstr. July 15, 2019)).

Next, the Special Masters' treatment of CRPS as a vaccine-caused injury was summarized with examples of entitlement decisions for and against petitioners. The key distinction drawn between the present case and prior successful ones was the presence of vaccine-induced trauma "close-in-time to vaccination that later resulted in CRPS" as contrasted with the less specific precipitation of symptoms over time here. *Id.* at 26.

The opinion then turns to petitioner's burden. The first, and outcome-determinative conclusion, was that petitioner had not established by a preponderance of evidence that she suffered from POTS or CRPS. The Special Master rejected Dr. Miller's conclusion that petitioner's symptoms fit within the criteria for CRPS. The Special Master found instead that the

contemporaneous evidence suggested close-in-time symptoms associated with menses and a urinary tract infection, followed by the development of more general pain in the back and legs two months later. *Id.* at 27. The extent of testing and number of examinations performed on petitioner with no suggestion of CRPS or of a trauma near-in-time to the vaccine suggested to the Special Master that that the CRPS diagnosis was unreliable.

Central to his holding was the "absence of corroboration of a regional pain syndrome" other than less-than-reliable and unqualified medical opinions from Dr. DeMio and Dr. Flynn. *Id.* Also very important to the Special Master was Dr. Li's notes that Ms. Hughes' symptoms would abate at times during her visit when she was not being examined for them and when she disrobed and then put her tight pants back on. This, to the Special Master, was evidence that the pain symptoms were not unrelenting, a necessary finding under the Budapest Criteria. *Id.* Lastly, on the issue of CRPS, the lack of any suggestion of CRPS from the treating doctors prior to genesis of the vaccine theory, was similarly decisive for the Special Master. *Id.* He afforded no weight to Dr. Miller's suggestion that the lack of an alternative etiology offered by the treating doctors should be deemed evidence of a vaccine cause because it is the petitioner's burden establish an injury. *Id.*

On the question of whether petitioner suffered from POTS, the opinion details the lack of substantiation in the records of any of the common symptoms of POTS in the months immediately following the vaccine. *Id.* Dr. Al-Huniti's listing of POTS as a potential explanation more than six months after vaccine administration was afforded little weight given lack of supporting evidence and the extensive testing performed on Ms. Hughes, including cardiac testing. *Id.* The Special Master also noted the fact that a tilt table test was never performed, which, according to the petitioner, is the "gold standard of POTS diagnosis." Pet.'s Ex. 50D at 1 (webpage of the Cleveland Clinic regarding POTS). The Cleveland Clinic's 2020 write up, which listed POTS as a potential explanation, was discounted as insufficient considering the other record evidence or lack thereof. 2021 WL 839092 at *27.

The opinion goes on to treat each of the Federal Circuit's factors for causation and rejects each in this case as unsupported by the record. It is unnecessary to detail each of those holdings, however, because we agree with the Special Master on the first point, that it was reasonable to conclude that petitioner has not established an injury in fact. There was insufficient proof of either CRPS or POTS.

DISCUSSION

This court has jurisdiction to review the Special Master's decision under the Vaccine Act. 42 U.S.C. § 300aa-12. Our review is deferential. We will only overturn an entitlement decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 300aa-12(e). When the Special Master has considered the relevant evidence and articulated a rational basis for the decision, reversible error is "extremely difficult to demonstrate." *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). We do not reweigh the evidence or make new reliability or credibility determinations. *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). Those are for the Special Master.

A petitioner may seek compensation for "any illness, disability, injury, or condition" sustained or significantly aggravated by a vaccine. 42 U.S.C. §§ 300aa-11(c)(1) to 13(a)(1)(A). When a petitioner seeks compensation for an injury other than those listed on the Vaccine Injury Table, petitioner must prove causation in fact. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1278, 1278 (Fed. Cir. 2005) (citing 42 U.S.C. § 300aa-13(a)(1)(A)). Petitioner must show that the vaccination caused the injury by proving three elements by a preponderance of the evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* Identification of an injury is prerequisite to the *Althen* inquiry, however. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). If the evidence does not support the injury alleged, causation cannot be established, and the petition fails for lack of proof. *Id.* In other words, without proof of the asserted injury, the theory of causation is *a priori* unreliable and unsupported by the evidence, and it is unnecessary to go through the remaining *Althen* factors.

Here, we find just such a case. Although the Special Master recognized Dr. Miller as sufficiently qualified to offer his opinion on the subject—a qualification not afforded to Dr. DeMio nor Dr. Lyons-Weiler—

he found Dr. Miller's conclusions unsupported or contraindicated by the bulk of the contemporaneous medical records.[9]

Petitioner responds on review that there was ample evidence of symptoms that demonstrate the propriety of Dr. Miller's diagnoses. Ms. Hughes' health took a c-turn in the months following vaccination, and the differential diagnoses are sufficient under the *Daubert* standard to infer causation, avers counsel. The documented pain in Ms. Hughes' legs and back is sufficient to support a diagnosis of CRPS, according to petitioner, and the cardiovascular symptoms recorded, such as sleeping problems and heart palpitations, carry the burden to support a finding of POTS. Pet.'s Mot. for Review 6. Petitioner points to the records of Dr. Flynn and the two-page record from the Cleveland Clinic as support of her position. Lastly, petitioner argues that she meets the Budapest criteria for CRPS and the diagnostic criteria for POTS, as listed by Dr. Miller. Procedurally, petitioner also finds error in the Special Master's decisions not to hold a hearing and not to require respondent to file a report on entitlement.

We find these arguments, although not completely without record support, unavailing because they do not address the central point of the Special Master's holding. Even were we to agree that the evidence is, in a vacuum, sufficient to support a diagnosis of CRPS and POTS, the Special Master clearly considered all of it but disagreed as to the conclusion. He did not miss the import of Dr. Miller's application of the diagnostic criteria. It is in fact those criteria that provide sound footing for the Special Master's contrary conclusion. He compared the criteria with Ms. Hughes' records. He found they did not fit. That is within his purview under the Vaccine Act. It is insufficient to point out contrary evidence when the Special Master is vested with the authority to weigh it, which he did. Dr. Flynn's, Dr. DeMio's, and the Cleveland Clinic's records were considered and given less weight than other contemporaneous records. Dr. Li's observations were particularly damning. The Special Master's consideration of all of it makes clear that he was not missing any facts or failing to understand the points made.

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[9] Even were we to find that these conclusions were arbitrary and capricious, an issue we need not reach nor presented by the motion for review, the conclusion would not change. The comparison of the record to the diagnostic criteria was supported by the record and not unreasonable. Additionally, the opinions of Drs. DeMio and Lyons-Weiler were directed more at the question of how the HPV vaccine would have caused the injuries asserted, not to establish the injuries themselves.

Specifically, on the criteria for CRPS, the onset of pain two months after immunization and Dr. Li's observations provide the evidence necessary to reach the conclusion that the Special Master did. Dr. Li's notes contraindicate the criteria of unrelenting pain under the Budapest criteria. This also answers petitioner's criticism that it was arbitrary not to require evidence from respondent. It was unnecessary to have opinion or other medical literature to weigh against that submitted by petitioner because her own medical records were sufficient ground for the Special Master's conclusion to find purchase. [10]

On the issue of POTS, the record is even clearer that the Special Master was well within the zone of reasonableness in reaching his conclusion. In sum, although plaintiff suspected cardiac problems and sought treatment for them, none were ever discovered by testing, nor was the single most determinative test for POTS ever performed. It was thus not irrational to find the record unavailing for petitioner on this diagnosis.

Although the discussion in the opinion of the Special Master's role and consideration of prior results achieved by the same experts or by similar causation theories was unnecessary and distracting, his holding regarding the injury is not irrational. In the final analysis, his conclusions were based on the evidence, or in some respects, the lack of it, in this case. The Special Master considered all the record evidence. He examined and explained why the literature presented by petitioner was insufficient to bridge the gaps in the record. He applied the very diagnostic criteria supplied by petitioner's expert and compared them with petitioner's medical records. More is not asked for on review.

CONCLUSION

Because the Special Master did not err in holding that petitioner had not established by preponderant evidence the injuries alleged, the petition was properly dismissed. Accordingly, petitioner's motion for review (ECF No. 96) is denied. The Clerk of Court is directed to enter judgment accordingly.

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[10] We also do not find error in the decision not to hold a hearing. Petitioner has not explained how the evidence would have been different or why a credibility determination would be necessary to support the Special Master's holding that the diagnoses of CRPS and POTS do not fit with the evidence. A hearing was unnecessary in these circumstances.

s/Eric G. Bruggink
ERIC G. BRUGGINK
Senior Judge