In the United States Court of Federal Claims

No. 19-559V
Filed: May 17, 2021
Reissued for Publication: June 15, 2021[1]

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MIKAYLA WHITFIELD,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Mikayla Whitfield, pro se, Atlanta, GA.

Sarah C. Duncan, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for respondent. With her was **Linda S. Renzi**, Senior Trial Counsel, Torts Branch Civil Division, **Catharine E. Reeves**, Deputy Director, Torts Branch, Civil Division, **C. Salvatore D'Alessio**, Acting Director, Torts Branch, Civil Division, and **Brian Boynton,** Acting Assistant Attorney General, Civil Division.

O P I N I O N

HORN, J.

On April 15, 2019, petitioner filed her original petition in this court, requesting compensation through the National Vaccine Injury Compensation Program, under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 to 300aa-34 (2018) (Vaccine Act), "for injurys including multiple skin problems including reoccurring skin Abscess and a rare skin cancer cell, sever persistent headache, and unidentified

[1] This Opinion was issued under seal on May 17, 2021. The parties did not propose any redactions to the May 17, 2021 Opinion, and the court, therefore, issues the Opinion without redactions for public distribution.

Fallopian Tube reoccurring mass/tumors,"[2] which injuries petitioner alleged were the result of a meningococcal vaccine she received on April 29, 2016. Petitioner subsequently filed an amended petition in which she rephrased her injuries as including "severe headaches that keep reocurring, multiple skin problems including skin Abscesses, and skin lesions, and unrecognized, unknown, and unidentified fallopian tube inflammation, that I believe with certain is caused by a likely recalled vaccine I received on March 16, 2017," and that "the vaccine I received April 29, 2016 caused my headaches and skin problems." As discussed below, petitioner submitted various medical records spanning from 2016 to 2019, as well as some in 2013 which pre-date her meningococcal vaccinations, to document medical visits in which she complained of ailments including headaches, blurred vision, low energy, sleeping trouble, eating issues, abdominal pain, and various skin irritations such as rash outbreaks and lesions over several parts of her body. The medical records submitted by petitioner also consisted of medical diagnoses and findings including ovarian cysts leading to the removal of petitioner's left fallopian tube, high cholesterol, vitamin D deficiency, chlamydia, eczema, and tinea versicolor.

On February 12, 2021 Special Master Moran issued a decision denying petitioner's claims, stating that petitioner "has not presented persuasive evidence to establish that the meningococcal vaccine was the cause-in-fact of any of her conditions contained in the medical records." Whitfield v. Sec'y of Health & Human Servs., No. 19-559V, 2021 WL 915908, at *3 (Spec. Mstr. Fed. Cl. Feb. 12, 2021). Special Master Moran also determined that petitioner's attempts at filing expert reports in this case, which consisted of two photographs of short letters received by petitioner from two doctors she had seen regarding her ailments in the case, "did not meaningfully advance petitioner's case primarily because they did not provide evidence to support that the meningococcal vaccine caused Ms. Whitfield's alleged injuries." Id. at *2. On March 11, 2021, petitioner filed a motion for review, which was assigned to the undersigned.

FINDINGS OF FACT

Petitioner's immunization records before the court indicated that petitioner first received two meningococcal vaccines on April 29, 2016, at age fifteen, and that the two meningococcal vaccines were administered that date were: (1) "MEN-ACYW (MENVEO) (meningococcal oligosaccharide ACYW-135)," and (2) "MENcn-ACYW (MENACTRA) (Meningococcal conjugate groups ACYW-135)." (capitalization in original). Petitioner also received another MENVEO meningococcal vaccine again on March 16, 2017, at age sixteen. Petitioner stated that prior to the administration of the vaccines on April 29, 2016, she "was of high energy in good health actively playing sports at Benjamin E. Mays High School" in Atlanta, GA, and "was not suffing from any medical condition." As discussed below, petitioner's medical records were not all submitted by petitioner at the time she filed her original petition. A number of the medical records were submitted by petitioner following Orders by Special Master Moran for respondent to report on "the sufficiency of

[2] When quoting from documents filed by petitioner, the undersigned has left petitioner's capitalization, choice of words, spelling choices, grammatical choices, and fragments of sentences unchanged from the quoted original document.

the medical records in this case," and for petitioner to supplement the record before the court with medical records identified missing by respondent. As part of one of petitioner's supplemental filings before the court, the medical records included a November 17, 2013 visit to the Atlanta Medical Center South Campus Emergency Department, more than two years prior to the first two meningococcal vaccines administered to petitioner, in which petitioner, at age thirteen, complained of nausea, vomiting, diarrhea, and abdominal pain "of the suprapubic area and left lower quadrant" which "radiat[ed] to [the] pelvis." In affidavits submitted to the court, petitioner "attest[ed] to having pre-dated Eczema which was referred to as Atopic Dermatitis," and that she "only had mild eczema that mainly showed up in the creases of my arms and wrists." Petitioner also attested that, prior to the meningococcal vaccines, she had asthma, and "experienced Headaches in my past, such as from hormonal changes, tension headaches, and stress related headaches caused by family life, grades and school."

On April 29, 2016, the day petitioner received her first two meningococcal vaccines, petitioner saw Dr. Loreen C. Doyle-Littles, petitioner's primary care physician at the time, at Kaiser Permanente (Kaiser) in Atlanta, GA, for a "well adolescent visit," and also for a refill of eczema medication. Dr. Doyle-Littles noted that petitioner had "hypopigmented plaques on chest c/w [consistent with] tinea versicolor," and "acanthosis nigricans on back of neck." In addition to receiving the two meningococcal vaccines on April 29, 2016, petitioner received prescriptions for tinea versicolor, acanthosis nigricans, atopic dermatitis, and allergic rhinitis. In a depression questionnaire completed during the April 29, 2016 visit, it was indicated that petitioner experienced "[t]robule falling or staying asleep, or sleeping too much," "[p]oor appetite, weight loss, or overeating," and "[f]eeling tired, or having little energy," several days per week. Dr. Doyle-Littles also noted that petitioner, who had a height of 5'5'', weighed 234 pounds, and had a body mass index in the 99th percentile at 39.02kg/m^2.

Petitioner's January 10, 2020 affidavit submitted with her amended petition stated that after receiving the first set of meningococcal vaccines on April 29, 2016, she "first started noticing" she was "developing headaches," and "[a]s time went on i noticed that my headaches were getting stronger and were lasting longer. sometimes lasting as long as 2 to 3 days at a time." She attested that she then "started noticing my skin was becoming very itchy and I couldn't stop itching all over my body, along with my headaches that was getting worse," and "[a]s time went on i started also noticing dark itchy patches of skin appearing on my chest in between my breasts, on my stomach and back, that was not there before."

On July 18, 2016, almost three months after the first two meningococcal vaccinations were administered on April 29, 2016, petitioner visited Kaiser complaining of eye swelling. A "Vision Screen" indicated 20/40 vision in petitioner's left eye, right eye, and both eyes. She was diagnosed with blurred vision.

Petitioner's original petition stated that on February 28, 2017, ten months after petitioner's first two meningococcal vaccinations, petitioner "visited my doctors office due to a burning and itching feeling from a Rash on my elbows, abdomen, and lower back."

The original petition further stated that she "tried applying cream but it made it burn worse. Also I had noticed unusual heavy cramping on my 1st and 2nd day of my period, that was not normal with my periods." The Progress Notes in the record before the court for petitioner's February 28, 2017 visit, written by Dr. Suleka Neelagaru, stated:

> Mikayla W Whitfield is a 16 year old old [sic] female who presents today brought by mother, with complaints of:
>
> 1. Eczema flare x 1 week, itching and burning. Inner elbows, abdomen, lower back. Tried using triamcinolone but burns. Using dove sensitive soap, unknown lotion, unknown detergent.
>
> 2. Has period 20 days ago, started again yesterday. Normally has 28 day cycle. LMP heavy cramping first and second day, unusual for patient. Menses usually last for 6 days, moderate flow.
>
> 3. Irregular patches of hypo and hyperpigmented macules on upper back and upper chest
>
> 4. Concerned that she may have yeast infection between breasts

Dr. Neelagaru also described these symptoms as "eczematous changes to antecubital fossae, abdomen, and lower back; hypo and hyperpigmented macules to upper chest and upper back; erythematous maculopapular rash between breasts." Under "[p]ertinent negatives," Dr. Neelagaru noted that petitioner had exhibited "no fever, sore throat, cough or abdominal pain." Under "Patient Active Problem List," the diagnoses of atopic dermatitis, allergic rhinitis and "BMI [Body-Mass Index] PEDS >= 95 PERCENTILE," were noted. (capitalization in original). It was also noted that a "[r]eview of patient's allergies indicates no known allergies," and that petitioner reported no history of smoking, or using smokeless tobacco, alcohol, or illicit drugs. Petitioner was diagnosed with atopic dermatitis, tinea versicolor, candida of skin, allergic rhinitis, dysmenorrhea, and irregular menstrual cycle.

On March 16, 2017, petitioner returned to Kaiser and saw her primary care physician, Dr. Doyle-Littles. Dr. Doyle-Littles diagnosed petitioner with acne, tinea versicolor on petitioner's abdomen, and "a large firm red tender abscess in pilonidal area," for which she referred petitioner to the emergency department for incision and drainage. The pilonidal abscess was drained at the Emergency Department of the Atlanta Medical Center South Campus the same day, March 16, 2017.

As discussed above, also on March 16, 2017, petitioner received a third meningococcal vaccine, MENVEO, which is the same as one of the meningococcal vaccines petitioner had received on April 29, 2016. On January 19, 2018, almost ten months after her meningococcal vaccine on March 16, 2017, petitioner returned to Kaiser and saw Dr. Jennifer Thomas. Under the heading, "**SUBJECTIVE**" (capitalization and

emphasis in original), Dr. Thomas' Progress Notes detailed petitioner's reported symptoms on January 19, 2018, stating:

> Mikayla Whitfield is a 17 year old female who presents today with headache(s) + multiple complaints.
>
> Eye burning, itching watery. Nasal congestion, RN. Worsens in the winter, but present in the spring with pollen as well. Has a dog at home. Allergy to cats. Not taking any meds for it.
>
> Headache:
> Onset of headache: 5-7 years ago, with onset of menstruation.
> Frequency of headaches: about QOD [quaque altera die, i.e., every other day]
> Average Duration: 3-4 hours
>
> Typical occurrence: Description of headache: throbbing pain, front and back of head
> Pain Scale: up to 10/10, last headache yesterday was a 6/10
> Associated Symptoms: none
> Associated Triggers: menstruation
> Relieved by: lying in a darkened room
> Frequency of analgesics: never
> Impact on child's life: Can Interfere with school
> Previous diagnostic imaging of head and/or neck: no
> History of head trauma: no
> Substance use: none
> Family Hx Headaches: no
>
> Skin: Scaly patches over abdominal area. Itch and burn. Has trialed dove and apple cider vinegar. Has been present for 1 month. Previously had a tinea versicolor on stomach and was given a Diflucan.
>
> Social History:
> Sexually active since NOvember [sic] 2017. Not using protection.
> LMP on 1/5/18, Last sexual activity on 1/1/18. This period shorter in duration and lighter than normal. No abml [abnormal] vaginal discharge, no dysuria, frequency or urgency.

(capitalization in original). Under the heading, "**ASSESSMENT**," Dr. Thomas noted: "Headache – unlikely to have organic CNS [central nervous system] lesions from H & P [health and physical], possible migraines." (capitalization and emphasis in original). Dr. Thomas diagnosed petitioner with a headache, tinea versicolor, and allergic conjunctivitis. Dr. Thomas also conducted a pregnancy test which came back negative, and collected blood and urine samples to test for sexually transmitted diseases (STDs), which came back positive for chlamydia, and for which petitioner was prescribed antibiotics on

January 26, 2018. On February 2, 2018, petitioner had a follow-up call with Dr. Thomas, in which petitioner reported that her "[h]eadache has been doing much better."

On February 8, 2018, petitioner returned to Kaiser and reported to Dr. Courtney Whittle with complaints of a "hyperpigmentation rash on her abdomen and back that has been present for some time," as well as a "'painful boil' lesion" on her left buttock. Petitioner again was diagnosed with tinea versicolor. Petitioner stated that on March 2, 2018, she returned to Kaiser "yet again," "with complaints of another skin problem (another) painful Abscess on my right butt check." (capitalization in original). Dr. Whittle collected a skin swab of the abscess and performed a culture. As described in respondent's Rule 4(c) report, the resulting pathology "demonstrated heavy growth of many different bacterial organisms."

On April 9, 2018, petitioner returned to Kaiser and again met with Dr. Whittle for a "well teen exam visit." Dr. Whittle's Progress Notes provided that petitioner reported at this visit that she "is working to lose weight but states that it keeps going up and down. She is playing softball for exercise but has not made significant changes to her diet. She also notes pruritis and peeling on the bilateral nipples." In a depression questionnaire, petitioner marked that she had been "feeling tired, or having little energy," for several days, and that she had experienced "poor appetite, weight loss, or overeating" on "**More Than Half the Days**." (capitalization and emphasis in original). Petitioner again was diagnosed with tinea versicolor, candida of skin, allergic rhinitis, and it was again noted that petitioner's BMI was in or above the ninety-fifth percentile. Petitioner also received a screening of "HEMOGLOBIN A1C," "LIPID PANEL," "TSH PROGRESSIVE," and "T4." (capitalization in original) As described in respondent's Rule 4(c) report, the bloodwork from the above screenings "revealed elevated cholesterol but normal hemoglobin A1C and normal thyroid studies." Also on April 9, 2018, petitioner was given another STD test for gonorrhoeae and chlamydia, both of which came back negative, having earlier been treated.

On August 27, 2018, petitioner reported to the Emergency Department of the WellStar Atlanta Medical Center with, according to respondent's Rule 4(c) report, complaints of abdominal pain.[3] Two days later, on August 29, 2018, petitioner reported to Dr. Tommie Haywood of Atlanta Gastroenterology Associates at the Atlanta Medical Center Office with chief complaints of abdominal pain, rectal bleeding and nausea. Dr. Haywood's notes from the August 29, 2018 visit inform that petitioner was referred by Dr.

[3] Petitioner does not discuss this August 27, 2018 visit in her original petition or in her amended petition, or any other of her filings before Special Master Moran, and the record before the court only contains lab work conducted this date. In respondent's Rule 4(c) report, respondent requested that "petitioner file complete records for this visit," however, petitioner did not do so. Special Master Moran also had requested on more than one occasion that petitioner comply with the record filing requests of respondent. Although petitioner filed some of the records that were requested, petitioner did not file all requested records.

Jackson Gates "for a gastroenterology evaluation for abdominal pain." Dr. Haywood's notes further stated:

> The patient has described the pain as mild to moderate and crampy occurring intermittently, and last minutes at a time. The pain has remained unchanged since it started. The location of the pain is in the RLQ [right lower quadrant] and has been present for the past 1 month. The pain is improved by no particular treatment and is aggravated by no particular treatment. The pain is not reproducible with palpitation over the area.
>
> Patient has no history of GERD, constipation, and heartburn.
>
> The patient admits to losing weight and feeling nauseated. She has lost 20 pounds in the last 3 months.
>
> The patient also complains of rectal bleeding. . . .
>
> The onset of the problem was 1 month ago. The stool is bright red. The blood was located in the toilet. Patient has had a few episodes episodes [sic] since the onset of symptoms.

Dr. Haywood also noted that he was "not sure of the etiology of the abdominal pain at this time. I feel a further work-up is warranted." Dr. Haywood recommended a colonoscopy, an esophagogastroduodenoscopy (upper gastrointestinal endoscopy) and a computerized tomography scan (CT scan) of petitioner's abdomen and pelvis. As discussed below, on November 19, 2018, after the endoscopy had been conducted, Dr. Haywood gave a postoperative diagnosis of mild nonerosive gastritis of the antrum.

According to the original petition filed with the Office of Special Masters of the United States Court of Federal Claims, on October 5, 2018, petitioner

> made a follow up visit to my PCP after recently visiting the ER for symptoms of vomiting, headache, Rectal Bleeding, abdominal pain, loss of Appetite and fatigue/weakness. The ER suggested that I have a colonoscopy however Dr Courtney N. Whittle M.D told me she didn't think I needed one. I also expressed very painful persistent headaches. She recommended that I take over the counter Tylenol for my pain, and nothing was prescribed to me for headache. I also was complaining of my vision being blurry at times with my headaches.

(capitalization in original). In the Progress Notes of Dr. Whittle on petitioner for October 5, 2018, Dr. Whittle noted:

> Mikayla W Whitfield is a [sic] 18 year old old [sic] female who presents today brought by self, with complaints of: follow up after ER visit. Patient was seen

> for a couple days of rectal bleeding without diarrhea. There was no bleeding on rectal exam, fissures or hemorrhoids. Stool guaiac was negative. CBC and labs were all within normal range. Patient notes that there has been no bleeding in the last week. Patient also note [sic] intermittent headache that resolves with tylenol. HA [headache] is not associated with emesis, blurry vision and pain does not wake her from sleep[.]

On October 11, 2018, petitioner returned to the emergency room at WellStar Atlanta Medical Center with abdominal pain. The medical notes of Dr. Jimson Smith stated:

> Paitent [sic] complains of abdominal pain for the past two days. Paitnet [sic] had an episode of hematochezia and states she vomited last night and noted blood in vomit which currently is not present. Patient has missed GI appointments with her gastroenterologist. Patient has had blood in stool for the past month. Patient denies fever. . . .
>
> The primary symptoms of the illness include abdominal pain and vomiting. The primary symptoms of the illness do not include fever or dysuria. The current episode started more than 1 week ago. The incident occurred at home. The problem has not changed since onset. The abdominal pain began more than 1 week ago. The abdominal pain is generalized. The abdominal pain does not radiate. The severity of the abdominal pain is 4/10. The vomiting began yesterday. Vomiting occurred once. The patient states that she believes she is currently not pregnant. Symptoms associated with the illness do not include chills.

Dr. Smith also noted upon examination that there was tenderness in the lower left quadrant of petitioner's abdomen, and that a "[r]ectal exam shows guaiac negative stool **(brown stool)**." (emphasis in original).

Also on the same day, October 11, 2018, A CT scan was performed on petitioner's abdomen and pelvis. The notes of Dr. Robert Price stated that the CT scan discovered

> a large cystic mass in the midline of the pelvis measuring 8 cm in height by 6.2 cm in depth by 10 cm in width. It has a very thin wall and has attenuation of fluid. Its [sic] consistent with a cyst likely arising from one of the other ovary, but its [sic] inseparable from both ovaries the and the [sic] uterus abutting them all.

Dr. Price's opinion was that there was a "[l]arge pelvic cyst or cystadenoma," and that an "[u]ltrasound of the pelvis might prove helpful in further evaluation."

Also on October 11, 2018, an ultrasound was performed on petitioner's pelvis, which included transabdominal and transvaginal examinations. The notes of Dr. Richard Stiles indicated that the ultrasound found: "Immediately superior and anterior to the uterus

there is a large simple cystic structure measuring 8.5 cm transversely by 8.1 cm superior to inferior by 5.6 cm anterior posterior. This is likely related to the left ovary. No ovarian tissue is identified." Dr. Stiles also noted:

> 1. Large, 8.5 cm, simple cystic structure in the central pelvis projecting anterior and superior to the uterus and superior to the bladder. Given the absence of visualization of left ovarian parenchyma, I suspect this is related to the left ovary.
>
> Differential diagnosis includes very large follicular cyst, and cystadenoma. I would recommend consideration for a follow-up ultrasound exam in 2-4 weeks at another point in the patient's menstrual cycle for further characterization and to determine if this is a hormonally responsive cyst or not.
> 2. Otherwise normal exam.

Petitioner's medical records before the court indicated that she visited OB/GYN Dr. Simmons of Prestige Healthcare OB/GYN on December 12, 2018, who recorded that petitioner had an ovarian cyst, dysuria and vaginal discharge. Dr. Simmons' records also indicated that petitioner had an active case of asthma, with an onset date of December 12, 2018, the date of the visit. Petitioner's lab work ordered by Dr. Simmons and conducted by GenPath Women's Health returned without abnormalities. On December 17, 2018, another CT scan was performed by Dr. Stiles of petitioner's abdomen and pelvis, which "[a]gain identified . . . a central fluid attenuation cystic mass immediately superior to the bladder and anterior to the uterine fundus. . . .This has not changed significantly in size or appearance." Dr. Stiles also noted that the "[d]ifferential diagnosis includes ovarian cystadenoma or possibly a urachal cyst," and that there were "[n]o other significant abnormalities." On December 26, 2018, petitioner returned to Dr. Simmons' office for a follow-up appointment, during which an "exploratory laparotomy" and an ovarian cystectomy were discussed with petitioner.

On January 4, 2019, petitioner returned to Dr. Simmons' office, during which Dr. Simmons performed a gynecologic examination and depression screening, and noted vaginal discharge. On January 17, 2019, petitioner again presented to Dr. Simmons for an annual examination, during which Dr. Simmons noted petitioner's high cholesterol (hypercholesterolemia), and a vitamin D deficiency. On February 12, 2019, petitioner underwent a "[m]ini laparotomy via pfannenstiel incision, partial right salpingectomy and removal of right tuboovarian cyst, drainage of left tuboovarian cyst," conducted by Dr. Simmons. The discharge summary notes from the procedure stated:

> 18yo presented with a pelvic mass on US [ultrasound], concerning for left ovarian cyst. On 2/12/19 she underwent a mini laparotomy via pfannenstiel incision, partial right salpingectomy and removal of tuboovarian mass, and drainage of left tuboovarian mass on 2/12. Intraoperative findings concerning for bilateral TOAs [tubo-ovarian abscess] versus hydrosalpinxes. Patient reported hx [history] of CT+ [chlamydia], but

> negative at preop visit; given this she likely has hx of PID [pelvic inflammatory disease] which would be consistent with intraop exam findings.

(capitalization in original).

On February 25, 2019, petitioner again returned to Dr. Simmons' office, complaining of "abdominal pain as well as vaginal odor." Dr. Simmons conducted a physical examination, and noted an "**abnormal vaginal discharge**." Dr. Simmons also diagnosed petitioner with dysmenorrhea, or painful menstrual cramps.

The next day, February 26, 2019, petitioner presented to the emergency room at WellStar Atlanta Medical Center. A rapid chlamydia test was conducted, which came back negative. Transabdominal and transvaginal ultrasounds were also conducted due to "RLQ pain," and it was noted that there was "[n]o sonographic abnormality identified." A urinalysis was also conducted this day, which, as described in respondent's Rule 4(c) report, "showed trace bacteria and many squamous epithelial cells."[4]

The next day, February 27, 2019, petitioner stated that she "was established as a new patient of Dr Alan K. Cu Chiam and blood work and labs were done." The medical records in the record before the court indicated that an HIV test was completed at Quest Diagnostics on this day, which came back negative, as well as a test of petitioner's cholesterol levels, which indicated several high, out of range results consistent with previous cholesterol tests performed for petitioner as discussed above.[5]

Petitioner stated in her original petition that on March 5, 2019, she presented to

> Emory Health Care of Midtown ER department for yet again (another) painful Abscess on my left lower buttock on my thigh, first on since my surgery on (Feb 12, 2019). I was given anastasia to numb the area so they could cut open the Abscess and culture the wound. . . . I was bandaged up and discharged and cultures done were sent to the lab for testing. A follow

[4] Although respondent requested and Special Master Moran ordered petitioner to file complete medical records in connection with petitioner's February 26, 2019 visit, the only medical records produced by petitioner for the February 26, 2019 visit were of the test results conducted.

[5] Respondent requested petitioner to file complete records related to the "elevated cholesterol profile ordered by a clinic." The medical records from the Quest Diagnostics lab results indicate that Dr. Cu Chiam worked at "GA CLINIC WEST END." (capitalization in original). Petitioner did not supplement the records in response to this request, and no records outside of the Quest Diagnostic lab results are included in the record before the court.

> up call from a RN in the ER department at Emory Health care called me with the anticipated Lab results done in the ER.

(capitalization in original). Petitioner stated that she had a follow up call from a nurse in the emergency room who reported to petitioner "that I had a rare form of skin cancer." As explained in respondent's Rule 4(c) report, "[l]ab results from March 5-6, 2019, indicate that petitioner had a leg abscess cultured with results indicating proteus mirabilis positive and staphylococcus coagulase negative. The gram stain had some white blood cells, gram positive cocci, and 'rare squamous epithelial cells.'"[6] (footnote and internal references omitted).

Petitioner's original petition stated that on March 10, 2019, she reported to "South Fulton Medical Center ER for feeling weak, tired, and shortness of breath along with a sever persistent headache." An "AFTER VISIT SUMMARY" for the March 10, 2019 visit to WellStar Atlanta Medical Center Emergency Room is included in the record before the court,[7] which indicated that petitioner was diagnosed with an "[a]cute non intractable tension-type headache," and a "[v]iral syndrome." (capitalization in original).

As explained in respondent's Rule 4(c) report, on March 31, 2019, at the Atlanta Medical Center Emergency Room,

> petitioner presented to the ER with continued right lower quadrant pain, which she rated at 8/10. An exam was normal except for costovertebral angle tenderness. A CBC, metabolic panel, pregnancy test, and urinalysis were negative or normal, except for a few squamous epithelial cells in the urine. An abdominal/pelvic CT showed bilateral ovarian complex cysts without free fluid. A pelvic ultrasound showed bilateral complex ovarian cysts with the appearance of hemorrhagic cysts with serous particulate levels. The obstetrician on call contacted Dr. Simmons, who offered to schedule an appointment, but petitioner and her mother refused because they were unhappy with his care. Petitioner was referred to another OB/GYN, Dr. Jewel Grant, for an appointment on April 10, 2019.

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[6] Respondent also requested petitioner to complete the records for her March 5-6, 2019 visit, as petitioner had only produced the lab results discussed in this paragraph, and no visit notes. Petitioner did not file additional records or information associated with her March 5-6, 2019 visit, or regarding the call she allegedly received from the nurse in the emergency room. Also, although "rare squamous epithelial cells" were found, it is not apparent from the medical records before the court that petitioner was diagnosed with a form of cancer.

[7] Petitioner again was asked by respondent and ordered to provide additional visit notes for her March 10, 2019 visit, as the record only included an after-visit summary. Petitioner did not do so.

> On April 16 2019, petitioner underwent a pelvic MRI, ordered by Dr. Grant, which did not show the two previous cysts, but revealed a 1.5 cm follicle in the left ovary and a complex cystic focus around the left ovary that was felt to be a hydrosalpinx or hemorrhagic cyst.
>
> On April 22, 2019, petitioner presented to the ER for drainage of an abscess and recurrent skin infection, and received antibiotics.

(footnote and internal references omitted).[8]

On May 22, 2019, petitioner underwent surgery at Northside Hospital, which was conducted by Dr. Clement Hsiao, at which time petitioner's left fallopian tube was removed. As explained in respondent's Rule 4(c) report:

> Dr. Clement Hsiao removed petitioner's left fallopian tube. Surgical findings included a nonfunctioning left hydrosalpinx, right ovarian simple cyst, and adhesion of uterine round ligament and tube to bowel in the left lower quadrant. Dr. Hsiao took fluid specimens to help identify the cause of the hydrosalpinges. [sic] A post-operative appointment was scheduled for June 12, 2019 with Dr. Hsiao.

(footnote and internal references omitted).[9] A surgical pathology report issued by Dr. H Jewel Chang, dated May 22, 2019, the same day as petitioner's surgery, indicated that the "**Final Pathologic Diagnosis**" of the "**LEFT FALLOPIAN TUBE (SALPINGECTOMY)**" was of "BENIGN SEROUS CYSTADENOMY OF OVARY" and a "PARATUBAL CYST." (capitalization and emphasis in original). The May 22, 2019 pathology report also stated that there was "[n]o malignancy identified."

The procedural history of petitioner's case following the filing of her original petition on April 15, 2019, initially pro se, and her motion to proceed in forma pauperis on the same day, follows. On April 17, 2019, the case was assigned to Special Master Moran.

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[8] Respondent's Rule 4(c) report stated "Respondent requests that petitioner file records from Dr. Grant. Petitioner has filed a record indicating that Dr. Grant saw her on April 8, 2019, and referred her for a pelvic MRI, but has not filed visit notes from Dr. Grant." Respondent's Rule 4(c) report also stated that petitioner failed to file "ER records" for the visit on April 22, 2019. Similar to respondent's other requests discussed above, petitioner did not file the additional requested records.

[9] Respondent's Rule 4(c) report stated that "[p]etitioner appears to have seen Dr. Hsiao for a preoperative visit on or about May 15, 2019, but has not filed the corresponding visit note. Respondent requests that petitioner file complete records for Dr. Hsiao" Respondent's Rule 4(c) report also requested that "petitioner file updated records since June 2019, including those corresponding to this appointment" on June 12, 2019 with Dr. Hsiao. Neither request was fulfilled by petitioner.

On May 6, 2019, a notice of appearance was filed by Kyle Moore, and on May 10, 2020, petitioner moved to substitute Mr. Moore as her attorney. The motion was granted on May 13, 2019.[10] On May 30, 2019, Special Master Moran held an initial status conference. In a May 31, 2019 Order documenting the initial status conference held the day before, Special Master Moran indicated "a concern about when some of Ms. Whitfield's symptoms started in relation to her vaccinations." Special Master Moran further stated in the May 31, 2019 Order:

> The record indicates that some of Ms. Whitfield's injuries may have, to some extent, predated her vaccinations. The record also indicates that some of Ms. Whitfield's claimed injuries may have started long after the vaccinations in question. Whether an appropriate temporal proximity exists between the vaccinations and petitioner's claimed injuries is unclear. Petitioner stated that she would file affidavits that would clarify some of these issues. In addition, the undersigned suggested that petitioner submit contemporaneously created records that may substantiate some of her claims regarding onset, such as social media posts.

According to the May 31, 2019 Order issued by the Special Master, at the May 30, 2019 status conference, respondent's counsel had represented that, after an "initial review of the medical records already submitted by Ms. Whitfield" along with her original petition, "[s]ome missing records were identified and shared with petitioner, including documentation of the April 26, 2016 vaccination, records associated with her visit on the date of vaccination, medical records from three years prior to the vaccination, and medical records from all visits to Dr. Simmons." Following the May 30, 2019 status conference, Special Master Moran ordered petitioner to file an amended petition, affidavits and exhibits with consecutive pagination, as well as any outstanding medical records.

On July 22, 2019, petitioner's attorney Mr. Moore first moved to withdraw himself as petitioner's representative. No basis for withdrawal was provided in Mr. Moore's July 22, 2019 motion. On July 30, 2019, Special Master Moran issued an Order denying Mr. Moore's July 22, 2019 request to withdraw, and stated that "[b]efore the undersigned grants petitioner's Motion to Withdraw as Attorney, Mr. Moore shall file an affidavit, signed by his client, attesting to the following:" (1) "Petitioner is aware of all materials that have been filed on the record and is current on the procedural posture of the case;" (2) "Petitioner has reviewed and understands any and all outstanding orders, particularly those relevant to the current posture of the case;" (3) "Petitioner is aware of any and all current deadlines;" and (4) "Petitioner is further aware that until new counsel makes an appearance, she will be proceeding *pro se* and is responsible for meeting any current or future deadlines set in this case." (emphasis in original). After filing a second and a third

[10] As discussed below, on July 22, 2019, Mr. Moore first moved to withdraw himself as petitioner's attorney, and, after denial of his initial July 22, 2019 motion, and the filing of a second and a third motion to withdraw, Special Master Moran granted Mr. Moore's request on September 20, 2019.

motion to withdraw, Special Master Moran granted Mr. Moore's request to withdraw on September 20, 2019.

On September 20, 2019, petitioner filed an amended petition along with an affidavit and some additional medical records. As stated above, in petitioner's amended petition, petitioner rephrased some of her claims as they were stated in her original petition, but the amended petition and accompanying affidavit also supplemented her original petition, adding to the exhibit list and providing, in her own words, descriptions of the new medical records submitted with the amended petition.

On November 6, 2019, Special Master Moran ordered respondent to "file a status report indicating the sufficiency of the medical records submitted by **Friday, December 20, 2019**." (emphasis in original). On December 20, 2019, respondent filed a response to Special Master Moran's November 6, 2019 Order, in which respondent requested petitioner to file four sets of medical records which respondent indicated were missing from petitioner's submissions up to that date: (1) "[m]edical records for three years prior to vaccination dating back to April 29, 2013, including any primary care, OB-GYN, dermatology, and neurology records;" (2) "[m]edical records for the April 29, 2016 visit during which petitioner received the meningococcal vaccine;" (3) "[m]edical records between April 29, 2016, and February 28, 2017;" and (4) "[m]edical records regarding appointments with Dr. Simmons prior to February 12, 2019." In a January 8, 2020 Order, Special Master Moran ordered petitioner to comply with respondent's request to file outstanding medical records. On January 16, 2020, petitioner responded by submitting additional medical records and an accompanying affidavit, responding to some, but not all, of respondent's requests.

On January 22, 2020, Special Master Moran ordered respondent to file another status report regarding the completeness of the record after petitioner's January 16, 2020 submissions. Respondent's February 21, 2020 status report stated that "while no critical records remain outstanding, respondent still requests that petitioner file . . . [m]edical records regarding appointments with Dr. Simmons prior to February 12, 2019." In a February 24, 2020 Order, Special Master Moran ordered petitioner to comply with respondent's filing request, to which petitioner responded with a filing on February 27, 2020. On the same date, February 24, 2020, Special Master Moran ordered respondent to file its Rule 4(c) report, which respondent did on April 20, 2020.

On May 7, 2020, Special Master Moran held a status conference and issued an Order stating that at the status conference, he "suggested to petitioner that she move forward in the case by obtaining an expert report from either a treating doctor or another expert willing to provide an opinion on her case." On June 25, 2020, petitioner requested an extension to file an expert report, stating:

> I currently have asked three medical experts for an expert medical opinion on my case. The current, and third medical expert I have asked is currently looking over my medical records in order to determine whether or not they are willing to provide a medical opinion on my case.

Petitioner's extension was granted on June 25, 2020. On July 14, 2020, petitioner filed an affidavit detailing her continuing search for a medical expert to provide a report, stating that the first doctor she asked, Dr. Clement Hsiao, who performed the May 22, 2019 surgery during which petitioner's left fallopian tube was removed, "turned me down." Petitioner's July 14, 2020 affidavit further stated that she next "went to doctor Jewel T. Grant Md and her medical staff, for help with a medical Expert opinion," and that "[a]fter a week of her medical office reviewing the case summary of medical facts . . . Dr. Jewel T Grant Md, denied my request for her medical Expert opinion on this matter, without an explanation or reason why." Petitioner's July 14, 2020 affidavit further stated that "[t]hen my mother Elizabeth Alvarez thought to go to Dr Precious L. Braswell MD the doctor that I was first referred to" to look at her ovarian cyst. According to petitioner, Dr. Braswell "informed my mother and I right away, upon request that it would be a conflict of interest for her to provide an opinion on this matter since she works so closely at times, with medical Expert physician, Dr Lorenza Simmons MD." The July 14, 2020 affidavit further stated that Dr. Braswell "told us she might have someone else that may be able to provide an Expert opinion," and referred petitioner and her mother to an individual named Dr. Brown, who ultimately determined that "he would not be willing to make a medical Opinion on this matter," and, furthermore, "that Dr Brown had said he didn't believe that I would find 'Any,' medical expert staff or physician, that would, be willing to provide me with an opinion in Support of the Facts of my medical Lab results." Petitioner, in her July 14, 2020 affidavit, stated that she took Dr. Browns statements as "[i]mplying or speaking on a possible unspoken Alliance between medical staff and Physicians for their fellow physicians."

On July 23, 2020, petitioner filed additional medical records, as well as another affidavit detailing her search for a medial expert's report, stating that she had

> continued my search for a Medical Expert Opinion / Diagnosis by asking a couple OB Oncologists Doctors for their medical diagnosis, based on my medical records and Lab results. I was told up front by one that she can only go off what the pathology report says. And the other never responded at all.

Petitioner's July 23, 2020 affidavit further stated that she "still asked another doctor, Dr Michelle Glasgow MD OB Oncologist, who is affiliated with Northside Hospital, for a medical diagnosis," and that after "much communication back and forth with her medical staff" and providing Dr. Glasgow with her medical records, petitioner "was extremely taken back and very disappointed to hear that after all that time of her knowing what I was requesting, ahead of time, that she had waited til the appointment her office had scheduled with me to tell me she couldn't give me her Opinion."

On July 24, 2020, Special Master Moran issued an Order discussing petitioner's efforts to secure an expert opinion. The July 24, 2020 Order stated:

> On June 25, 2020, the undersigned issued an order setting a deadline of August 24, 2020, for petitioner's expert report. On July 14, 2020, and July 23, 2020, petitioner filed affidavits detailing efforts she has made to attempt to retain an expert. However, she has so far been unsuccessful.
>
> The undersigned reminds petitioner that "[t]he special master may not make . . . a finding [in petitioner's favor] based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion." 42. U.S.C. § 300aa-13(a)(1). Thus, although petitioner may sincerely believe that she has suffered a vaccine-caused injury, petitioner's belief alone is not enough to find entitlement to compensation. The undersigned will extend petitioner's expert report deadline by 60 days to allow her to make further attempts at retaining an expert.

(alterations in original). Special Master Moran's July 24, 2020 Order provided petitioner until October 23, 2020 to file an expert report.

On September 21, 2020, petitioner filed another affidavit as well as offered two items she labeled, respectively, as: "EXPERT REPORT of Lorenza A. Simmons," and "EXPERT REPORT of Alan Cu Chiam." (capitalization in original). The first item, "EXPERT REPORT of Lorenza A. Simmons," was a photograph of a note written by Dr. Simmons on August 26, 2020, which stated:

> The patient [sic] mother called regarding the follow up pathology after her daughter's surgery. The patient was found to have a large 10 cm right paratubal cyst intra-operatively. The tube and cyst was removed as one specimen. The patient preoperative diagnosis was hydrosalpix [sic] due to possible PID. The patient pathological findings is [sic] consistent with a paratubal cyst of unknown origin and does not appear to be infected at the time of surgery. The information was explained to the patient and her mother again and their questions were answered.

The second item, the "EXPERT REPORT of Alan Cu Chiam," was a photograph of a note written by Dr. Chiam on September 18, 2020, which stated:

> On 3/28/2019, Mikayla presented with hyperpigmentation on the right side of her abdomen. In my opinion, this is unlikely to be fungal in etiology.
>
> This is being written upon the request of Elizabeth Alvarez, mother of Mikayla Whitfield.

In the affidavit filed by petitioner on the same day as the two above Doctors' submissions, September 21, 2020, petitioner detailed her requests to Doctors Simmons and Chiam to provide expert reports, and made additional allegations with respect to the causes of the various ailments she indicated had appeared throughout her medical records and which she had described in her amended petition and various affidavits.

On November 2, 2020, Special Master Moran issued an Order for petitioner to show cause, which stated, in part:

> Though Ms. Whitfield submitted what she deems expert reports as ordered, the documents she filed do not meaningfully advance her case. At best, the reports describe that Ms. Whitfield is suffering from some condition. However, neither Dr. Simmons nor Dr. Chiam linking [sic] her injuries to her vaccination. Thus, these reports do not carry Ms. Whitfield's burden. Though Ms. Whitfield's medical records and September 21, 2020 submissions may support a diagnosis of one or more [sic] the injuries she alleges, they do not provide any support linking her injuries to her vaccination. Therefore, with respect to causation, the only evidence provided in the record as it currently stands are Ms. Whitfield's unsupported assertions. But, a special master may not rule in a petitioner's favor based on petitioner's contentions alone, without additional support from medical records and/or expert opinion. 42 U.S.C. § 300aa-13(a)(1); Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1349 (Fed. Cir. 1999).
>
> When a petitioner (or plaintiff) fails to comply with Court orders to prosecute their cases, the Court may dismiss their case. Padmanabhan v. Sec'y of Health & Human Servs., 638 Fed. App'x 1013 (Fed. Cir. 2016); Sapharas v. Sec'y of Health & Human Servs., 35 Fed. Cl. 503 (1996); Tsekouras v. Sec'y of Health & Human Servs., 26 Cl. Ct. 439 (1992), aff'd, 991 F.2d 819 (Fed. Cir. 1993) (table); Vaccine Rule 21(c); see also Claude E. Atkins Enters., Inc. v. United States, 889 F.2d 1180, 1183 (Fed. Cir. 1990) (affirming dismissal of case for failure to prosecute for counsel's failure to submit pre-trial memorandum); Adkins v. United States, 816 F.2d 1580, 1583 (Fed. Cir. 1987) (affirming dismissal of case for failure of party to respond to discovery requests).
>
> Accordingly Ms. Whitfield is ORDERED TO SHOW CAUSE why her case should not be dismissed by **Friday, December 4, 2020**.

(capitalization and emphasis in original).

On November 5, 2020, petitioner filed a response to Special Master Moran's November 2, 2020 Order for petitioner to show cause, in which she provided, in her own words, the various theories which petitioner believed point to the meningococcal vaccines as the cause of the various injuries alleged in her petition, amended petition, and various affidavits submitted to the court. In her November 5, 2020 submission, petitioner offered what she referred to as a "strategic process of eliminating and exhausting all other possibilities that my injuries could have come from somewhere else" other than the vaccines, including her age, genetic makeup, or a sexually transmitted disease, as well as other theories, but she never produced any expert report in support of her petition.

On February 12, 2021, Special Master Moran issued a decision, titled: "**UNPUBLISHED DECISION DENYING COMPENSATION**,"[11] denying compensation for petitioner's claims. Whitfield v. Sec'y of Health & Human Servs., 2021 WL 915908, at *1 (capitalization and emphasis in original). The Special Master pointed out:

> A special master may not find entitlement based on a petitioner's claim alone, without medical or expert opinion evidence supporting causation. 42 U.S.C. § 300aa-13(a) (preventing special masters from awarding compensation "based on the claims of petitioner alone, unsubstantiated by medical records or medical opinion"); Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1349 (Fed. Cir. 1999); Carter v. Sec'y of Health & Human Servs., No. 04-1500V, 2007 WL 415185, at *21 (Fed. Cl. Spec. Mstr. Jan. 19, 2007).

Whitfield v. Sec'y of Health & Human Servs., 2021 WL 915908, at *2. The Special Master wrote further:

> Here, while Ms. Whitfield has provided medical records that may prove diagnoses for her conditions, she has not presented any evidence linking her conditions to the vaccination, other than her individual assessment. In her response to the order to show cause, which specifically highlighted the lack of proof of causation in her submissions that she deemed "expert reports," Ms. Whitfield reiterated her position that, through a "process of elimination" of other potential causes for her conditions, she has come to the conclusion that her conditions were caused by the meningococcal vaccine. She also points to her submissions from Dr. Simmons and Dr. Chiam as expert opinion evidence supporting causation. However, as stated in the order to show cause, these submissions appear to be confirmations of Ms. Whitfield's conditions for which these doctors were treating her. They did not provide any opinion as to a causal link between

[11] Special Master Moran explained in a footnote in his February 12, 2021 decision:

> Because this decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). This means the decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material before posting the decision.

Whitfield v. Sec'y of Health & Human Servs., 2021 WL 915908, at *1 n.1.

> the vaccination and these conditions. The attachments to petitioner's response also fail to shed any light on the question of causation.
>
> Because, Ms. Whitfield has not presented any evidence of a causal connection between her vaccination and alleged injuries, other than her bare assertions and personal conclusions drawn from the medical records, the undersigned finds that petitioner has not met her burden.

Id. at *3 (internal references omitted). Special Master Moran concluded that "Ms. Whitfield has not presented persuasive evidence to establish that the meningococcal vaccine was the cause-in-fact of any of her conditions contained in the medical records. Therefore, the undersigned finds that Ms. Whitfield has not met her burden to show entitlement to compensation." Id.

On March 10, 2021, Special Master Moran issued a public version of his February 12, 2021 decision denying petitioner's claims. The next day, March 11, 2021, petitioner submitted a motion for review, which was randomly assigned to the undersigned on the same day. On April 12, 2021, respondent filed a response to petitioner's motion for review.

DISCUSSION

As discussed above, petitioner in this case brings her claim under the Vaccine Act, 42 U.S.C. § 300aa-1 to 300aa-34. In her various submissions before Special Master Moran, petitioner provided various medical records spanning from 2016 to 2019, which document a litany of complaints, ailments, symptoms and diagnoses, including headaches, blurred vision, low energy, sleeping trouble, eating issues, abdominal pain, various skin irritations such as rash outbreaks and lesions over several parts of her body, tinea versicolor, ovarian cysts leading to the removal of one of petitioner's fallopian tubes, high cholesterol, vitamin D deficiency, chlamydia, eczema and asthma. In her various submissions to the court, petitioner has attempted to explain, in her own words, how these ailments were the result of, or exacerbated by, the meningococcal vaccines she received.

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) (2018). 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 Markovich v. Secretary of Health & 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 K.G. v. Sec'y of Health & Human Servs., 951 F.3d 1374, 1379 (Fed. Cir. 2020); Oliver v. Sec'y of Health & Human Servs., 900 F.3d 1357, 1360 (Fed. Cir. 2018) (citing Milik v. Sec'y of Health & Human Servs., 822 F.3d 1367, 1375-76 (Fed. Cir. 2016)); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1366 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2013) (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.'" (brackets in original) (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000))); W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1355 (Fed. Cir. 2013); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1350 (Fed. Cir. 2008); 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); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1277; Duncan v. Sec'y of Health & Human Servs., No. 16-1367V, 2021 WL 1748217, at 7 (Fed. Cl. May 4, 2021); Faup v. Sec'y of Health & Human Servs., 147 Fed. Cl. 445, 458 (2019); 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 Health & Human Servs., 970 F.2d 863, 870 (Fed. Cir. 1992); see also McIntosh v. Sec'y of Health & Human Servs., 139 Fed. Cl. 238, 246 (2018). 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 Health & Human Servs., 970 F.2d at 871 n.10; see also Carson ex rel. Carson v. Sec'y of Health & Human Servs., 727 F.3d 1365, 1369 (Fed. Cir. 2013); 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 1242, 1249 (Fed. Cir. 2011) (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") reh'g and reh'g en banc denied (Fed. Cir. 2012); Sanchez ex rel. Sanchez v. Sec'y of Health & Human Servs., No. 11-685V, 2021 WL 1083671, at 5 (Fed. Cl. Mar. 22, 2021); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56. "[T]he special masters have broad discretion to weigh evidence and make factual determinations." Dougherty v. Sec'y of Health & Human Servs., 141 Fed. Cl. 223, 229 (2018).

> 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 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 v. Sec'y 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 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 1366-67 (modification in original) (quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)); 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 United States Court of Appeals for the Federal Circuit has 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.'" Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 (modification in original) (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1363); see also K.G. v. Sec'y of Health & Human Servs., 951 F.3d at 1379 ("With respect to factual findings, however, we will uphold the special master's findings of fact unless they are clearly erroneous." (citing Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278)); 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 at 1338).

> The United States Court of Appeals for the Federal Circuit has explained that:
>
> > A petitioner can establish causation in one of two ways. Id. [Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1341] If the petitioner shows that he or she received a vaccination listed on the Vaccine Injury Table, 42 U.S.C. § 300aa–14, and suffered an injury listed on that table within a statutorily prescribed time period, then the Act presumes the vaccination caused the injury. Andreu[ex rel. Andreu] v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009). Where, as here, the injury is not on the Vaccine Injury Table, the petitioner may seek compensation by proving causation-in-fact.

Milik v. Sec'y of Health & Human Servs., 822 F.3d at 1379 (citing Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1374); see also 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); M.D. v. Sec'y of Health & Human Servs., No. 10-611V, 2021 WL 1625084, at 2 n.3 (Fed. Cl. Apr. 9, 2021) (citing Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1351–53); Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992); Faup v. Sec'y of Health & Human Servs., 147 Fed. Cl. at 458; Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 50; Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. 457, 467-68 (2012); Fesanco v. Sec'y of Health & Human Servs., 99 Fed. Cl. 28, 31 (2011).

For petitioner to establish a *prima facie* case in a vaccine case, 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 Sharpe v. Sec'y of Health & Human Servs., 964 F.3d 1072, 1085 (Fed. Cir. 2020); Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322, 1332 n.4 (Fed. Cir. 2011), cert. denied, 566 U.S. 956 (2012); Andreu ex rel. Andreu v. Sec'y 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."), aff'd, 746 F.3d 1344 (Fed. Cir. 2014). 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." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280 (citing Knudsen ex rel. Knudsen v. Sec'y 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 a petitioner of an off-Table injury under the Vaccine Act, such as those alleged by Ms. Whitfield, petitioner may not rely on his or her assertions 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." 42 U.S.C. § 300aa-13(a)(1). A petitioner who meets his or her burden is entitled to recovery under the Vaccine Act, unless the respondent proves by preponderant evidence that the injury was caused by factors unrelated to the vaccine. See Stone v. Sec'y of Health & Human Servs., 676 F.3d 1373, 1379-80 (Fed. Cir. 2012); Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007); see also Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. 672, 680 (2016) (citing 42 U.S.C. § 300aa-13(a)(1)(B); Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995)). "But, regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case." Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. at 680 (citing Stone v. Sec'y of Health & Human Servs., 676 F.3d at 1379; de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1353).

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. See Shyface v. Sec'y of Health & 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) (1965)); see also Oliver v. Sec'y of Health & Human Servs., 900 F.3d at

1361 (citing Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1321); 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 (citing 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 the United States Court of Federal Claims has explained the relationship between "but-for" causation and "substantial factor" in Deribeaux ex rel. Deribeaux v. Secretary of Health & Human Services:

> The de Bazan [v. Sec'y of Health & Human Servs., 539 F.3d at 1351] 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).

In order to recover under the Vaccine Act, a petitioner "must show, by a preponderance of the evidence, 'that the injury or death at issue was caused by a vaccine.'" Milik v. Sec'y of Health & Human Servs., 822 F.3d at 1379; (quoting Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1341 (citing 42 U.S.C. §§ 300aa–11(c)(1), –13(a)(1))); see also Oliver v. Sec'y of Health & Human Servs., 900 F.3d at 1360–61; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355-56 ("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))); Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351, 1355, 1359 (Fed. Cir. 2019); La Londe v. Sec'y of Health

& Human Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014); Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1350 (Fed. Cir. 2011) ("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."); Faup v. Sec'y of Health & Human Servs., 147 Fed. Cl. at 458; Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. 353, 358 (2012), aff'd, 503 F. App'x 952 (Fed. Cir. 2013); Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54 (2011). "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." W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 (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 v. Sec'y of Health & Human Servs., 940 F.2d at 1525.

While scientific certainty is not required, the Special Master "is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1324; see also Hazlehurst v. Sec'y of Health & Human Servs., 88 Fed. Cl. 473, 439 (2009), aff'd, 604 F.3d 1343 (Fed. Cir. 2010) (quoting Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1379). 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, 562 U.S. 223, 228-29 (2011) (footnotes omitted); see also Kennedy v. Sec'y of Health & Human Servs., 99 Fed. Cl. 535, 539 (2011), aff'd, 485 F. App'x 435 (Fed. Cir. 2012).

The Federal Circuit in Althen v. Secretary of Health & Human Services defined a three-prong test by which a petitioner can meet his or her burden 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 [v. Sec'y of Health & Human Servs.], 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[v. Sec'y of Health & Human Servs.], 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[v. Sec'y of Health & Human Servs.], 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 (first three sets of brackets in original); see also Boatmon v. Sec'y of Health & Human Servs., 941 F.3d at 1354-55; Oliver v. Sec'y of Health & Human Servs., 900 F.3d at 1361; 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); Miles v. Sec'y of Health & Human Servs., 142 Fed. Cl. 136, 145 (2018); Faup v. Sec'y of Health & Human Servs., 147 Fed. Cl. at 458; C.K. v. Sec'y of Health & Human Servs., 113 Fed. Cl. 757, 766 (2013).

With regard to the first Althen prong, "a medical theory causally connecting the vaccination and the injury," Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278, the Federal Circuit in Althen analyzed the preponderance of evidence requirement as allowing medical opinion as proof, even without scientific studies in medical literature that provide "objective confirmation" of medical plausibility. See id. at 1278, 1279-80; see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. at 358. In rejecting a requirement that a claimant under the Vaccine Act prove confirmation of medical plausibility from the medical community and medical literature, the Althen court turned to the analysis undertaken in Knudsen ex rel. Knudsen v. Secretary of Health & Human Services, 35 F.3d at 549. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80. In Knudsen ex rel. Knudsen v. Secretary of Health & Human Services, the United States Court of Appeals for the Federal Circuit wrote, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 549. The Federal Circuit in Knudsen stated further:

> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP [diphtheria-tetanus-pertussis vaccine] and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies.

> The special masters are not "diagnosing" vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury or that the [petitioner's] injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury. See 42 U.S.C. § 300aa-13(a)(1), (b)(1).

Id. (brackets added).

The Federal Circuit also has indicated that:

> Although a finding of causation "must be supported by a sound and reliable medical or scientific explanation," causation "can be found in vaccine cases . . . without detailed medical and scientific exposition on the biological mechanisms." Knudsen v. Sec'y of the Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of the evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be.

Simanski v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1384 (Fed. Cir. 2012) (omission in original).

Regarding the use of epidemiological evidence in a case in which causation is at issue, the United States Court of Appeals for the Federal Circuit has found that a Special Master may consider epidemiological evidence in determining causation. See Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1379 ("Although Althen[v. Secretary of Health & Human Services,] and Capizzano[v. Secretary of Health & Human Services] make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury." (brackets added)); see also Grant v. Sec'y of Health & Human Servs., 956 F.2d at 1149 ("These epidemiological studies are probative medical evidence relevant to causation."); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280.

The second prong of the Althen test requires the petitioner to demonstrate "a logical sequence of cause and effect, showing that the vaccination was the reason for the injury" by a preponderance of the evidence. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; see also Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355. In order to prevail, the 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." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). In Capizzano v. Secretary of Health & Human Services,

the Federal Circuit stated, "'[a] logical sequence of cause and effect' means what it sounds like – the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326 (quoting 42 U.S.C. §§ 300aa-11(c)(1)-13(a)(1) (2006)); see also Cozart v. Sec'y of Health & Human Servs., 126 Fed. Cl. 488, 498 (2016). The Federal Circuit has found that treating physicians' opinions can help satisfy the second prong of the Althen test:

> Such testimony is "quite probative" since "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." Id. [Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326] (citations and internal quotation marks omitted); see also Althen[v. Sec'y of Health & Human Servs.], 418 F.3d at 1279–80 (noting that the Vaccine Act provides for the use of "medical opinion as proof" of causation); Zatuchni v. Sec'y of Health & Human Servs., 69 Fed. Cl. 612, 623 (Fed. Cl. 2006) (relying heavily on the testimony of treating physicians in concluding that Vaccine Act causation had been established).

Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1375 (first set of brackets in original); see also Paluck v. Sec'y of Health & Human Servs., 786 F.3d at 1385 (finding "the special master erred in disregarding contemporaneous statements from K.P.'s [petitioners' minor child] treating physicians regarding the cause of his neurodegeneration" and "[a]s we explained in Andreu, 'treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.' [Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.,] 569 F.3d at 1375" (brackets added)).

The third prong of the Althen test requires the petitioner to demonstrate, by a preponderance of evidence, "a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278. The United States Court of Appeals for the Federal Circuit emphasized the importance of a temporal relationship in Pafford v. Secretary of Health & Human Services, when the court noted that "without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm." Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1358. Requiring evidence of strong temporal linkage is consistent with the third requirement articulated in Althen because "[e]vidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis." Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1358 (citing Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326). The Pafford court further explained,

> [i]f, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor. Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury.

Id. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1352. Determining what constitutes a medically appropriate timeframe, thus, is linked to the petitioner's theory of how the vaccine can cause petitioner's injury. See id.; see also K.T. v. Sec'y of Health & Human Servs., 132 Fed. Cl. 175, 186 (2017); Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542 (2011).

According to the Federal Circuit in Capizzano v. Secretary of Health & Human Services, evidence used to satisfy one of the Althen prongs may overlap with and be used to satisfy another prong. See Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326 ("We see no reason why evidence used to satisfy one of the Althen [v. Secretary of Health & Human Services, 418 F.3d at 1278] prongs cannot overlap to satisfy another prong." (brackets added)). If a petitioner satisfies the Althen test, the petitioner prevails, "unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 547 (brackets in original; quotation omitted).

The Special Master has discretion to determine the relative weight of evidence presented, including contemporaneous medical records and oral testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (finding that the Special Master had thoroughly considered evidence in the record and had discretion not to hold an additional evidentiary hearing); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1368 (finding it was not arbitrary or capricious for the Special Master to weigh diagnoses of different treating physicians against one another, including when their opinions conflict).

> "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 Health & Human Servs., 970 F.2d at 870 n.10); see also Rich v. Sec'y of Health & Human Servs., 129 Fed. Cl. 642, 655 (2016); Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. at 467 ("So long as those findings are 'based on evidence in the record that [is] not wholly implausible,' they will be accepted by the court." (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1363 (alteration in original))). "Determinations subject to review for abuse of discretion must be sustained unless 'manifestly erroneous.'" Heddens v. Sec'y of Health & Human Servs., 143 Fed. Cl. 193 (2019) (quoting Piscopo v. Sec'y of Health & Human Servs., 66 Fed. Cl. 49, 53 (2005) (citations 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) (brackets added); see also Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. at 467 ("[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 1349, 1355 (Fed. Cir. 2010)], he [or she] cannot dismiss so much contrary evidence that it appears that he 'simply failed to consider genuinely the evidentiary record before him.'" (brackets added) (quoting Campbell v. Sec'y of Health & Human Servs., 97 Fed. Cl. 650, 668 (2011))).

With regard to the Special Master's weighing of evidence when testimony, or assertions, conflict with contemporaneous medical records, a Special Master generally should afford contemporaneous medical records greater weight than conflicting assertions or testimony offered after the fact. See Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991) (citing United States v. United States Gypsum Co., 333 U.S. 364, 396 (1947) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")), aff'd, 968 F.2d 1226 (Fed. Cir.) reh'g denied, (Fed. Cir. 1992); see also Burns v. Sec'y of Health & Human Servs., 3 F.3d at 417 (quoting Cucuras v. Sec'y of Health & Human Servs. 993 F.2d 1525, 1528 (Fed. Cir. 1993)). This is because medical records, created contemporaneously with the events they describe are presumed to be accurate and complete. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d at 1528.

As discussed above, Ms. Whitfield had the burden to prove in her off-table case, by a preponderance of the evidence, that the various, alleged injuries scattered throughout her petition, amended petition, affidavits, and documented in the medical records before the court, were caused-in-fact by any of the three meningococcal vaccinations she received. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) (stating that "[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 not set forth in the Vaccine Injury Table but which was caused by a vaccine"); see also Milik v. Sec'y of Health & Human Servs., 822 F.3d at 1379 ("Where, as here, the injury is not on the Vaccine Injury Table, the petitioner may seek compensation by proving causation-in-fact."). As discussed above, when proving eligibility for compensation for a petitioner of an off-Table injury under the Vaccine Act,

such as those alleged by Ms. Whitfield, petitioner may not rely on his or her assertions 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." 42 U.S.C. § 300aa-13(a)(1). A petitioner who meets his or her burden is entitled to recovery under the Vaccine Act, unless the respondent proves by preponderant evidence that the injury was caused by factors unrelated to the vaccine. See Stone v. Sec'y of Health & Human Servs., 676 F.3d at 1379–80; Walther v. Sec'y of Health & Human Servs., 485 F.3d at 1151; see also Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. at 680. "But, regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case." Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. at 680. If the Special Master's decision was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, the reviewing court shall uphold that decision. See 42 U.S.C. § 300aa-12(e)(2).

Special Master Moran found that petitioner failed to establish a nexus between any of the ailments described by her and the medical records submitted to the court to the meningococcal vaccines Ms. Whitfield received. The Special Master's decision denying compensation explains:

> Here, while Ms. Whitfield has provided medical records that may prove diagnoses for her conditions, she has not presented any evidence linking her conditions to the vaccination, other than her individual assessment. In her response to the order to show cause, which specifically highlighted the lack of proof of causation in her submissions that she deemed "expert reports," Ms. Whitfield reiterated her position that, through a "process of elimination" of other potential causes for her conditions, she has come to the conclusion that her conditions were caused by the meningococcal vaccine. She also points to her submissions from Dr. Simmons and Dr. Chiam as expert opinion evidence supporting causation. However, as stated in the order to show cause, these submissions appear to be confirmations of Ms. Whitfield's conditions for which these doctors were treating her. They did not provide any opinion as to a causal link between the vaccination and these conditions. The attachments to petitioner's response also fail to shed any light on the question of causation.
>
> Because, Ms. Whitfield has not presented any evidence of a causal connection between her vaccination and alleged injuries, other than her bare assertions and personal conclusions drawn from the medical records, the undersigned finds that petitioner has not met her burden.

Whitfield v. Sec'y of Health & Human Servs., 2021 WL 915908, at *3.

After careful review of the record, Special Master Moran's decision denying petitioner compensation for petitioner's claims was not "arbitrary, capricious, an abuse of

discretion, or otherwise not in accordance with law." See 42 U.S.C. § 300aa-12(e)(2). Petitioner did not meet her burden to demonstrate by a preponderance of the evidence that the meningococcal vaccines administered to her were the "causation[s]-in-fact" of her various injuries. See Milik v. Sec'y of Health & Human Servs., 822 F.3d at 1379. Moreover, petitioner's independent allegations that the meningococcal vaccines caused her various injuries failed to satisfy the requirement set forth in 42 U.S.C. § 300aa-13(a)(1) that petitioner may not establish her case "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." See id. Petitioner was unable to secure expert opinions to support her position that the meningococcal vaccines caused her various ailments. The two respective exhibits, produced by petitioner and labeled by petitioner as expert reports from two of her treating doctors, did not address petitioner's requirement to prove by preponderant evidence that her various alleged injuries were caused-in-fact by the meningococcal vaccinations administered to her. Neither of the two very brief photographs of doctors' notes submitted by petitioner suggested the vaccines administered caused her various medical issues. The note from Dr. Simmons, one of petitioner's OB/GYNs, dated August 26, 2020, which was after petitioner filed her claim, and over three years after the administration of the last meningococcal vaccine in March of 2017, which stated:

> The patient [sic] mother called regarding the follow up pathology after her daughter's surgery. The patient was found to have a large 10 cm right paratubal cyst intra-operatively. The tube and cyst was removed as one specimen. The patient preoperative diagnosis was hydrosalpix [sic] due to possible PID [pelvic inflammatory disease]. The patient pathological findings is [sic] consistent with a paratubal cyst of unknown origin and does not appear to be infected at the time of surgery. The information was explained to the patient and her mother again and their questions were answered.

Dr. Simmons' brief descriptions of the pathological findings pre- and post-surgery do not in any way establish that the meningococcal vaccines administered to petitioner were the "causation-in-fact" of petitioner's medical issues. See Milik v. Sec'y of Health & Human Servs., 822 F.3d at 1379. Similarly, the note provided by Dr. Chiam, dated September 18, 2020, which stated:

> On 3/28/2019, Mikayla presented with hyperpigmentation on the right side of her abdomen. In my opinion, this is unlikely to be fungal in etiology.
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> This is being written upon the request of Elizabeth Alvarez, mother of Mikayla Whitfield.

As with Dr. Simmons' note, Dr. Chiam's note also did not even suggest that the hyperpigmentation (discoloration of skin) identified on petitioner's abdomen in March 2019, just over two years after petitioner received her last meningococcal vaccine in March of 2017, was the result of any of the meningococcal vaccinations administered to petitioner. In fact, as detailed earlier in this Opinion, the contemporaneous medical

records before the court indicated that on April 29, 2016, the day on which petitioner received her first two meningococcal vaccines, that earlier in the day, petitioner reported to her primary care physician for a "well adolescent visit," during which her primary care physician identified "hypopigmented plaques on chest c/w [consistent with] tinea versicolor," "acanthosis nigricans on back of neck," and refilled petitioner's eczema medication. In one of petitioner's affidavits submitted before Special Master Moran, petitioner, in her own words, "attest[ed] to having pre-dated Eczema which was referred to as Atopic Dermatitis." Special Master Moran did not abuse his discretion by determining, "[a]fter reviewing these submissions" by Doctors Simmons and Chiam, that "they did not meaningfully advance petitioner's case primarily because they did not provide evidence to support that the meningococcal vaccine caused Ms. Whitfield's alleged injuries." Whitfield v. Sec'y of Health & Human Servs., 2021 WL 915908, at *2.

Petitioner's unsupported allegations that the meningococcal vaccines caused, or exacerbated, her various injuries failed to satisfy the requirement set forth in 42 U.S.C. § 300aa-13(a)(1) that petitioner may not establish her case "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." See id. Ms. Whitfield provided many records of visits to medical facilities and doctors in which there is no recorded suggestion that the vaccinations administered to Ms. Whitfield caused her medical issues. Therefore, Special Master Moran did not abuse his discretion when he stated that "while Ms. Whitfield has provided medical records that may prove diagnoses for her conditions, she has not presented any evidence linking her conditions to the vaccination, other than her individual assessment." Whitfield v. Sec'y of Health & Human Servs., 2021 WL 915908, at *3.

Moreover, the court notes that many of the medical issues detailed by petitioner were documented before or well after the vaccines were administered. For example, the record suggests: a history of pre-dating injuries, as documented in a November 17, 2013 visit to the emergency room, three years prior to the administration date of the first two meningococcal vaccinations on April 29, 2016, in which she complained of nausea, vomiting, diarrhea, and abdominal pain "radiat[ing] to [the] pelvis;" eye swelling and blurred vision noted in a doctor's visit on July 18, 2016, three months after the first vaccination date on April 29, 2016; tinea versicolor, candida on her breasts, allergic rhinitis, and a single occurrence of irregular menses and dysmenorrhea noted on February 28, 2017, ten months after her first vaccination date on April 29, 2016; a pilonidal cyst near petitioner's tailbone noted on March 16, 2017, on the same date she subsequently received her third and final meningococcal vaccination, and almost eleven months after the first, April 29, 2016 vaccination date; and allergic conjunctivitis, headaches and tinea versicolor on January 19, 2018, and chlamydia based on a sample drawn on that same date, ten months after the third and final vaccination on March 16, 2017. Indeed, as discussed above, to the extent that petitioner attempted to connect her skin issues to the meningococcal vaccines, petitioner's reporting with skin conditions of "hypopigmented plaques on chest c/w [consistent with] tinea versicolor," and "acanthosis nigricans on back of neck," hours before she received her first two meningococcal

vaccines in April of 2016, refutes such a contention.[12] Petitioner did not establish that the timeframes between the administration of the vaccines and her various injuries were temporally significant timeframes, and not unrelated to pre-existing conditions or other explanation for causation unrelated to the administration of the vaccines. See de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1352 (stating that a petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation"). As explained by Special Master Moran in his order to show cause and his

[12] In Special Master Moran's decision denying petitioner compensation, Special Master Moran did not separately analyze whether petitioner had established entitlement to compensation for her ailments based on a theory of exacerbation, also known as significant aggravation. To the extent petitioner attempted to allege that the meningococcal vaccines caused significant aggravation to some of her ailments, such as her skin conditions and headaches, petitioner similarly failed to meet her burden of proof. As explained by the United States Court of Appeals for the Federal Circuit in W.C. v. Secretary of Health & Human Services, a cause-in-fact injury claim based on a theory of significant aggravation requires the following six elements of proof to have been met by preponderant evidence, the last three of which are very similar to the three Althen prongs, discussed above:

> "(1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) . . . a proximate temporal relationship between the vaccination and the significant aggravation.

W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1358 (quoting Loving ex rel. Loving v. Sec'y of Dept. of Health & Human Servs., 86 Fed. Cl 135, 144 (2009)). For the same reasons as discussed above, petitioner has failed to causally connect, by preponderant evidence, her allegations of aggravation to the administration of meningococcal vaccines because the record contains, outside of her own allegations, no medical opinions or medical records linking any alleged aggravations to the meningococcal vaccinations. See 42 U.S.C. § 300aa-13(a)(1). Furthermore, the contemporaneous medical records before the court do not support by preponderant evidence that some of her injuries, such as headaches, indeed worsened after the administration of the meningococcal vaccines, despite petitioner's characterizations that they did. For example, with respect to her headaches, the contemporaneous medical records indicate that on February 2, 2018, within a month of her first documented complaints of headaches, petitioner informed her physician that her headaches had improved, and petitioner only intermittently reported headaches to have occurred thereafter.

decision denying petitioner's claims, without any credible, scientific explanation linking her alleged injuries to the meningococcal vaccinations, petitioner's own allegations and theories are not sufficient to meet her burden to show by preponderant evidence that the meningococcal vaccines were the causes-in-fact of her various alleged injuries. See Whitfield v. Sec'y of Health & Human Servs., 2021 WL 915908, at *2–3 (citing 42 U.S.C. § 300aa-13(a) (1) ("The 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.")).

CONCLUSION

As stated above, petitioner's claim that the meningococcal vaccines administered to her were the causes-in-fact of her alleged injuries are unsubstantiated by medical records or by any medical opinion, as required by 42 U.S.C. § 300aa-13(a)(1). Petitioner's own assertions, alone, are insufficient to establish by preponderant evidence that her alleged injuries were caused-in-fact by the meningococcal vaccines. See id. While understanding and sympathetic to the difficulties of petitioner's personal medical history, Special Master Moran did not err in finding that petitioner did not meet her burden of proof to demonstrate that petitioner's medical issues were caused by the vaccines she received. In fact, not only do petitioner's medical records raise questions as to underlying, pre-existing conditions, but her failure to provide even one expert report leaves her claims unsubstantiated and not in conformance with the proof requirements in the Vaccine Act. Therefore, Special Master Moran's decision was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. See 42 U.S.C. § 300aa-12(e)(2). The court, therefore, **AFFIRMS** the decision of the Special Master, and **DISMISSES** the above-captioned case brought by Ms. Whitfield.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge