In the United States Court of Federal Claims

No. 14-580V
Filed: September 9, 2016
Reissued for Publication: October 5, 2016[1]

HOLLY LASNETSKI, **Petitioner,** **v.** **SECRETARY OF HEALTH AND HUMAN SERVICES,** **Respondent.**	**National Vaccine Injury Act; HPV Vaccine; Defined and Recognized Injury; Application of Althen Test.**

Randall Knutson, Knutson Casey Law Firm, Mankato, MN, for Petitioner. With him was **Peter Hemberger**, Knutson Casey Law Firm.

Debra A. Filteau Begley, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent. With her was **Benjamin Mizer**, Principal Deputy Assistant Attorney General, **Rupa Bhattacharyya**, Director, Torts Branch, Civil Division, **Catharine Reeves**, Acting Deputy Director, Torts Branch, Civil Division, and **Gabrielle Fielding**, Assistant Director, Torts Branch, Civil Division.

O P I N I O N

HORN, J.

On July 9, 2014, Petitioner Holly Lasnetski filed a petition for compensation under the National Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (the Vaccine Act). Special Master Lisa D. Hamilton-Fieldman of the United States Court of Federal Claims dismissed the petition for failure to state a claim upon which relief can be granted and denied compensation in a decision issued on April 29, 2016. See Lasnetski v. Sec'y Health & Human Servs., No. 14-580V, slip op. at 6 (Fed. Cl. Spec. Mstr. April 29, 2016). Following the decision, on May 26, 2016, Petitioner filed a timely Motion for Review of the Special Master's decision pursuant to Rule 23 of the Rules of

[1] This opinion was issued under seal on September 9, 2016. The parties did not propose redactions to the September 9, 2016 opinion, and, thus, the court issues the opinion for public distribution.

the United States Court of Federal Claims (RCFC), Appendix B (2016). This case comes to the court upon that motion.

FINDINGS OF FACT

Holly Lasnetski was born on November 30, 1986. She claimed in her petition that she was "a healthy adult female prior to receiving the Gardasil (HPV) vaccination,[2] with the exception of the following conditions: neck sprain, migraine headaches, depression and sinusitis." She alleged that she subsequently

> suffered sensory nervous system problems and sensory dysesthesia, as well as typical symptoms associated with sensory dysesthesia, including fatigue, fever, nausea, vomiting, constipation, heartburn, reflux, abdominal pain and cramping, urine frequency issues, rash, memory impairment, muscle weakness, alteration in menstrual pattern, ataxia[3], flushing, chills and fever, and aggravated back problems; all caused-in-fact by the Gardasil (HPV) vaccination administered on July 18, 2011.

In making her determination, Special Master Hamilton-Fieldman examined the administrative record, including Ms. Lasnetski's relevant medical history, both prior to receiving the Gardasil vaccine and subsequent thereto. According to the Special Master:

> In 2008, Petitioner sought treatment for a history of headaches, tingling in her left arm, and anxiety. In 2009, she again sought treatment for headaches; numbness in her face, throat, arms, and hands; and anxiety-related shortness of breath. In early 2011, she sought treatment for a viral illness, as well as a cough, a sore throat, a fever, headaches, and dizziness.

Lasnetski v. Sec'y Health & Human Servs., slip op. at 6 (citations omitted).

The record before the Special Master and the court demonstrates that, throughout the pre-Gardasil-vaccine period, Ms. Lasnetski sought medical treatment for various symptoms and illnesses and received a variety of diagnoses from various health care professionals. In 2008, at a visit to a chiropractor, Dr. D.L. Duininck, in Willmar, Minnesota, in which Petitioner mentioned symptoms of headache and tingling in her left arm, she was diagnosed with a "[h]eadache of cervical origin." In 2008, Dr. Raymond

---

[2] "Gardasil is a vaccine that immunizes against four strands of human papillomavirus ('HPV'). The vaccine, administered in three doses, contains virus-like particles created from an HPV protein, as well as an adjuvant, which assists in generating a robust immune response to promote long-term immunity." Koehn v. Sec'y of Health & Human Servs., 773 F.3d 1239, 1241 (Fed. Cir. 2014).

[3] Ataxia is defined as: "failure of muscular coordination; irregularity of muscular action." Dorland's Illustrated Medical Dictionary 170 (32nd ed. 2012).

Mellema, at an urgent care facility in Willmar, Minnesota, "advised Holly that she probably belongs at the Crisis Center" for treatment of anxiety and insomnia. In April 2009, she was "diagnosed with aphthous ulcers[4] and was told it was the herpes virus" by Dr. Kristin Wegner in Willmar, Minnesota. Again, in June 2009, she complained of "a cold on and off" and was diagnosed by Dr. Steve Meister in Willmar, Minnesota with an "[u]pper respiratory infection." In July 2009, Ms. Lasnetski "thought she had a miscarriage"; she was "worn down and tired," and Dr. Michael Nicklawsky, in Willmar, Minnesota, diagnosed sinusitis, depression and migraine headaches. At the end of July 2009, while starting and stopping the medications Topamax, Citalopram and Augmetin, Ms. Lasnetski suddenly felt numb all over her body, had shortness of breath, and felt as if she was going to have a panic attack. Dr. Wegner thought the numbness was "probably secondary to anxiety or panic," although, he added, it could have been a reaction to starting and stopping medication. In February 2011, Petitioner presented at an urgent care facility, in Willmar, Minnesota, "with urinary frequency and burning." She also complained of back pain. Dr. Mellema assessed a "[p]robable UTI." On April 3, 2011, Dr. Mellema, in Willmar, Minnesota recorded a diagnosis of "[c]hronic rhinitis" after noting:

> She gives a history of having been ill a lot this winter and seems to be describing more of [a] progression of viral illnesses rather than one specific thing. . . . She has been on antibiotics multiple times without benefit and this has been through other clinics. . . . [S]he thinks there is some mold in her current living environment.

As noted above, the vaccine at issue was administered on July 18, 2011. On the date of the vaccine, Ms. Lasnetski was seen by her primary care doctor at the St. Cloud Medical Group in St. Cloud, Minnesota for "an annual preventive health examination." At this appointment, Lasnetski reported "new health concerns [of] sore throat, chronic cough." Additionally, she was diagnosed by the treating physician, Dr. Sara Jorgenson, with genital warts. Petitioner had previously tested positive for HPV, and the doctor recommended the Gardasil vaccination. Initially, Ms. Lasnetski declined the vaccine. Following a discussion with Ms. Lasnetski about the risks and benefits of Gardasil, a Human Papillomavirus (HPV) vaccine, Dr. Jorgenson administered the vaccine to Ms. Lasnetski.

There are discrepancies both in Ms. Lasnetski's filings in the present case and elsewhere in the record as to when Ms. Lasnetski began suffering the symptoms she alleges were caused by the July 18, 2011 vaccine. Ms. Lasnetski's July 9, 2014 petition for compensation and her May 26, 2016 motion for review present different symptomatology. The petition reads: "Petitioner began to develop . . . pain . . . within a few days after receiving the Gardasil (HPV) vaccination." The motion to review, however, reads: "Petitioner reported problems the day after receiving the Gardasil vaccination. . . . Petitioner developed acute complications including but not limited to

[4] Aphthous ulcer is defined as "the ulcerative on the oral mucosa seen in recurrent aphthous stomatitis." Dorland's Illustrated Medical Dictionary 1997.

low back pain, tingling into the legs, tingling in the face, neck pain, migraines, constipation, increased urination, rash, hair loss and abdominal pain." (citations omitted). Review of the record before the court does not clarify the inconsistencies. Dr. Melissa Ensign's report dated Aug. 17, 2011, states: "She [Ms. Lasnetski] first noticed symptoms a few hours after her gardasil [sic] injection on 7/28/11 with the tingling in her L lower leg and then into her right leg." The Special Master found, however, based on the record before her that almost a year after the vaccination, "[p]etitioner reiterated her symptoms [to the Mayo Clinic doctors on May 22-24, 2012], adding that almost all of them appeared within a month after her vaccination."

In her petition, Ms. Lasnetski alleges that the vaccine resulted in a wide array of health effects, including:

> sensory nervous system problems and sensory dysesthesia, as well as typical symptoms associated with sensory dysesthesia, including fatigue, fever, nausea, vomiting, constipation, heartburn, reflux, abdominal pain and cramping, urine frequency issues, rash, memory impairment, muscle weakness, alteration in menstrual pattern, ataxia, flushing, chills and fever, and aggravated back problems.

Ms. Lasnetski's list of ailments are referred to by Petitioner's own medical expert, Dr. James Dahlgren and by treating physician Dr. Michael Severson as a "constellation of symptoms."

On July 26, 2011, eight days after the vaccine was administered to Petitioner, Ms. Lasnetski visited a health care professional for the first time after receiving the vaccine. She complained to a chiropractor, Dr. Lacie Mockros, at the Minser Chiropractic Clinic, in St. Cloud, Minnesota, that "[s]he has had a migraine headache for the last 3 days." She also complained of pain in her neck, shoulders and lower back and tingling in the left leg. The chiropractor indicated in his report, "[s]he [Ms. Lasnetski] has a history of a mild strain to her neck about a year ago that was treated by a chiropractor and resolved. She has no other health problems." On a visit two days later her headache had improved, but she had been having a sharp pain in her lower back the previous night at her job at a liquor store, where she had "to lift heavy cases of bottles."

On August, 10, 2011, Petitioner went to the emergency trauma center at the St. Cloud Hospital suspecting she was pregnant because of "passed tissue." The pregnancy test was negative, and she was diagnosed with vaginal bleeding and cramping. Her primary care doctor, Dr. Sara Jorgensen, saw Ms. Lasnetski the next day and noted that she had been "diagnosed with nothing." This is also the first time in the record that the Petitioner spoke of her symptoms in the context of the Gardasil injection: "She states she has had a multitude of symptoms since her annual on 7/26/11. She states she started to experience nausea and a stiff neck after her Gardasil injection. She then developed a migraine that lasted for 4 days."

One day later, on August 12, 2011, Dr. Gary Kolle, at the St. Cloud Medical Group, heard a recitation of Ms. Lasnetski's symptoms: lower back pain, headaches,

numbness, urinary frequency, and "pain radiat[ing] in[] both legs." He wrote in his report, "Holly Lasnetski has a history of back problems in the past. [Her] neck was stepped on in a mosh pit last year." He further postulated a diagnosis of: "1. Paresthesia[5] of the leg; . . . 2. Headaches with paresthesias of the face; . . . 3. Urinary frequency; . . . 4. GERD [Gastroesophageal Reflux Disease] symptoms."

On August 14, 2011, Petitioner visited the emergency room at St. Cloud Hospital, "[d]ue to the fact [that] she has had an increase in progressive numbness." The treating doctor, Dr. Michael Severson, ordered an MRI and MRA, both of which were negative, and diagnosed "[p]aresthesias, left side, migraine headaches." Dr. Severson recommended Lasnetski follow up with a neurologist. He noted, "[i]t could be complex migraines but there is some correlation with timing with the vaccination she had last month, but no evidence for Guillain-Barré at this point, stroke syndrome, aneurysm or subarachnoid hemorrhage."

On August 22, 2011, Ms. Lasnetski visited with a neurologist, Dr. Iris Brossard. Dr. Brossard took a medical history, which recounts, in part:

> Patient has had migraines since about the age of 6th or 7th grade. There is a significant history of migraines in her mother as well as other family members.
>
> The patient says the migraines have come and gone. She has also had chronic pain and tingling in all of her body. She has what she calls "organ pain" around her upper torso especially on the left. She will have tingling that goes from her legs to her feet up to her arm, neck and chest. Her migraines have been much worse over the last several weeks. She says, however, they are getting better over the last few days. She seems to have pain virtually everyplace [sic] and filled out quite a few symptoms on her history list.
>
> . . .
>
> With the headaches patient sees spots in her vision, has tearing of the eyes, experiences light, noise and odor sensitivity. She becomes nauseated and fatigued. She may have numbness before, during or after on the face, arm and leg, mainly on the left. She has difficulty understanding people and feels as though she is going to faint.
>
> Of note, the patient had a Gardasil shot to which she attributes these headaches and the other forms of pain. This was done on July 26,

[5] Paresthesia is "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." Dorland's Illustrated Medical Dictionary 1383.

> 2011[6]. . . . She thinks she might have had a miscarriage, although her pregnancy tests were negative.
>
> . . .
>
> Patient suffers from anxiety and depression. . . . She says she has a poor immune system, getting frequent viruses, sinus infections and sore throat. She has had heartburn and she thinks she has had carpal tunnel syndrome.

Dr. Brossard subsequently conducted a series of neurological tests, including an antinuclear antibodies ("ANA") test[7] that was negative, and diagnosed Ms. Lasnetski "with many, many, many symptoms," "likely due to chronic migraines, a possible fibromyalgia syndrome with chronic muscle pain and depression and anxiety." Dr. Brossard noted that he "tried to reassure the patient and her mother that I did not think these symptoms were from her vaccine as this is fairly unusual."

The following day, Ms. Lasnetski came into the emergency room at St. Cloud Hospital for "severe numbness, tingling and shortness of breath." Dr. Brett Stolzenberg, the attending physician, determined that the "etiology [was] unclear," and stated, "I [Dr. Stolzenberg] do not have a clear etiology for her symptoms."

On September 30, 2011, Ms. Lasnetski met with a new primary care physician, Dr. Sam Camp, in Willmar, Minnesota, for a second opinion. Ms. Lasnetski related to Dr. Camp that she may have miscarried because of the injection, and, that her menstrual cycle had been different since the injection. She also reported a rash, abdominal pains, and canker sores in her mouth. Dr. Camp stated:

---

[6] This is a different date from the one specified in the petition and found in all other medical reports in the record, which state that Ms. Lasnetski received the vaccine on July 18, 2011.

[7] As the Special Master explained:

> An ANA test reveals the level of antinuclear antibodies in the blood, which are antibodies that attack the body's own tissues. Mayo Clinic Staff, *ANA test: Definition*, http://www.mayoclinic.org/tests-procedures/ana-test/basics/definition/prc-20014566 (last visited April 25, 2016). Typically, a 'positive ANA test indicates that [one's] immune system has launched a misdirected attack on [one's] own tissue—in other words, an autoimmune reaction.

Lasnetski v. Sec'y Health & Human Servs., slip op. at 3 n. 4. Respondent's expert Dr. Thomas Leist also added: "A positive ANA with a titer of ≤1:40 can be observed in about 30% of the normal population and by itself, a positive ANA test does not indicate the presence of an autoimmune disease."

> I am truly not sure what is the cause of these symptoms. . . . Potentially she may need to be sent to an immunologist at Mayo or another research center to determine whether the Gardasil vaccine has caused some type of autoimmune disorder. I told Holly that I think this is unlikely, but I cannot say that with 100% confidence. . . . So far, diagnostics and exam have been normal. At what point is she willing to stop testing and seek other modalities for treatment of her symptoms. [sic] At this time she is not interested in this consideration.

On December 9, 2011, Ms. Lasnetski saw a rheumatologist, Dr. Robert Tierney. In addition to her previous symptoms, abdominal pain, myalgias, fatigue and migraines, she now indicated that she "had some itching and sores on the head." Dr. Tierney noted that the "[e]tiology of her symptoms is unclear." Dr. Tierney performed a battery of tests, including a test for lupus or connective tissue disease. All of these tests were "completely normal."

On January 28, 2012, Ms. Lasnetski again arrived in the emergency trauma center complaining of "[c]ramping in the abdomen, left upper quadrant abdominal pain . . . and blood and mucus in the stools" along with "ongoing problems with her GI tract." The report of the admitting physician, Dr. Mark E. Hoffman, noted that Ms. Lasnetski had seen a neurologist and a rheumatologist and that "[g]iven the constellation of other symptoms, apparently she had a positive ANA and a positive rheumatoid factor[8], but they have not pinpointed a specific autoimmune disorder." Dr. Hoffman ultimately diagnosed Ms. Lasnetski with a "[c]onstellation of multiple symptoms, not otherwise specified."

On February 2, 2012, Dr. Camp saw Ms. Lasnetski for an ER follow up. Dr. Camp noted that Ms. Lasnetski "and her family have been quite convinced that her Gardasil vaccine has caused a systemic autoimmune type disorder resulting in neuralgias, paresthesias, headaches, fatigue, and pain." Dr. Camp summarized the medical findings and diagnoses up to this point:

> She has been referred to Neurology and Rheumatology and no clear answer for her symptoms have been found. Fibromyalgia has been diagnosed at one time. Vitamin D deficiency has been another diagnosis. Otherwise autoimmune testing has been negative, as have general lab studies and evaluations. This has been very frustrating to Holly and she is quite certain that she has some systemic illness.

In his summary assessment from the visit, Dr. Camp stated:

[8] The origin of this rheumatoid result is unclear. Dr. Camp's screening in the record does not note such a result.

> Multiple unexplained symptoms. There is one paper that suggests a POTS[9] syndrome resulted due to the Gardasil vaccine. Certainly this can be associated with a strange myriad of symptoms with profoundly negative serological testing. The patient has been evaluated by Neurology and Rheumatology without a definitive explanation of her symptoms. We will see if the patient is open to being evaluated for POTS syndrome, although this will likely need to be evaluated at Mayo. I am skeptical that this is the underlying source of her symptoms, but certainly lack the ability to do the appropriate evaluation here.

On a follow up visit with Dr. Camp, on March 28, 2012, he similarly recorded, "[s]he [Ms. Lasnetski] is still fixated on her symptoms because of her immunization for HPV." At his next appointment with Ms. Lasnetski, on April 26, 2012, Dr. Camp confirmed Ms. Lasnetski as pregnant.

At approximately eight weeks pregnant, on May 22, 2012, Ms. Lasnetski began a full workup under a POTS framework upon Dr. Camp's referral at the Mayo Clinic, in Rochester, Minnesota. Her first consult at the Clinic was with a cardiovascular specialist, Dr. Kari Carter. Dr. Carter delivered the following diagnoses: dizziness, dyspnea, vision disturbances, paresthesias, positive ANA and positive RF, sleep-disordered breathing, colon polyp, migraines, and pregnancy. The ANA and RF result, at one time apparently both positive, are referenced by multiple doctors at the Mayo Clinic. Dr. Carter noted:

> Ms. Lasnetski states, and her medical records bear this out, that she had a rheumatologic workup completed. An ANA titer was drawn, and this was positive as was her RF. She saw a rheumatologist who according to Ms. Lasnetski checked her for two muscle diseases as well as lupus, these came back negative. She is still concerned that her ANA and RF are positive, and she is unsure the implications that this may have.

After seeing Ms. Lasnetski, on May 24, 2012, Dr. R.D. Fealey summarized Ms. Lasnetski's history with the following comments:

> The patient states she was relatively stable and well without most of her current symptoms until she received the HPV vaccination during a time when she had active lesions present apparently. The Gardasil shot within days seemed to produce a variety of symptoms. . . . The patient has had continued symptoms since that time. . . .
>
> . . .

---

9 "[P]ostural orthostatic tachycardia syndrome ABBR: POTS. Inability to tolerate a standing position as a result of a sudden increase in heart rate when rising from a seated or recumbent position. It is thought to be one of the dysautonomic syndromes." Taber's Cyclopedic Medical Dictionary 1879 (22nd ed. 2013).

> The patient's menstrual cycles changed. . . . The patient's bladder seemed to develop an irritation. . . . The paresthesias do not produce a deficit of sensation, and although she reports arm weakness, this is much better now. The patient has had a comprehensive POTS evaluation, and she, for instance, did not have POTS criteria on the tilt in Neurology at ten minutes. . . . The patient's 24-hour Holter BP monitor showed some spontaneous variation in heart rate some of which occurred when she would first get up in the morning and some of that exceeded 30 beats per minute. Again, however, this is a nonspecific finding, and I suspect relates more to her moderately-severe deconditioning [from pregnancy].
>
> The patient has a possible immuno-inflammatory tendency. Apparently she has a positive ANA and rheumatoid factor. She does not really have a well-defined connective tissue disease, however. Still, the input of Rheumatology on some of her symptoms will be welcome especially on some of her blood test abnormalities.
>
> Autonomic testing showed no evidence of an underlying autonomic neuropathy. We were able to review the photographs of the developing sweat test particularly the areas where she has some tingling, and there was no hint of any superficial sensory neuropathy affecting the smaller sudomotor nerves.

Dr. Fealey's report also noted that Ms. Lasnetski's "neurological examination also is normal including tests of sensation in the lower extremities. There was no weakness appreciated and no postural tachycardia of significance nor any drops in blood pressure going from supine to upright." Dr. Fealey diagnosed Ms. Lasnetski with a "***[s]ensory dysesthesias following HPV vaccination***." (emphasis in original). He elaborated, "I suspect this is a benign syndrome related to activation of her immune system at worst perhaps some inflammatory neuritis that I would expect to eventually settle down and which will likely not have significant implications as far as any permanent neuropathy."

On May 25, 2012, Dr. C.J. Michet, Jr., a rheumatologist at the Mayo Clinic, followed upon this diagnosis with the further explication of "***[i]diosyncratic severe reaction to vaccination***," while concluding, "I have reassured her [Ms. Lasnetski] that the extensive testing done at Mayo reveals that she has not suffered any type of permanent autonomic injury." (emphasis in original). Moreover, he clarified, "We can be reassured with no evidence of additional autoantibodies appearing."

Following her visit to the Mayo Clinic on May 22, 2012, Ms. Lasnetski, apparently, did not seek medical attention again until a May 10, 2013 appointment with Dr. Camp. At this follow up with Dr. Camp, Ms. Lasnetski expressed frustration with the medical outcomes and findings: "Holly has had strange vague symptoms from the time I first met her. She has long felt that her symptoms are due to a Gardasil vaccination that

she received in her teens.[10] She has been sent to Rheumatology, Mayo, and Cardiology." In his report, Camp emphasized, "No obvious source of her symptoms has been determined." Dr. Camp returned to this conclusion later in his report, stating: "The patient and her family has [sic] long felt that her symptoms in her late teens to her early 20s are a complication of the Gardasil vaccine. I have my skepticism. She has been seen by several specialists and there is truly no confirmation."

Ms. Lasnetski was evaluated by a disease specialist, Dr. Minces in Willmar, Minnesota on May 22, 2013. Dr. Minces reported, "She [Lasnetski] is very frustrated because she was never given a definitive diagnosis." Dr. Minces found that his inquiry was non-conclusive: "26-year-old female with multiple diffuse complaints. I do not find any clinical evidence for infection, or concerns that prompt me to any particular tests. She was extensively evaluated by rheumatology, and no diagnosis was found." Dr. Minces further indicated a "concern for somatization."[11] His opinion was that "there is no evidence of infection, and from my standpoint, no evidence of rheumatological condition. . . . She does fit the profile for somatization, given her multiple complaints, anxiety, and depression, and the fact that she gets upset to hear that she may not have a clear physical diagnosis." His recommendation was to refer Lasnetski to "psychiatry and therapy to optimize her treatment for depression, and anxiety, and also for somatization."

In 2014, Ms. Lasnetski visited the emergency room a number of times for viral infections, C. difficile colitis secondary to Augmentin medication, upper respiratory tract infection, migraines, and abdominal pain, the last one in the record before the court on May 18, 2014.

Petitioner filed her petition for compensation on July 9, 2014. The Petition for Compensation alleged that the sensory dysesthesias and the idiosyncratic severe reaction Ms. Lasnetski experienced following July 18, 2011 were caused by the Gardasil vaccine. Her petition further alleged that her current health problems were "all caused-in-fact by the Gardasil (HPV) vaccination," and that Petitioner "will require substantial future medical care and monitoring."

In response to the petition, respondent's Vaccine Rule 4(c) Report filed October 7, 2014 argued that Petitioner "[did] not allege that she suffered a table injury" and, moreover, she had not met her burden of proof for entitlement to compensation under the Vaccine Act for an injury not on the Table. Respondent argued that for a non-Table injury, Petitioner must prove by the preponderance of the evidence that her injury was caused-in-fact by the vaccine. Respondent further argued that no compensation should be awarded because 1) it was not clear what injury Petitioner claimed was caused by

[10] The record indicates that the Petitioner received the vaccination when she was twenty-four, not as a teenager.

[11] Somatization is defined as "in psychiatry, the conversion of mental experiences or states into bodily symptoms." Dorland's Illustrated Medical Dictionary 1734.

the HPV vaccination; and 2) that "there [was] no medical literature or scientific evidence that the HPV vaccine can cause the injuries alleged by petitioner."

In the proceedings before the Special Master, Petitioner produced Dr. James Dahlgren, a toxicologist and internist, as her medical expert. Dr. Dahlgren interpreted "the doctors at the Mayo Clinic [as having] diagnosed adverse vaccination reactions." Dr. Dahlgren stated, "[t]hey diagnosed Ms. Lasnetski with an adverse vaccination event with ongoing illness since that event." In support, he noted the frequency of her visits to doctors and that "[h]er health status is obviously changed radically as a result of the vaccination based upon the objective medical records." In reviewing her medical history he found a "constellation of sensory nervous system abnormalities." He further concluded, "[t]he positive ANA is an indication of an abnormal autoimmune occurrence. The clinical and laboratory picture is compatible with adverse autoimmune reactions on Ms. Lasnetski's nervous system. In this case it is predominantly the sensory nervous system that has been impacted by the deranged immune system." In Dr. Dahlgren's view, Petitioner's symptoms were consistent with an autoimmune illness, for which "[a] large study of Gardasil® exposed women found an elevated occurrence of autoimmune diseases." Although he observed that a specific auto-immune disease had not been identified, stating that "[t]he Mayo clinic doctors noted a positive ANA (anti-nuclear antibody) titer but other serological tests did not provide a more specific auto-immune diagnosis," he ultimately concluded that "[t]here is no other causative factor in this patient/subject to have developed these objective and subjective abnormalities."

During the proceedings, Special Master Hamilton-Fieldman asked Petitioner to submit a supplemental expert report, due May 19, 2015, after articulating "concerns with the potential pre-existing condition(s), the rapid onset of symptoms, and the lack of a definitive diagnosis." Petitioner never submitted such a report. Instead, on the date the supplemental report was due, May 19, 2015, Petitioner filed for judgment on the administrative record.

On October 28, 2015, the government submitted an expert report by Dr. Thomas Leist, a neuroimmunologist and biochemist. Dr. Leist professed skepticism that a diagnosis of a condition or illness could be made by mere conversation and consultation alone with a patient and remarked: "As did Dr. Fealey, Dr. Michet did not render a diagnosis but merely lists petitioner's claim of a 'severe reaction to the vaccine'. Neither physician appears to have reviewed records of practitioners involved in Petitioner's case following the vaccination with Gardasil. Neither physician recommended additional testing to reach a diagnosis." Dr. Leist's opinion further advised that the labels of "sensory dysesthesia" and "idiosyncratic severe reaction" did not amount to medical diagnoses. Rather, Dr. Leist indicated "these statements are a description of the symptoms Ms. Lasnetski described to her doctors." Additionally, he stated "sensory dysesthesia could be a symptom consistent with many different diagnoses, none of her treating doctors actually assessed her with any of those conditions" and "an 'idiosyncratic severe reaction,' is not a diagnosis and is really another way of saying that petitioner may have suffered a reaction." Finally, he indicated "the onset of those symptoms, within a day of the administration of the vaccine would be too soon for the vaccine to be a plausible immunological cause of those symptoms." Ultimately, Dr. Leist

questioned the nature of the adverse event and argued that the method and studies used by Dr. Dahlgren were "not designed to evaluate causality" and "not related to the alleged condition in petitioner's case."

In a decision dated April 29, 2016, the Special Master dismissed the petitioner's claim. See Lasnetski v. Sec'y Health & Human Servs., slip. op at 6-7. In her decision, the Special Master reviewed the record and made a number of factual findings. The Special Master noted that Ms. Lasnetski had travelled to the Mayo Clinic on May 22, 2012 and that, while at the Mayo Clinic, she was seen by Drs. Fealey and Michet. See id. at 3-4. With regard to Dr. Fealey, the Special Master found:

> The treating neurologist, Dr. Fealey, concluded that Petitioner had neither autoimmune neuropathy nor POTS, but that she could have an "immuno-flammatory tendency." And even though she had a positive ANA test, she did not have a "really well-defined connective tissue disease." Although Dr. Fealey indicated that her sensory dysesthesias "follow[ed]" the HPV vaccination, he made no finding as to whether it was caused by the vaccination.

Id. at 3 (citations omitted and brackets in original). With regard to Dr. Michet, the Special Master found: "[T]he treating rheumatologist, Dr. Michet, asserted that Petitioner had an 'idiosyncratic severe reaction to vaccination,' and thus, 'it would probably be prudent in the future' for her to be 'cautious about any further vaccinations.'" Id. at 3-4 (citation omitted). The Special Master also summarized the findings in the reports of the Petitioner's and defendant's experts, Drs. Dahlgren and Leist, respectively. See id. at 4-6. The Special Master's summary of the conclusions of Dr. Dahlgren included:

> 1. The subject, Ms. Lasnetski, developed an adverse and persisting illness in the proper time frame after the vaccination to qualify for it being recognized as consistent with the temporality requirement of a vaccine injury.
>
> 2. The illness she developed is consistent with the known illnesses cause[d] by vaccine adverse illness.
>
> 3. There is no other causative factor in this patient/subject to have developed these objective and subjective abnormalities.
>
> 4. There are human and animal studies that illuminate the mechanism that explains this young woman's current state of poor health.

Id. at 5 (footnote omitted). With regard to the report of Dr. Leist, the Special Master found:

> Addressing the claimed "diagnoses" of "sensory dysesthesia" and "idiosyncratic severe reaction to vaccination" Dr. Leist opined that these are not diagnoses at all, but mere descriptions of her symptoms. Moreover, he noted that Dr. Dahlgren and Petitioner's doctors at the Mayo

> Clinic reached these "diagnoses" seemingly without consulting Petitioner's medical history. As to Dr. Dahlgren's expert report, Dr. Leist explained that the data underlying the report suffers from limitations including "underreporting, selective reporting, lack of a control group, inadequate denominator data to calculate event rates, and diagnostic uncertainty of events"; Dr. Leist also emphasized that Dr. Dahlgren "cites articles that are not related to the alleged condition in [P]etitioner's case." Ultimately, Dr. Leist argued that one could not say that the vaccine caused Petitioner's condition because (1) Petitioner had not actually received a diagnosis; (2) Petitioner's symptoms occurred too rapidly after the vaccination to be causally linked to the vaccination; and (3) Dr. Dahlgren's expert report cited flawed data, referenced studies of autoimmune conditions that Petitioner does not have, and failed to offer a "reputable theory explaining how HPV vaccine could cause the numerous symptoms."

Id. at 5-6 (citations omitted and brackets in original).

After reviewing the administrative record, the Special Master concluded that "Petitioner is not entitled to compensation under the Vaccine Act because she has failed to identify the underlying injury from which all of her alleged symptoms arise," and dismissed the petition. Id. at 6. The Special Master's decision states:

> To receive compensation under the Vaccine Act, a petitioner must prove, by a preponderance of the evidence, that she suffered an injury that was caused by a vaccine. *See* 42 U.S.C. §§ 300a-11(c)(1), -13(a)(1)(A) (2012). Where, as here, the petitioner alleges no "Table Injury," *see* § 300a-13(a)(1)(A), she must demonstrate, 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." *Althen*, 418 F.3d at 1278.
>
> That being said, "[i]n the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached." *Lombardi v. Sec'y Health & Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). Under the Vaccine Act, the petitioner must show "at least one defined and recognized injury" and "not merely a symptom or manifestation of an unknown injury." *Id.* Stated differently, the special master's role "is not to diagnose vaccine-related injuries, but instead to determine based on the record evidence as a whole and the totality of the case," if a vaccine caused Petitioner's claimed injury. *Id.* at 1351 (internal quotation marks omitted).
>
> Here, after reviewing Petitioner's medical records in conjunction with Dr. Dahlgren's expert report, the undersigned concludes that Petitioner has failed to allege a "defined and recognized injury." As an

> alternative, Petitioner relies on the diagnoses of "sensory dysesthesias" and "idiosyncratic severe reaction to vaccination," but as Dr. Leist pointed out, the former is "merely a symptom or manifestation of an unknown injury" and the latter is an umbrella term which could be used to describe any manifestation of symptoms that post-dates a vaccination. Finding that either of these medical conditions actually constituted an injury under the Vaccine Act would effectively eliminate the Act's injury-requirement, as petitioners would need only prove that they manifested a medical symptom after receiving a vaccination to meet it. Because the undersigned cannot countenance such a result, the petition must be dismissed.

Id. at 6-7.

On May 26, 2016, Petitioner filed a motion for review of the Special Master's decision, and the case was assigned to the undersigned. In her motion, Petitioner alleged that the Special Master had abused her discretion and had acted not in accordance with the law. Ms. Lasnetski requested that her petition be remanded to the Special Master with a "direction to apply the Althen[v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005)] analysis to the facts presented." In her motion, Petitioner specifically asserted that the Special Master had erred: 1) by requiring Petitioner to allege "a defined and recognized injury" as a threshold matter; 2) by not concluding that the Petitioner had specified a "defined and recognized injury," 3) and by failing to conduct an Althen causation analysis.

The government's response to the motion to the review, filed on June 27, 2016, argued that the Special Master's decision should be affirmed. The government argued that this case indistinguishable from Lombardi v. Sec'y of Health & Human Servs., which required an allegation of "'a defined and recognized injury'" and "'not merely a symptom or manifestation of an unknown injury.'" Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1353, 1356 (Fed. Cir.), reh'g en banc denied (Fed. Cir. 2011). Respondent argued that the Special Master in Ms. Lasnetski's case correctly and logically decided that the causation question should not be reached.

DISCUSSION

As noted, Ms. Lasnetski alleges that the Special Master erred on three grounds. First, Petitioner alleges that the Special Master erred by requiring Petitioner to allege a "defined and recognized injury," which petitioner alleges amounted to an "increased burden" not supported by the Vaccine Act's definition of "vaccine-related injury." Petitioner argues that this was an error "in the interpretation of the law and not questions of fact" and, thus, subject to "complete and independent review" by this court. Second, Petitioner alleges that, even if the Special Master did not err in requiring Petitioner to allege a "defined and recognized injury," Petitioner met this standard by alleging that she had suffered sensory dysesthesia and an "idiosyncratic severe reaction to vaccination." According to Petitioner, the Special Master's determination that Petitioner had not alleged a "defined and recognized injury" amounted to an abuse of

discretion. Third, Petitioner alleges that the Special Master erred as a matter of law by failing to conduct an Althen v. Secretary of Health and Human Services analysis to allow her to prove that the vaccine caused her alleged injuries. Petitioner argues that, had the Special Master analyzed the evidence in the record under the Althen standard, Petitioner would have met her initial burden of showing causation and the burden would have shifted to the government to show that her injury was caused by a factor unrelated to the vaccine.

In its response to Petitioner's motion for review, the government rejects each of petitioner's alleged grounds for alleged error. First, the government argues that the Special Master's decision applied the proper standard for alleging the existence of an injury, correctly requiring that Petitioner prove the existence of an injury, rather than just symptoms of an injury. In support of this argument, the government cites Broekelschen v. Secretary of Health and Human Services, 618 F.3d 1339 (Fed. Cir. 2010), and Lombardi v. Secretary of Health and Human Services, 656 F.3d 1343, the latter of which was relied upon by the Special Master in her decision and which the government argues is "indistinguishable" from the present case. Second, the government argues that "[t]he Special Master carefully considered the evidence in the record . . . in an effort to understand the nature of petitioner's alleged injury" and ultimately concluded that petitioner had "'failed to identify the underlying injury from which her alleged symptoms [arose].'" (quoting Lasnetski v. Sec'y Health & Human Servs., slip op. at 6) (alteration is respondent's). Finally, the government argues that the Special Master properly determined that, in the absence of a showing of at least one defined and recognized injury, the question of causation under the Althen analysis could not be reached. According to the government, because Petitioner has failed to demonstrate that the Special Master erred or that her actions were arbitrary, capricious, an abuse of discretion or otherwise legally prohibited, the petition for review should be denied and the Special Master's decision should be affirmed.

When reviewing a Special Master's decision, the assigned Judge of the United States Court of Federal Claims shall:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The legislative history of the Vaccine Act states: "The conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those

cases in which a truly arbitrary decision has been made." H.R. Rep. No. 101-386, at 517 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3120.

In order to recover under the Vaccine Act, petitioners must prove that the vaccine caused the purported injury. See W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1355-56 (Fed. Cir. 2013) ("The Vaccine Act created the National Vaccine Injury Compensation Program, which allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had significantly aggravated' a vaccine-related 'illness, disability, injury, or condition.'" (quoting 42 U.S.C. § 300aa–11(c)(1)(C))); Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1350 ("A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine."); see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. 353, 358 (2012), aff'd, 503 Fed. App'x 952 (Fed. Cir. 2013); Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54 (2011). Regarding the standard of review, articulated in Markovich v. Secretary of Health and Human Services, the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1355-56 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1366 (Fed. Cir.) (The United States Court of Appeals for the Federal Circuit stated that "we 'perform[ ] the same task as the Court of Federal Claims and determine[ ] anew whether the special master's findings were arbitrary or capricious.'" (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000))) (brackets in original), reh'g and reh'g en banc denied (Fed. Cir. 2013); W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355; Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012); Avera v. Sec'y of Health & Human Servs., 515 F.3d 1343, 1347 (Fed. Cir.) ("Under the Vaccine Act, we review a decision of the special master under the same standard as the Court of Federal Claims and determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" (quoting 42 U.S.C. § 300aa-12(e)(2)(B))), reh'g and reh'g en banc denied (Fed. Cir. 2008); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1350 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2008); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1277; Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 47 (2013); Taylor v. Sec'y of Health & Human Servs., 108 Fed. Cl. 807, 817 (2013). The arbitrary and capricious standard is "well understood to be the most deferential possible." Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d at 870.

Therefore, this court may set aside a Special Master's decision only if the court determines that the "findings of fact or conclusion of law of the special master . . . [are] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." 42 U.S.C. § 300aa-12(e)(2)(B); see also Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1350 ("We uphold the special master's findings of fact unless they are arbitrary or capricious.") (internal citations omitted); Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1321; Markovich v. Sec'y of

Health & Human Servs., 477 F.3d at 1356-57; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360. The United States Court of Appeals for the Federal Circuit has indicated that:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard . . . ; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.

Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d at 871 n.10; see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355; Griglock v. Sec'y of Health & Human Servs., 687 F.3d 1371, 1374 (Fed. Cir. 2012); Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1249 (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1345) (explaining that the reviewing court "do[es] not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder"); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 43, 56.

"With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The Claims Court owes these findings and conclusions by the special master great deference – no change may be made absent first a determination that the special master was 'arbitrary and capricious.'" Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d at 870; see also 42 U.S.C. § 300aa-12(e)(2)(B). Generally, "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.'" Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (quoting Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)); see also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1253-54; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360; Avila ex rel. Avila v. Sec'y of Health & Human Servs., 90 Fed. Cl. 590, 594 (2009); Dixon v. Sec'y of Dep't of Health & Human Servs., 61 Fed. Cl. 1, 8 (2004) ("The court's inquiry in this regard must therefore focus on whether the Special Master examined the 'relevant data' and articulated a 'satisfactory explanation for its action including a "rational connection between the facts found and the choice made."'" (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)))).

As noted by the United States Court of Appeals for the Federal Circuit:

> "Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these

> painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute."

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366 (quoting Hodges v. Sec'y of Dept. of Health & Human Servs., 9 F.3d at 961) (modification in original); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363; Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1380 (Fed. Cir. 2012). The Court of Appeals for the Federal Circuit has further explained that the reviewing courts "'do not sit to reweigh the evidence. [If] the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.'" See Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1363) (modification in original); see also Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (citing Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010). "'Clearly it is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.'" Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56 (quoting Munn v. Sec'y of Dept. of Health & Human Servs., 970 F.2d at 870 n.10); see also Paluck v. Sec'y of Health & Human Servs., 113 Fed. Cl. 210, 224 (2013) ("A special master's findings regarding the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are 'supported by substantial evidence.'" (quoting Doe v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir.), cert. denied, 562 U.S. 1029 (2010))). Additionally, as instructed by the United States Court of Appeals for the Federal Circuit, "[u]nder the Vaccine Act, Special Masters are accorded great deference in determining the credibility and reliability of expert witnesses. Indeed, we have held that a Special Master's 'credibility determinations are virtually unreviewable.'" Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1347 (quoting Hanlon v. Sec'y of Health & Human Servs., 191 F.3d 1344, 1349 (Fed. Cir. 2010) (quotation omitted)).

Additionally, a Special Master is "not required to discuss every piece of evidence or testimony in [his or] her decision." Snyder ex rel. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 728 (2009); see also Paluck ex rel. Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. 457, 467 (2012) ("[W]hile the special master need not address every snippet of evidence adduced in the case, see id. [Doe v. Sec'y of Health & Human Servs., 601 F.3d at 1355], he cannot dismiss so much contrary evidence that it appears that he 'simply failed to consider genuinely the evidentiary record before him.'" (quoting Campbell v. Sec'y of Health & Human Servs., 97 Fed. Cl. 650, 668 (2011))).

Regarding the causation analysis, as indicated by the United States Court of Appeals for the Federal Circuit in Althen v. Secretary of Health and Human Services:

> The [Vaccine] Act provides for the establishment of causation in one of two ways: through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ("Table injury"), see 42 U.S.C. § 300aa-14(a); or where the complained-of injury is not listed in the Vaccine Injury Table ("off-Table injury"), by proving causation in fact, see 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I).

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356; Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346; Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 551 U.S. 1102 (2007); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 50; Paluck v. Sec'y of Health & Human Servs., 113 Fed. Cl. at 212; Fesanco v. Sec'y of Health & Human Servs., 99 Fed. Cl. 28, 31 (2011). The United States Supreme Court has explained that:

> Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation. No showing of causation is necessary; the Secretary bears the burden of disproving causation. A claimant may also recover for unlisted side effects, and for listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation.

Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1073-74 (2011) (footnotes omitted); Kennedy v. Sec'y of Health & Human Servs., 99 Fed. Cl. 535, 539 (2011), aff'd, 485 Fed. App'x. 435 (Fed. Cir. 2012).

As both parties recognize, the injuries Petitioner alleges she suffered as a result of the Gardasil vaccination are not included on the Vaccine Injury Table. See 42 U.S.C. § 300aa-14. Plaintiff, therefore, must proceed under an off-Table theory of recovery. Under the off-Table theory of recovery, a petitioner is entitled to compensation if he or she can demonstrate, by a preponderance of the evidence, see 42 U.S.C. § 300aa-13(a)(1)(A), that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table, but which was caused by a vaccine that is listed on the Vaccine Injury Table. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 ("Nonetheless, the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." (quoting Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322)); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d at 1525.

Additionally, Petitioner must

> prove causation-in-fact. Grant [v. Sec'y of Health & Human Servs.], 956 F.2d [1144,] 1147-48 [(Fed. Cir. 1992)]. [The United States Court of Appeals for the Federal Circuit has] held that causation-in-fact in the Vaccine Act context is the same as the "legal cause" in the general torts context. Shyface v. Sec'y of Health and Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "a substantial factor in bringing about the harm."

de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting the Restatement (Second) of Torts § 431(a)); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 ("To prove causation, a petitioner must show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352–53)). A "'substantial factor' standard requires a greater showing than 'but for' causation." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). "However, the petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor." Id. (citing Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007)). A judge of this court has explained the relationship between "but-for" causation and "substantial factor" causation in our court's decision in Deribeaux ex rel. Deribeaux v. Secretary of Health and Human Services:

> The de Bazan court defined but-for causation as requiring that "the harm be attributable to the vaccine to some nonnegligible degree," and noted that, although substantial is somewhere beyond the low threshold of but-for causation, it does not mean that a certain factor must be found to have definitively caused the injury. Id. [de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351] Accordingly, a factor deemed to be *substantial* is one that falls somewhere between causing the injury to a non-negligible degree and being the "sole or predominant cause." Id.
>
> This definition of substantial—somewhere between non-negligible and predominant—is applicable to respondent's burden to prove a sole substantial factor unrelated to the vaccine. Accordingly, a respondent's burden is to prove that a certain factor is the only *substantial* factor—one somewhere between non-negligible and predominant—that caused the injury.

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 105 Fed. Cl. 583, 595 (2012), aff'd, 717 F.3d 1363 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2013) (emphasis in original).

A petitioner must prove his or her case by a preponderance of the evidence. See 42 U.S.C. § 300aa-13(a)(1)(A). According to the United States Court of Appeals for the Federal Circuit, the preponderance of evidence standard is "one of proof by a simple

preponderance, of 'more probable than not causation.'" Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80 (citing concurrence in Hellebrand v. Sec'y of Dep't of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 ("In this off-table case, the petitioner must show that it is 'more probable than not' that the vaccine caused the injury." (quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80)). Decisions of the Federal Circuit permit the use of circumstantial evidence, which the court described as "envisioned by the preponderance standard" and by the vaccine system created by Congress, in which "close calls regarding causation are resolved in favor of injured claimants" without the need for medical certainty. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280; see also Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322, 1332 n.4 (Fed. Cir. 2011), cert. denied, 132 S. Ct. 1908 (2012); Andreu ex rel. Andreu v. Sec'y of Dept. of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009) ("In Althen, however, we expressly rejected the Stevens test, concluding that requiring 'objective confirmation' in the medical literature prevents 'the use of circumstantial evidence . . . and negates the system created by Congress' through the Vaccine Act.") (modification in original); La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 198 (2013) ("Causation-in-fact can be established with circumstantial evidence, i.e., medical records or medical opinion."). The Althen court further noted that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id. (citing Knudsen by Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356. When proving eligibility for compensation for an off-Table injury under the Vaccine Act, however, Petitioner may not rely on her testimony alone. According to the Vaccine Act, "[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." See 42 U.S.C. § 300aa-13(a)(1).

The Federal Circuit in Althen defined a three-prong test which a petitioner must meet to establish causation in an off-Table injury case:

> To meet the preponderance standard, [Petitioner] must "show a medical theory causally connecting the vaccination and the injury." Grant v. Sec'y of Health & Humans Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]" Grant, 956 F.2d at 1148. [Petitioner] may recover if she shows "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant, 956 F.2d at 1149. Concisely stated, [Petitioner's] burden is to

> show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (brackets in original); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367; Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1249; Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322; Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355; Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006); C.K. v. Sec'y of Health & Human Servs., 113 Fed. Cl. 757, 766 (2013); Contreras v. Sec'y of Health & Human Servs., 107 Fed. Cl. 280, 291 (2012).

Ms. Lasnetski first alleges that the Special Master subjected Petitioner to an increased burden not supported by the Vaccine Act by requiring her to allege a "defined and recognized injury." In this regard, Petitioner appears to be challenging the following statement by the Special Master: "Under the Vaccine Act, the petitioner must show 'at least one defined and recognized injury' and 'not merely a symptom or manifestation of an unknown injury.'" Lasnetski v. Sec'y Health & Human Servs., slip op. at 6 (quoting Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1353). Petitioner argues that this standard involves a too "narrow interpretation" of the injury allegation and demonstration required by the Vaccine Act. In support of her argument Petitioner, argues that the Vaccine Act has a "broad and inclusive" definition of "vaccine-related injury" and that the case from which the Special Master drew the her standard, Lombardi v. Secretary of Health and Human Services, is distinguishable from the present case.

If a petitioner's diagnosis is not in dispute, the Special Master should proceed directly to the Althen causation analysis. See W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1357 (holding that, because the parties agreed on petitioner's diagnosis, the Special Master "should have expressly applied the analysis set forth in *Althen*" rather than first resolving the "preliminary question of whether Petitioner had subclinical multiple sclerosis before the vaccination" (internal quotation marks omitted)); see also Contreras v. Sec'y of Health & Human Servs., 121 Fed. Cl. 230, 243 (2015) ("In a typical Vaccine Act case adding this threshold inquiry [into the diagnosis of petitioner's injury] does not serve a useful purpose and may actually cause significant harm . . . ."). However, "if the existence and nature of the [petioner's] injury itself is in dispute, it is the special master's duty to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test to determine causation of that injury." Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1352 (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346. In such a case, the United States Court of Appeals for the Federal Circuit has held in Lombardi v. Secretary of Health and Human Services that the Vaccine Act "places the burden on the petitioner to make a showing of at least one defined and recognized injury." Id. at 1353. Stated

another way, it is a petitioner's "burden to show by a preponderance of the evidence that she suffered from any medically recognized 'injury,' not merely a symptom or manifestation of an unknown injury." Id.

Initially, Ms. Lasnetski cites the Vaccine Act's definition of "vaccine-related injury or death" in 42 U.S.C. § 300aa-33(5) to argue that the term "vaccine-related injury," as used in the Vaccine Act, has a "broad and inclusive meaning."[12] Section 300aa-33(5) defines the term "vaccine-related injury or death," as used throughout the Vaccine Act, as "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table." 42 U.S.C. § 300aa-33(5). Petitioner's argument appears to be that this definition of "vaccine-related injury" is broader than the one implied by the Special Master's standard. As noted above, however, the Federal Circuit has held that the Vaccine Act itself places the burden on Petitioner that the Special Master required in the present case: "to make a showing of at least one defined and recognized injury." Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1353. Further, the Federal Circuit has explicitly rejected virtually the same argument made by Petitioner based on § 300aa-33(5). In Broekelschen v. Secretary of Health and Human Services, 618 F.3d 1339, the dissenting opinion argued that because § 300aa-33(5) "broadly defines 'vaccine-related injury or death,'" claimants could meet the Vaccine Act's criteria "even in the absence of a definitively diagnosed injury." Id. at 1352 (Mayer, J., dissenting). The majority, however, rejected this argument, holding that § 300aa-33(5) "does not support [the dissent's] argument that proof of an "illness, condition, or disability" is something less than proof of an "injury" under the Vaccine Act." Id. at 1349. Instead, the Broekelschen court held that "[m]edical recognition of the injury claimed is critical and by definition a 'vaccine-related injury,' i.e., illness, disability, injury or condition, has to be more than just a symptom or manifestation of an unknown injury." Id.; see also Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1353. This is the same standard that the Special Master applied to Petitioner in the present case.[13]

---

[12] Petitioner also cites 42 U.S.C. § 11(c)(1)(C)(i) (2012) in support of her argument. This provision, however, is inapposite to Petitioner's case as it applies only to petitioners seeking compensation for Table injuries. See 42 U.S.C. § 300aa-11(c)(1)(C)(i) ("A petition for compensation under the Program for a vaccine-related injury or death shall contain . . . an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died . . . sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table . . . ." (emphasis added)).

[13] Petitioner also cites the use of the word "harm" in place of "injury" in the Federal Circuit's decision in Flores v. Secretary of Health and Human Services as evidence that the term "vaccine-related injury" should be given and "broad and inclusive meaning." The Flores decision stated:

> As noted above, the Federal Circuit, in *Althen,* distilled this prior precedent into a three-part test, holding that to prove causation-in-fact, a petitioner must provide "(1) a medical theory causally connecting the vaccination

As noted above, the "defined and recognized injury" standard utilized by the Special Master was quoted directly from the Federal Circuit's decision in Lombardi v. Secretary of Health and Human Services. Petitioner argues, however, that the Special Master's reliance on Lombardi was "inappropriate," because the facts and "resulting legal analysis" in Lombardi "are distinguishable from the facts on the record in this matter." In particular, Petitioner argues that whereas "[t]he experts and physicians in *Lombardi* could neither define nor recognize any one consistent injury," in the present case "physicians Dr. Fealey and Dr. Michet, as well as Dr. Dahlgren, agreed upon defined and recognized injuries; specifically, the injuries of sensory dysesthesias following HPV vaccination and idiosyncratic severe reaction to vaccination." Further, while the various diagnoses in Lombardi conflicted with one another, the two diagnoses plaintiff received are "entirely consistent" with one another. According to Petitioner, "[b]ecause of the competing and contradictory diagnoses, the *Lombardi* court concluded that the petitioner failed to meet her burden of showing 'at least one defined and recognized injury.'" Plaintiff argues that this distinction from the present case is relevant because "[t]he purpose of the requirement for a 'defined and recognized injury' in *Lombardi* was not to create a new, narrower set of compensable injuries, but was instead used to highlight the fact that the petitioner in Lombardi failed to provide evidence of any one injury."

In Lombardi, the petitioner's experts offered three different diagnoses for her injury, each of which was disputed by the government's experts, who offered five different diagnoses of their own. Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1348-49. After examining the evidence in the record, as well as the opinions of the

---

> 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." 418 F.3d at 1278. All three prongs "must cumulatively show that the vaccination was a 'but-for' cause of the **harm**, rather than just an insubstantial contributor in, or one among several possible causes of, the **harm**." *Pafford v. Sec'y of HHS,* 451 F.3d 1352, 1355 (Fed. Cir. 2006).

Flores v. Sec'y of Health & Human Servs., 115 Fed. Cl. 157, 162, aff'd, 586 F. App'x 588 (Fed. Cir. 2014) (emphasis added by Petitioner). In Flores, there was no issue regarding the sufficiency or nature of the alleged injury as "all three experts agreed that petitioner had suffered a spinal cord stroke." Id. at 160. Instead, the dispute centered on causation, "whether the special master properly held that petitioner had not established that the HPV vaccine caused [the Flores petitioner's] spinal cord stroke." Id. at 161. Nor did the Flores court anywhere in its opinion discuss the Vaccine Act's definition of "vaccine-related injury" or otherwise elaborate on its use of the word "harm" in the passage cited by petitioner. In the absence of any such indications, the Federal Circuit's use of the generic word "harm" in place of the word "injury" in a single sentence cannot be interpreted as providing an additional interpretation of the Vaccine Act's requirements for alleging a "vaccine-related injury," altering the standard the Federal Circuit had set forth less than three years earlier in Lombardi.

various testifying experts, the Special Master concluded that the petitioner, Ms. Lombardi, was not entitled to compensation because she had not established that she, actually, had suffered from any of the three conditions proposed by her experts, a decision which was affirmed, upon review, by the United States Court of Federal Claims. See id. at 1349-50. Ms. Lombardi challenged the rulings of the Special Master and the United States Court of Federal Claims on the grounds that the focus on whether she suffered from one of her three claimed conditions "imposed on her an improper burden of proving a diagnosis with scientific certainty even before she could prove causation under *Althen.*" Id. at 1352.

In rejecting Ms. Lombardi's arguments, the Federal Circuit turned to its decision in Broekelschen v. Secretary of Health & Human Services, 618 F.3d 1339, which, it found, "addressed the same issue as that presented" in Lombardi. Id. at 1352. The court noted that, in Broekelschen, the petitioner "suffered from symptoms that were consistent with two different conditions . . . which differ[red] significantly in their pathology," and that the Special Master denied the petition on the grounds that the condition the petitioner "actually suffered from was not the one for which he had claimed or presented causation evidence." Id. at 1352 (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1344, 1346). The Broekelschen court upheld the Special Master's decision on the grounds that "the question of causation turned on which injury the petitioner suffered" and thus, "if the existence and nature of the injury itself is in dispute, it is the special master's duty to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test to determine causation of that injury." Id. (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346). Finding that Ms. Lombardi's case was similar to the petitioner's in Broekelschen, the court held:

> In the face of such extreme disagreement among well-qualified medical experts, each of whom had evaluated the petitioner, it was appropriate for the special master to first determine what injury, if any, was supported by the evidence presented in the record before applying the *Althen* test to determine causation. *Broekelschen,* 618 F.3d at 1346. In the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached.

Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1352–53.

Petitioner is correct that in Lombardi, the petitioner offered "competing and contradictory diagnoses." Petitioner, however, is incorrect that this alone was the reason why the *Lombardi* court "concluded that the petitioner failed to meet her burden of showing 'at least one defined and recognized injury.'" As the Federal Circuit recognized in Broekelschen, the existence of competing diagnoses is not necessarily fatal to an off-Table vaccine claim. See Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346 (distinguishing the finding in Kelley v. Sec'y of Health & Human Servs., 68 Fed. Cl. 84, 100–01 (2005) that "the petitioner was not required to categorize his injury" among two possible diagnoses on the grounds that, in Kelley, "the competing diagnoses were variants of the same disorder"). Instead, the problem with the competing diagnoses in

Lombardi (as in Broekelschen) was that, despite their common symptoms, the competing diagnoses "differed significantly in their pathology." Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1352 (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346); see also Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346 ("Moreover, while the two conditions . . . have overlapping symptoms, their underlying causes or etiology are completely different."). The existence of these potentially different potential pathologies meant that "nearly all of the evidence on causation was dependent on the diagnosis of [the petitioner's] injury." Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346. Similarly, the reason both Lombardi and Broekelschen held that a "vaccine-related injury" must "be more than just a symptom or manifestation of an unknown injury," was because such a symptom or manifestation could indicate any number of different underlying injuries, each with its own pathology, making it impossible for the court to accurately determine causation. See Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1352 (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1349 (Fed. Cir. 2010)). The purpose of the "defined and recognized injury" standard in Lombardi was, thus, not, as Petitioner argues, merely "to highlight the fact that the petitioner in Lombardi failed to provide evidence of any one injury." Instead the purpose of the standard was to set the minimum standard of definitiveness for injuries required for a court to be able to proceed to perform the Althen causation analysis. See Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1352 ("Thus, under *Broekelschen,* identification of a petitioner's injury is a prerequisite to an *Althen* analysis of causation."); see also Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1349 ("Medical recognition of the injury claimed is critical . . . .").

In the present case, the government's expert, Dr. Leist, challenged the arguments of Petitioner's expert, Dr. Dahlgren, that plaintiff's sensory dysesthesia or idiosyncratic severe reaction to vaccination amount to defined and recognized injuries, instead arguing that both amount to mere descriptions of symptoms. "[T]he existence and nature of the [Petitioner's] injury itself" was thus "in dispute." Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1352. The Special Master, therefore, properly "place[d] the burden on the petitioner to make a showing of at least one defined and recognized injury." Id. at 1353.

Petitioner alternatively argues that, even if the Special Master did not err in requiring Petitioner to allege a "defined and recognized injury," the Special Master abused her discretion in finding that the petitioner had not done so. In particular, Petitioner alleges that the evidence in the record demonstrates that the dysesthesia and idiosyncratic severe reaction to vaccination she alleged she suffered amount to defined and recognized injuries. The Special Master's analysis and conclusions regarding whether the Petitioner had alleged a "defined and recognized injury," although succinctly stated, were correct based on a review of the record before the court. See Lasnetski v. Sec'y Health & Human Servs., slip op. at 6-7. The Special Master stated that she had concluded that Petitioner had failed to allege a "defined and recognized injury" "after reviewing Petitioner's medical records in conjunction with Dr. Dahlgren's expert report." Id. at 6. The Special Master specifically rejected Petitioner's reliance on her diagnosis of "sensory dyesthesias" and "idiosyncratic severe reaction to vaccination"

on the grounds that "as Dr. Leist pointed out, the former is 'merely a symptom or manifestation of an unknown injury' and the latter is an umbrella term which could be used to describe any manifestation of symptoms that post-dates a vaccination." Id. The Special Master then concluded: "[f]inding that either of these medical conditions actually constituted an injury under the Vaccine Act would effectively eliminate the Act's injury-requirement, as petitioners would need only prove that they manifested a medical symptom after receiving a vaccination to meet it." Id. at 6-7.

Petitioner challenges the Special Master's conclusions on the grounds that dysesthesia is a "defined" injury and that both of the alleged injuries were "recognized" through the diagnoses of two doctors. Petitioner first argues that dysesthesia is a defined injury because it is included in Dorland's Illustrated Medical Dictionary, asserting that "[a]n injury that is defined by Dorland's Medical Dictionary is a defined injury." Petitioner is correct that dysesthesia is defined in Dorland's. See Dorland's Illustrated Medical Dictionary 577. The mere inclusion of an item in Dorland's, however, does not mean that the item is a defined injury for the purposes of the Vaccine Act. Dorland's contains, as noted in its preface, approximately 124,000 entries, id. at vii, covering a wide range of topics, including medical procedures, medical instruments, anatomy, symptoms, and chemical compounds. See, e.g., id. at 1808 (surgery), 1673 (scalpel), 728 (foot), 1665 (salt). Of particular note, the dictionary contains a number of entries defining what are, indisputably, symptoms of injuries, rather than injuries. See, e.g., id. at 1363 (pain), 1691 (sensation). Thus, the fact that dysesthesia is included in Dorland's Illustrated Medical Dictionary, is not evidence that the Special Master's conclusion that dysesthesia was "merely a symptom or manifestation of an unknown injury" was arbitrary, capricious, or incorrect based on the record provided to his court. See Lasnetski v. Sec'y Health & Human Servs., slip op. at 6.

Ms. Lasnetski next argues that Petitioner's injuries amounted to recognized injuries because they were diagnosed by Drs. Clement Michet and Dr. Robert Fealey at the Mayo Clinic. Plaintiff argues that these facts "run[] counter" to the opinion of defendant's expert, Dr. Leist that Petitioner had not actually received a diagnosis, an opinion which was relied upon by the Special Master. Dr. Fealey, did include "***Sensory dysesthesias following HPV vaccination***" in the list of "**DIAGNOSES**" he noted in his report after seeing Ms. Lasnetski on May 24, 2012. (capitalization and emphasis in original). Similarly, Dr. Michet included "***Idiosyncratic severe reaction to vaccination***" in the list of "**DIAGNOSES**" he noted in his report after seeing Ms. Lasnetski on May 25, 2012, although he also noted that he had "reassured her that the extensive testing done at Mayo reveals that she has not suffered any type of permanent autonomic injury," suggesting that he doubted the impact or severity of this diagnosis. (capitalization and emphasis in original). The conclusions of Drs. Michet and Fealey were both noted by the Special Master in the factual background portion of her decision. See Lasnetski v. Sec'y Health & Human Servs., slip op. at 3. The Special Master's decision also contained a summary of Dr. Leist's opinion, including that the he believed "that [plaintiff's expert] Dr. Dahlgren and Petitioner's doctors at the Mayo Clinic reached these 'diagnoses' [of sensory dysesthesia and idiosyncratic severe reaction to vaccination] seemingly without consulting Petitioner's medical history," a conclusion that the Petitioner does not presently challenge. See id. at 5-6. The Special Master stated

that she came to her conclusion "after reviewing Petitioner's medical records in conjunction with Dr. Dahlgren's expert report." Id. at 6. But after reviewing the record, including both expert reports, she chose to adopt Dr. Leist's opinion that the petitioner's diagnoses of sensory dysesthesias and idiosyncratic severe reaction to vaccination were "merely a symptom or manifestation of an unknown injury" and "an umbrella term which could be used to describe any manifestation of symptoms that post-dates a vaccination." Id. The Special Master did what she was required to do, review the record, including weighing the opinions of two treating physicians, Drs. Fealey and Michet, and the two experts, Drs. Dahlgren and Leist. Ultimately, the Special Master found Dr. Leist's expert opinion to be more credible, when combined with the record before the court. Petitioner essentially asks this court to second guess the Special Master's determination of how to assess the relative weight of the evidence before her, which absent arbitrariness or capriciousness is not the appropriate role of this court. Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366 ("'The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process.'" (quoting Hodges v. Sec'y of Dept. of Health & Human Servs., 9 F.3d at 961) (modification in original)). Given Ms. Lasnetski's medical records included in the record before the Special Master, the issues which Dr. Leist demonstrated regarding the diagnoses provided by Drs. Fealey and Michet, and the credibility the Special Master afforded Dr. Leist's expert opinion, the decision of the Special Master was based on sufficient evidence and was not arbitrary or capricious.

The third and final ground on which Petitioner objects to the Special Master's decision is that the Special Master allegedly erred as a matter of law by failing to apply Althen v. Secretary of Health and Human Services to the evidence in the record. As the Federal Circuit has noted:

> "[A] careful reading of *Althen,* shows that each prong of the *Althen* test is decided relative to the injury: (1) medical theory connecting the vaccination to the *injury*; (2) cause and effect showing the vaccination was the reason for the *injury*; and (3) proximate temporal relationship between the vaccination and the *injury*."

Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346 (citing Althen v. Secretary of Health and Human Services, 418 F.3d at 1278 and Doe v. Sec'y of Health & Human Servs., 601 F.3d at 1351) (emphasis in original). "Thus, . . . identification of a petitioner's injury is a prerequisite to an *Althen* analysis of causation." Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1352; see also Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346 (holding same). The logical extension of this conclusion is that, "[i]f a special master can determine that a petitioner did not suffer the injury that she claims was caused by the vaccine, there is no reason why the special master should be required to undertake and answer the separate (and frequently more difficult) question whether there is a medical theory, supported by 'reputable medical or scientific explanation,' by which a vaccine can cause the kind of injury that the petitioner claims to have suffered." Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1365

(quoting Althen, 418 F.3d at 1278)); see also Dillon v. Sec'y of Health & Human Servs., 114 Fed. Cl. 236, 244 (2014) ("[I]n the event that the special master determines that the petitioner cannot demonstrate that he or she actually suffers from the injury alleged, compensation may be denied without reaching an *Althen* analysis." (citing Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1353)). The Special Master stated specifically, "'[i]n the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached.'" Lasnetski v. Sec'y Health & Human Servs., slip op. at 6 (quoting Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1353). Because, as noted above, the Special Master properly found that Petitioner had failed to sufficiently identify an "injury" to support her claims, the Special Master's decision to forego the application of Althen to Petitioner's case was not in error. See Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1356 (affirming Special Master's decision to deny compensation to an off-Table petitioner without performing Althen analysis when the Special Master determined that petitioner "had failed to prove by a preponderance of evidence that she suffered from any of the three claimed medical conditions" was not arbitrary, capricious, an abuse of discretion or contrary to law); see also Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346 (holding that, when the "injury itself" was in dispute, "it was appropriate . . . for the special master to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test").

CONCLUSION

Petitioner has failed to persuade this court that the Special Master's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Accordingly, the Special Master's decision that Petitioner is not entitled to compensation under the Vaccine Act is **AFFIRMED**. The clerk's office shall enter **JUDGMENT** consistent with this opinion.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge