In the United States Court of Federal Claims

OFFICE OF THE SPECIAL MASTERS

No. 09-631V
Filed: March 7, 2012

LAWRENCE COPPOLA,	)	
	)	TO BE PUBLISHED
Petitioner,	)	
	)	
v.	)	Entitlement; Varicella Vaccine;
	)	Chronic Fatigue Syndrome
SECRETARY OF	)	(CFS); Systemic Inflammatory
HEALTH AND HUMAN SERVICES,	)	Response Syndrome (SIRS)
	)	
Respondent.	)	
	)	

Mark T. Sadaka, Englewood, NJ, for Petitioner,
Alexis B. Babcock, United States Dep't of Justice, Washington, D.C., for Respondent.

DECISION[1]

I. INTRODUCTION AND SUMMARY

Petitioner maintains that he suffered permanent injuries and damages as a result of receiving a varicella vaccination on October 3, 2006. Petitioner asserts that between 24 and 72 hours after vaccination, he experienced chills and high fevers, general aching, headaches, and fatigue. He alleges lasting health problems as a result of the vaccine, namely chronic fatigue syndrome ("CFS"), chills and sweats, congestion in his chest, and muscular pain.

Petitioner's case does not present preponderant evidence of any of the elements necessary to prove causation in fact. Petitioner's expert offered no reliable theory to explain how Petitioner could have suffered the alleged vaccine reaction. In this respect, the expert's theory changed completely between the time he submitted his supplemental expert report and the hearing. In his report, Petitioner's expert identified a direct viral reaction from the vaccination as the cause of Petitioner's ailment. Pet'r's Ex. 45 at 5 (indicating that the cause of Petitioner's illness was "viral, e.g., direct relationship to the vaccine administration"). But when asked at the hearing whether he found "evidence in the symptoms or in the laboratory results" of viral infection from the

[1] In accordance with Vaccine Rule 18(b), Petitioner has 14 days to file a proper motion seeking redaction of medical or other information that satisfies the criteria in 42 U.S.C. § 300aa-12(d)(4)(B). Redactions ordered by the Special Master, if any, will appear in the document as posted on the United States Court of Federal Claims' website.

vaccine, he stated "I find no evidence of that." Tr. at 74. [2] Petitioner's medical record showed no evidence to support the allegation of a post-infectious reaction. At hearing, Petitioner's expert postulated a different theory: serum sickness leading to an inflammatory syndrome as the cause of Petitioner's continuing medical issues. Tr. at 36. No persuasive evidence supports this theory or explains why it fits Petitioner's case. Further, Petitioner presented no reliable evidence to link, even theoretically, his vaccination with an inflammatory response resulting in symptoms years after his initial illness resolved. See Tr. at 72 ("certainly if you look at the strict definition of the systemic inflammatory response, it's resolved in Mr. Coppola in several days"), 78.

Petitioner thus failed to satisfy Prong 1 of the Althen test. [3] This is sufficient to deny the claim for compensation; however, for the sake of completeness, the other prongs of Althen also are analyzed.

Prong 2 of Althen requires that the petitioner demonstrate a logical sequence of cause and effect between vaccination and injury. Determination of Prong 2 in this case requires consideration of two themes. The first involves the allegation that Petitioner suffered an acute vaccine injury in the days following his vaccination. The second is that Petitioner for years afterward suffered a variety of symptoms related to the alleged initial reaction. I find reliable but not preponderant evidence to support the first contention, and no reliable evidence to support the second.

As to the initial alleged vaccine reaction, the strongest evidence consists of notations by three physicians who treated Petitioner on an emergent basis several days after his vaccination. These doctors noted a vaccine reaction, but they made the association based on the temporal relationship between vaccination and Petitioner's illness. The treating physicians recognized that Petitioner also had a urinary tract infection ("UTI"), confirmed by laboratory testing, for which they treated him. The most detailed note by a treating physician states that Petitioner had a UTI and a vaccine reaction. This doctor believed that most of Petitioner's symptoms were caused by the vaccine reaction but stated that the cause of all Petitioner's symptoms also could be the UTI. The two other treating physician notes document flu symptoms as the primary diagnosis, followed by vaccine reaction. The treating physicians' notations are, in context, equivocal. Further, the treating physicians who saw Petitioner apparently were unaware or took no account of several pertinent facts relating to Petitioner's medical condition – including pre-existing disorders and medications he was taking. As Respondent's expert testified, these factors made it much more likely that Petitioner was suffering from the symptoms of a serious UTI, not a vaccine reaction.

Based on all of the circumstances documented in the record, and giving due consideration to the stated opinions of the doctors who treated Petitioner in the emergency room and during his brief hospitalization, I find reliable but not preponderant

[2] The transcript in this case mistakenly gives a case number of 07-631V; the correct case number is 09-631V.

[3] Althen v. Sec'y of Dep't of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

evidence of a logical sequence of cause and effect between vaccination and Petitioner's initial illness.[4]

In contrast to the initial, acute event, the notations by the three treating physicians furnish no logical support for Petitioner's contention that he has suffered a variety of long-term symptoms caused by vaccination. The treatment notes identify an acute reaction that, based on undisputed evidence, resolved after a few days. The treating physicians' diagnoses do not implicate vaccination as a likely cause of Petitioner's long-term complaints. A barebones, conclusory affidavit submitted by Petitioner's personal physician for the purpose of this litigation does not, even on its face, purport to connect Petitioner's alleged initial vaccine reaction with his continuing ailments years thereafter.

In addition, the medical record contains documentation greatly undermining Petitioner's contentions. His records disclose unrelated medical conditions that explain Petitioner's symptoms much more persuasively than the alleged long-term reaction to his varicella vaccination. As Respondent's expert testified, it is more likely that Petitioner's symptoms, especially his fatigue, were caused by his other medical problems, especially chronic sinusitis. In the absence of evidence of a logical sequence of cause and effect, Petitioner fails to satisfy prong 2 of Althen.

Further, there was no reliable evidence, as required by Althen prong 3, that the Petitioner's illness occurred within a time frame that is consistent with a disease process such as that alleged in the Petition, or proposed by the Petitioner's expert.

Petitioner also has not presented preponderant evidence of a vaccine injury that caused residual effects or complications for more than six months after administration of the vaccine, as required. 42 U.S.C § 300aa-11(c)(1)(D)(i). For all these reasons, the Petition is dismissed.

II. PERTINENT FACTUAL BACKGROUND

A. The Petition

The Petition alleges that Petitioner received the varicella vaccine on October 3, 2006, at Kitsap County Health District in Bremerton, Washington, and that he "quickly began experiencing severe fatigue, generalized aching, chills, headaches, and a temperature of 106." Pet. at ¶ 8. At 4:51 a.m. on October 8, 2006, Petitioner sought emergency treatment at Harrison Medical Center in Silverdale, Washington (the "Silverdale facility"). Pet. at ¶ 9; see also Pet'r's Ex. 2. The Petition states that at the Silverdale facility he underwent a urinalysis, CBC (complete blood count) and blood culture, and "was treated for dehydration, which he suffered as a result of his condition

[4] I have considered the possibility that Petitioner initially had both a vaccine reaction and a UTI. For the reasons discussed below, I conclude that Petitioner's symptoms were not caused by a vaccine reaction, and that all of his initial symptoms are more persuasively explained by the UTI.

after receiving the Varicella vaccine," and received morphine for his generalized aching. Pet. at ¶¶ 10-12. He was discharged from the Silverdale facility at approximately 6:46 a.m. on October 8, 2006, with a prescription for Bactrim DS and Percocet. Pet. at ¶ 13.

That evening, Petitioner returned to the Silverdale facility. Pet. at ¶ 14. He was treated for acute nerve pain and myalgia, with administration of two liters of saline and Dilaudid for pain. Pet. at ¶¶ 15-16. He was discharged at about 10 p.m., with a prescription for oxycodone. Pet. at ¶ 17.

The next day, October 9, 2006, Petitioner was admitted to the Harrison Medical Center in Bremerton (the "Bremerton facility") complaining of difficulty in breathing and presenting with a fever of 104.6. Pet. at ¶¶ 18-19. It was noted that he was "very anxious." Pet'r's Ex. 3. He was discharged two days later after receiving IV fluids, Ativan for anxiety, and Albuterol nebulization for shortness of breath. Pet. at ¶ 20; Pet'r's Ex. 3.[5]

Six months later, on April 14, 2007, Petitioner presented at the Silverdale facility with chest discomfort, specifically "a feeling of 'a weight on chest.'" Pet'r's Ex. 2 at 34, 37. Petitioner told ER staff that he did not have shortness of breath or nausea but complained of "a substernal pressure." Pet'r's Ex. 2 at 37. Medical records of this visit indicate that Petitioner complained of "an emotional event earlier today that caused him to become 'very angry.'" He refused the services of a social worker, Id. at 34, 37, and was discharged the next day. Pet. at ¶ 22.

Petitioner has "continued to suffer from myofascial pain and chronic fatigue syndrome, which its effect [sic] include chronic fatigue, unpredictable swings in body temperature resulting in fevers and chills, and constant congestion in his chest as a result of receiving the Varicella vaccine." Pet. at ¶ 23.[6] Petitioner "suffered no preexisting conditions or serious disabilities" before his vaccination. Pet. at ¶ 24.

"After receiving the Varicella vaccine," Petitioner "has been unable to participate in previously enjoyed activities, including exercising and playing with his 5 year-old grandson, due to his constant fatigue." Pet. at ¶ 25. Petitioner will need "continuous and lifelong care and treatment for myofascial pain and chronic fatigue syndrome." Pet. at ¶ 26.

According to the Petition "[t]here is no question" that Petitioner's injuries "are directly related to the administration of the Varicella vaccine." Before the vaccination, Petitioner "was perfectly healthy." Pet. at ¶ 27. Petitioner's "condition of myofascial pain and chronic fatigue syndrome and its effect, including chronic fatigue,

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[5] The Discharge Summary from the Bremerton facility notes that he had been on Bactrim "for the last five days total." Pet'r's Ex. 3 at 2.

[6] "Myofascial" is defined as "pertaining to or involving the fascia surrounding and associated with muscle tissue." Dorland's Illustrated Medical Dictionary 1223 (32nd ed. 2012). "Fascia" is defined as "a sheet or band of fibrous tissue such as lies deep to the skin or forms an investment for muscles and various other organs of the body." Id. at 679.

unpredictable swings in body temperature resulting in fever and chills, and constant congestion in his chest, were caused-in-fact by Varicella vaccine." Pet. at ¶ 28. Petitioner claims "an incurable and lifelong condition of myofascial pain and chronic fatigue syndrome." Pet. at ¶ 30.

Petitioner's Affidavit similarly alleges that prior to receiving the varicella vaccination he "suffered no serious preexisting conditions or disabilities, exercised regularly and enjoyed normal physical activities, including playing with my grandson," but that after receiving the vaccine he "quickly began experiencing severe fatigue, generalized aching, chills, headaches and a temperature of 106," and has continued to suffer from temperature swings, fever, and persistent congestion/cough. Pet'r's Ex. 4 at 1. In his supplemental Affidavit, filed August 30, 2010, he stated that he received a prescription from Dr. Michael J. Butler on September 13, 2006, for "eight (8) ounces of phenergan with codeine for a sinus infection," and that he "took the prescribed dosage." Pet'r's Ex. 28 at 1; see Pet'r's Ex. 7 at 4. "Consequently, on the day that went [sic] to the Kitsap County Health Department I was still on the phenergan with codeine." Pet'r's Ex. 28 at 1.

B. Treating Physician Records

The linchpin of Petitioner's claim for compensation is the contention that his treating physicians at the Silverdale and Bremerton facilities identified vaccination as the cause of his acute disorder. See Pet'r's Post-Hr'g Br. 2, Mar. 28, 2011, ECF No. 49; see also Pet'r's Reply to Resp't's Post-Hr'g Br. 3, May 12, 2011, ECF No. 51.

As described in the Petition, Petitioner presented to the ER in Silverdale five days after receiving the varicella vaccine, on October 8, 2006. Pet'r's Ex. 2 at 10-12. The ER physician, Timothy J. Dahlgren, M.D., indicated that Petitioner was suffering from a vaccine reaction and a urinary tract infection, for which latter condition he prescribed Bactrim. Id. He stated that he believed that the UTI had "nothing to do with the rest of his symptoms." Id. at 11. Petitioner was discharged from the Silverdale ER but returned later that day. Medical records indicate that Petitioner "states feeling worse and wants to be admitted to hospital." Id. at 20.

Petitioner made a third trip to the emergency room on October 9, 2006, but this time went to the Bremerton facility. At the Bremerton facility, Petitioner was treated by D. William H. Moore, DO, and diagnosed with flu syndrome, suspected systemic reaction to varicella vaccination, and leukopenia, "which I suspect is secondary to his systemic viral reaction to varicella vaccination." Pet'r's Ex. 3 at 16.

Medical records from the Bremerton facility indicate that Petitioner "states feeling worse and wants to be admitted to hospital." Pet'r's Ex. 2 at 20. Petitioner was admitted to the hospital at Bremerton and discharged on October 11, 2006. Id. at 2. During his Bremerton admission, Petitioner also was seen by his primary care physician, Dr. Butler, whose notes state: "Final Diagnoses: 1. Flu Syndrome, 2. Systemic Reaction to varicella Vaccination." Pet'r's Ex. 3 at 11. The Emergency

Department Report by Dr. Moore notes: "He has taken Vicodin and has taken Bactrim for a presumed urinary tract infection, as diagnosed a few days at Silverdale." Id. at 15.

Other than the treating physician records noted above, there are no treatment records from any source that mention a vaccine injury or any sequelae thereof.

C. Medical Expert Reports

1. Petitioner's Expert – Larry W. Rumans, M.D.

Dr. Larry Rumans outlined Petitioner's medical history, noting that three days after vaccination, Petitioner "developed an undefined febrile illness." Pet'r's Ex. 8 at 2. He noted Petitioner's initial outpatient treatment and subsequent hospitalization. He cited laboratory studies "remarkable for leukopenia and modest thrombocytopenia." Id.[7] He noted that "a urinary tract infection was evident by urinalysis and culture (E. coli)" with a virtual absence of clinical symptoms. Id.[8] "There were no findings of prostate or pyelonephritis." Id.[9] He noted that upon recovery "from the acute portion of his illness," Petitioner "has continued to subjectively experience symptoms of illness characterized by prominent fatigue, tiredness and chronic cough." Id.

Dr. Rumans noted Petitioner's history of hypertension, hyperlipidemia, and GERD, conditions which, he stated, "antedate the varicella immunization." Pet'r's Ex. 8 at 2.

Dr. Rumans opined that Petitioner "experienced an important or life-threatening adverse reaction to varicella vaccine characterized by high fever, rigors, musculoskeletal symptoms of severe myalgias and arthralgias, leukopenia and thrombocytopenia and prolonged constitutional symptoms." Pet'r's Ex. 8 at 3. He noted that "this diagnosis was also held by the treating physicians who assessed Mr. Coppola in the emergency room and upon hospitalization." Id.

Dr. Rumans acknowledged the contemporaneous diagnosis of UTI by Emergency Room physicians on October 8, 2006, but opined that "the likelihood this was responsible for his symptoms is considered remote due to the frank paucity of

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[7] "Leukopenia" is defined as a "reduction in the number of leukocytes in the blood below about 5000 per mm." Dorland's at 1030. A "leukocyte" is defined as "a colorless blood cell capable of ameboid movement; . . . [c]alled also white blood cell." Id. at 1028. "Thrombocytopenia" is a decrease in the number of platelets. Id. at 1922.

[8] "E. coli" is defined as "the principal species of the genus, a predominant facultative organism of the intestines of many different animals. . . . Most are nonpathogenic, but pathogenic strains producing fevers and diarrhea are common. The fever-causing strains are found in urinary tract infections, abscesses, conjunctivitis, and occasionally septicemic conditions . . . ." Dorland's at 646.

[9] "Pyelonephritis" is defined as "inflammation of the kidney and renal pelvis because of bacterial infection." Dorland's at 1559.

clinical findings (history, ROS and laboratory analysis)." Pet'r's Ex. 8 at 3.[10] He stated that Petitioner's dysuria could have been secondary to dehydration "given the magnitude of his fever." Id.

In addition, Dr. Rumans stated that CFS was "most unlikely as a cause of continuing clinical symptomatology, "adding that Petitioner "clearly does not meet the requisite criteria" for CFS. Pet'r's Ex. 8 at 3.

Petitioner's Supplemental Expert Report

On December 23, 2010, Petitioner filed a supplemental report from Dr. Rumans. Pet'r's Ex. 45. This report included additional literature and presented for the first time a theoretical basis for his opinion. Pet'r's Exs. 42, 43. See Althen v. Sec'y of Dep't of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005) (requiring a medical theory causally connecting the vaccination and the injury). Dr. Rumans stated that Petitioner's ongoing symptoms were "viral, e.g., direct relationship to the vaccine administration." Pet'r's Ex. 45 at 5.

Dr. Rumans stated that individuals may react differently to various vaccines, "[i]n fact, there may be a broad range of responses." Pet'r's Ex. 45 at 5. "Adverse reactions or unanticipated responses may occur." Id. He noted that there is "extremely limited" medical literature concerning adult vaccination with varicella vaccine. Id. He said the available literature indicates that "symptoms, like fever, do start about an average of three (3) days after administration of the vaccine." Id. Dr. Rumans continued, "Mr. Coppola's symptoms started approximately three (3) days after the administration of the vaccine." Id.[11]

Dr. Rumans disputed the finding by Dr. Dahlgren, the treating physician, that Petitioner was suffering contemporaneously from a urinary tract infection and pyelonephritis. In support of this opinion, he noted that Petitioner had:

-- No prior history of urinary tract infection
-- No supporting urinalysis
-- Absence of clinical signs and symptoms (Dysuria of a minor degree would not be unusual with fever of 105 degrees and concomitant dehydration)
-- No leukocytosis or immature shift in leukocyte differentials
-- Absence of positive blood culture
-- No findings of sepsis syndrome or shock

[10] "ROS" refers to "review of systems." Medical Abbreviations 284 (15th ed. 2011).

[11] Petitioner approximated an onset of symptoms 48 to 72 hours after receiving the vaccination. See Tr. at 132 ("Probably about 48 hours afterwards. Somewhere between 48 and 72 hours afterwards.") Petitioner's Affidavit states, "I received the Varicella vaccine on October 3, 2006 . . . and quickly began experiencing severe fatigue, generalized aching, chills, headaches, and a temperature of 106." Pet'r's Ex. 4.

-- No genitourinary evaluations performed by any of the evaluating physicians, again supporting lack of presence of notable clinical signs and symptoms in this regard
-- Minimal treatment measures with limited oral antibiotic
-- No subsequent history of documentation of further occurrence of UTI

Pet'r's Ex. 45 at 5; see also Pet'r's Ex. 3; Tr. at 41-42.

In addition, Dr. Rumans commented on Petitioner's "recurring variations in temperature sensation." Pet'r's Ex. 45 at 6. He explained that varicella is a member of the herpes family of viruses, and that "Varicella-zoster virus is clearly associated with neurologic deficts [sic] and sensory variations including post herpetic neuralgia and among which would be included thermal sensation." Id. Thus, Dr. Rumans seemed to be intimating in his testimony that vaccination had produced in Petitioner a reaction akin to herpes infection: "Mr. Coppola's wide-range in temperature sensation[] . . . is not inconsistent with the medical literature regarding post-herpes infection. . . . Mr. Coppola suffers from post-infectious neurological damage resulting in variations in temperature sensation." Id. However, Dr. Rumans testified at hearing that there was no evidence of herpes infection. Tr. at 74.

2. Respondent's Expert – Raoul Wientzen, M.D.

Dr. Raoul Wientzen's opinion, dated April 29, 2010, began with a summary of Petitioner's claimed reaction to and injuries resulting from the varicella vaccine, namely chronic fatigue, unpredictable swings in body temperature leading to fever and chills, constant chest congestion, myofascial pain, and CFS. Resp't's Ex. A at 1-2.

Dr. Wientzen noted that there were no documented medical visits between the follow-up visit after Petitioner's hospitalization, on October 20, 2006, and an episode of stress-induced chest pain on April 14, 2007. Id. at 2.

Dr. Wientzen reviewed Dr. Rumans's reports, noting that Petitioner's own expert rejected Petitioner's claim that he suffered from CFS, as claimed in the Petition. Id.

Dr. Wientzen stated several conclusions. First, noting Petitioner's history following vaccination and laboratory results, Dr. Wientzen concluded that Petitioner's medical complaints when he presented to the ER on October 8, 2006, were unrelated to vaccination and were caused by an "aggressive" UTI. Resp't's Ex. A at 3; see also Tr. at 3. He disputed the ER physicians' attribution of Petitioner's dysuria to dehydration, stating that there was no laboratory confirmation of dehydration. Resp't's Ex. A at 3 According to the medical records and Petitioner's own admission, he did not have a fever of any great magnitude on the first day of his post-vaccination illness, and Dr. Wientzen noted that it is "extraordinarily rare" for an adult to develop dehydration over the course of one day of febrile illness. Id. In addition, Dr. Wientzen noted that Petitioner continued to experience dysuria through October 8, 2006, after he had received intravenous fluids "to correct any possible fluid deficit." Id. at 3-4. In further

disproving dehydration, Dr. Wientzen relied on the evidence from the medical records indicating that Petitioner had voided six times on October 8, 2006, but continued to complain of burning on urination. Id. at 4.

Dr. Wientzen conceded that "the treating physicians during the 10/08-10/09/06 time frame blamed the Varicella vaccine" for Petitioner's illness. Resp't's Ex. A at 4. He noted that there is no explanation in the record to support that assessment, and he believes this conclusion was reached simply because of the close proximity in time between Petitioner's vaccination and his ER visit on October 8, 2006. Id. Dr. Wientzen stated that in his review of available medical literature he was unable to uncover even a single case in which varicella vaccine caused fever of greater than 106 degrees in an adult. Id.

In regard to Petitioner's complaints over the years following his vaccination, Dr. Wientzen noted that there was no evidence in the medical records to support the complaint of myofascial pain or a diagnosis of CFS. Resp't's Ex. A at 4; see also Tr. at 4. The medical records did mention ongoing complaints of fatigue and cough/congestion, but not fevers and chills. Resp't's Ex. A at 4.[12] Dr. Wientzen noted that Petitioner had undergone extensive testing for his cough and congestion, including evaluation by a pulmonary specialist. Id. "The end result of this evaluation was an exoneration of his pulmonary system and the finding of chronic sinusitis on CAT scan." Id. The pulmonary medical specialist referred Petitioner to an ear, nose and throat ("ENT") specialist, but Dr. Wientzen found no record of an ENT evaluation. Id. He noted that chronic sinusitis is "a well known cause of fatigue syndromes." Id.

Dr. Wientzen attributed Petitioner's symptoms in the months following his vaccination to chronic sinusitis and noted that that problem had existed before his vaccinations on October 3, 2006. "He had a month of sinus symptoms, cough and congestion when he was seen and treated on 9/13/06 at the Doctors Clinic." Resp't's Ex. A at 5. Dr. Wientzen further noted that he did not believe Petitioner suffers from CFS, and that Petitioner's expert, Dr. Rumans, had reached the same conclusion. Id.

Dr. Wientzen noted that the Petition asserted that Petitioner was "perfectly healthy" before receiving the varicella vaccine. Dr. Weintzen disputed this claim and opined that Petitioner "was not in perfect health before his vaccine was administered." Resp't's Ex. A at 2; see also Pet. ¶ 27. Dr. Wientzen explained that a review of Petitioner's medical records showed that he suffered from

> obesity, high blood pressure, hypercholesterolemia, gout, chest pain induced by stress, gastroesophageal reflux, benign prostatic hypertrophy with reduced urinary stream, an abnormality of the distal esophagus

[12] Notwithstanding the absence of documentation in the medical record, I credit the testimony at hearing from Petitioner and Mrs. Coppola indicating that Petitioner has suffered chills consistently over the past several years, and that this problem continues. Tr. at 121-22, 126-27. As discussed below, I do not find preponderant evidence that this symptom was caused by or even is related to Petitioner's varicella vaccination.

requiring dilatation, and some abnormality of the upper airway, likely obstructive sleep apnea or snoring, requiring uvulopalatopharyngoplasty (UPPP) and perhaps further surgery.

Resp't's Ex. A at 5.[13, 14, 15]

Dr. Wientzen summarized his opinion as follows: "there is no evidence that Mr. Coppola was injured by the Varicella vaccine he received. He developed a UTI that caused marked and expected symptoms, which was well treated by his physicians. His symptoms following recovery from his UTI are from his upper airway/sinusitis problem, and have nothing to do with the Varicella vaccine." Resp't's Ex. A at 5.

Respondent's Supplemental Expert Report

Responding to the supplemental report filed following the hearing by Dr. Rumans, Dr. Wientzen disputed the assertion that symptoms like fever start about three days after administration of the varicella vaccine. Resp't's Ex. D at 1. In the study relied upon by Dr. Rumans "no patient of the 200 studied had fever in the first 72 hours following vaccination." Id. (citing Pet'r's. Ex. 18).[16] In fact, "there is no documentation in this article to support the incidence of fever after a varicella vaccination, whether within 72 hours or beyond that time." Id.

Dr. Wientzen stated that the medical records did not support Dr. Rumans's assertions, and refuted each of Dr. Rumans's points as follows:

-- Contrary to Dr. Rumans's assertion, medical records submitted by the Petitioner indicate that a urinalysis was performed on petitioner during Petitioner's first ER visit and was distinctly abnormal, showing "2+ white blood cells, a positive nitrite test and the presence of blood, all of which are highly suggestive of urinary tract infection." Resp't's Ex. D at 1.

-- Petitioner "had classic signs and symptoms of urinary tract infection: very high fever, aching, fatigue, dysuria, frequency, flank tenderness," contrary to Dr. Rumans's assertions. Id. at 2. Further, Dr. Wientzen disputes Dr. Rumans's

[13] See, e.g., Tr. at 172-73 (Dr. Wientzen testifying that Petitioner's complaints of chest pains were documented in 2004, and several years before that).

[14] See Pet'r's Ex. 7 at 14 (record of Dr. Butler, which notes that Petitioner may have "gout or calcium pyrophosphate deposition disease," as well as "glucose intolerance").

[15] "UPPP" is an abbreviation for uvulopalatopharyngoplast, Medical Abbreviations at 333, and is defined as "a trimming back of excessive palatal and pharyngeal tissue, done in order to widen the airway and relieve obstructive sleep apnea or severe snoring." Dorland's at 1352 (listed under "palatopharyngoplasty").

[16] See Rosemarie Berger et al., A Dose-Response Study of a Live Attenuated Varicella-Zoster Virus (Oka Strain) Vaccine Administered to Adults 55 Years of Age and Older, 178 (Suppl. 1) J. Infect. Disease S99 (1998).

dismissal of one of Petitioner's signs of UTI, dysuria, as being caused by dehydration, rather than a UTI; Dr. Wientzen concludes from the Petitioner's medical records that Petitioner was not dehydrated. Dr. Wientzen also noted that even if Petitioner had not presented with classic signs of UTI, this would not necessarily rule out a UTI, as "many patients with pyelonephritis (upper tract UTI) have absolutely no symptoms of lower urinary tract infection." Id.

-- When Petitioner was admitted to the hospital on October 9, 2006, he had "developed significant leucopenia," which Dr. Wientzen stated is "consistent with the sepsis syndrome," and pointed out that medical literature, including that submitted by Petitioner's expert, Dr. Rumans, also indicates that this data is "supportive of the diagnosis of sepsis." Id.

-- The majority of patients with upper or lower UTI are not bacteremic, so the absence of positive blood culture is not inconsistent with a UTI. Id.

-- Petitioner met the diagnostic criteria for sepsis syndrome/urosepsis – "high fever, a markedly elevated heart rate and respiratory rate, and later a low WBC [white blood cell] count." Id.[17]

-- Dr. Rumans mischaracterizes Petitioner's treatment with oral antibiotics as "minimal" and "limited," as oral Bactrim is a standard treatment for UTI and "has been shown to be as effective as intravenous antibiotic therapy for 90% of patients with pyelonephritis. Id.

-- Petitioner's lack of recurring UTIs does not demonstrate, as Dr. Rumans suggests, that Petitioner did not have a UTI at the time of his three visits to the emergency room on October 8 and 9, 2006. At the time of those visits, Petitioner had "three simultaneous conditions that increased his susceptibility to UTI . . . longstanding BPH, benign prostatic hypertrophy, the use of codeine, the use of promethazine." Id. These two drugs "make it more difficult to fully empty the bladder, as does BPH. Residual urine is the most common underlying cause of UTI." Id. Petitioner's lack of further episodes "probably came about because he was no longer taking drugs that induce residual urine." Id.

-- Recurring variation in temperature sensation due to zoster infection can occur at the site of the "localized area of the body innervated by nerves arising from an infected dorsal root ganglion." Id. at 3. This would be "a small area of the chest wall or face or back." Id. Thus, in contrast to the assertions of Dr. Rumans, "total body sensation of temperature fluctuations" has no connection with post-herpetic neuralgia. Id. Further, Petitioner never was diagnosed with herpes zoster, "[t]hus, he clearly cannot be suffering from any form of post-herpetic neuralgia." Id. Further, Dr. Wientzen stated unequivocally: "To claim that Mr. Coppola's fluctuations in body temperature sensation are somehow a

[17] See Medical Abbreviations at 343.

post-zoster manifestation of thermal perception is without precedent in medicine, and completely lacking scientific or factual support in this case." Id.

In sum, it was Dr. Wientzen's opinion that Petitioner, when he presented at the ERs at Silverdale and Bremerton on October 8 and 9, 2006, was suffering from a UTI brought on by underlying medical conditions and contraindicated medications he was taking for a sinus infection; that Petitioner also likely had sepsis; that Petitioner's treatment with Bactrim was an aggressive treatment and would explain the resolution of Petitioner's UTI; that the chills, sweats and fever experienced by Petitioner were not caused by his vaccination; that Petitioner was not healthy prior to his vaccination, but had a number of conditions that the record indicates were not thoroughly worked up; and that the record does not indicate that Petitioner was infected with herpes zoster.

D. Hearing

1. For Petitioner

a. Dr. Rumans

Dr. Rumans testified that he is board certified in internal medicine and infectious disease, with a certificate of knowledge in travelers' health and tropical medicine. Tr. at 14. Based on his curriculum vitae ("CV") and testimony, he has never held an academic appointment. Pet'r's Ex. 9; Tr. at 48.[18] He treats adult patients in Tucson, Arizona. Tr. at 48.

Dr. Rumans testified that in the days following his vaccination Petitioner suffered a "type" of "serum sickness-like reaction" in which patients develop significant fever, arthralgias, myalgias, leukopenia, thrombocytopenia, and an inflammatory response, "which Mr. Coppola clearly exhibited," called "systemic inflammatory response syndrome" ("SIRS"). Tr. at 36.[19] He characterized this as a "hypersensitivity reaction." Tr. at 37.[20]

Dr. Rumans testified that he believed the Petitioner had a UTI, but disputed the evidence that Petitioner's symptoms following vaccination were caused by the UTI. Tr. at 43, 49. He also stated that the attribution of Petitioner's symptoms to his UTI by

[18] Dr. Rumans previously held what is called a voluntary appointment as an Associate Clinical Professor at the University of Kansas. See Pet'r's Ex. 9. Counsel for Respondent noted that Dr. Rumans did not identify this appointment as voluntary on his CV, in violation of University rules. Tr. at 48.

[19] Systemic inflammatory response syndrome ("SIRS") is "an inflammatory cascade that is initiated by the host response to an infectious or noninfectious trigger. . . . This inflammatory cascade is triggered when the host defense system does not adequately recognize and/or clear the triggering event." Robert M. Kliegman et al., Nelson Textbook of Pediatrics 307 (19th ed. 2011).

[20] "Hypersensitivity reaction" is defined as a reaction "in which the body mounts an exaggerated or inappropriate immune response to a substance either foreign or perceived as foreign, resulting in local or general tissue damage." Dorland's at 1599.

treating emergency room physicians on October 8, 2006, was incorrect, because a UTI could not explain certain of Petitioner's symptoms (e.g., his trouble breathing), and Dr. Rumans believed that other symptoms would have been present in a UTI, namely a stronger sense of burning on urination (than that which Petitioner described), urgency in urination, and superpubic pain. Tr. at 22-25. Dr. Rumans stated that, in his opinion, Petitioner's dysuria could have been secondary to dehydration "given the magnitude of his fever." Id.

Dr. Rumans testified that he believed that Petitioner's complaints on October 8, 2006, were not caused by his UTI, but rather a "serum sickness-like reaction" to vaccination, which in turn caused a systemic inflammatory response syndrome. Dr. Rumans testified that the emergency room physicians who attended to Petitioner on October 8 and 9, misdiagnosed his symptoms as being caused by his UTI, when in fact, he believes, Petitioner's UTI was asymptomatic. Tr. at 32-36. Dr. Rumans reasoned that, if Petitioner's symptoms of abnormal urinalysis, fever, chills, myalgias, arthralgias, and elevated Creatinine were the result of his UTI, Petitioner should also have had signs of "septic phenomenon, . . . sepsis syndrome, or perhaps even septic shock," and if that were the case the ER physicians, who would have been very accustomed to signs of septic shock, would have admitted him immediately. Tr. at 31, 34, 43, 50. Dr. Rumans testified that he did not believe that Petitioner had septic shock, but rather that he had a "serum-like reaction," which can cause "an inflammatory response . . . called systemic inflammatory response syndrome" and "that is what he had." Tr. at 36.

Dr. Rumans testified that "the serum sickness-like reaction occurs in response to the administration of . . . the vaccine, and the development by the individual . . . [of] antibodies, [which in turn] results in the development of immune complexes. That's what causes the febrile response, the fever, the aching, the chills, the leucopenia, the thrombocytopenia." Tr. 36-37. Dr. Rumans conceded that the ER physicians did not diagnose Petitioner with serum sickness, and that Petitioner did not have a rash, which is a common symptom of serum sickness. Tr. at 51-52. Significantly, Dr. Rumans agreed that Petitioner recovered from the serum sickness, as people "generally" do, and did not seek medical treatment for six months thereafter, when he presented with a complaint concerning his heart. Tr. at 78.

Dr. Rumans also testified that although the Varivax package insert documented adverse reactions occurring within 14 to 24 days post-vaccination, he interpreted that documentation to indicate only that "the largest number of febrile responses occur [within 14 to 24 days], but it doesn't mean that febrile responses don't occur outside of that interval. They do." Tr. at 45. Dr. Rumans gave no basis for this opinion other than his testimony that he does administer vaccinations to adults in the course of his medical practice. Id.

He could not describe any theoretical basis for his opinion that the varicella vaccination resulted in ongoing fatigue months and years after the immediate vaccination reaction had resolved. Tr. at 69-70. Dr. Rumans conceded that "fatigue is associated with many different conditions." Tr. at 60.

He testified that he was unaware of any literature concerning systemic inflammatory response syndrome. Tr. at 71.[21] Dr. Rumans also could not provide information on the expected duration of a systemic inflammatory response. Tr. at 72. He admitted that "certainly if you look at the strict definition of the systemic inflammatory response, it's resolved in Mr. Coppola in several days." Id.[22] According to Dr. Rumans, the systemic symptoms triggered lingering effects. Id. He was unable to opine as to how long those effects could last, stating that it would depend on the individual. Tr. at 73. Nor did he present any scientific data to support this assertion. Id.

Dr. Rumans appeared to rely on the package insert for the Varivax vaccine as the basis for his opinion that Petitioner's vaccination and his alleged injury were causally connected. Tr. at 62; see Pet'r's Ex. 36. He read aloud the following paragraph from the package insert:

> [T]he most frequently (≥1%) reported adverse experiences, without regard to causality, are listed in decreasing order of frequency: upper respiratory illness, headache, fatigue, cough, myalgia, disturbed sleep, nausea, malaise, diarrhea, stiff neck, irritability/nervousness, lymphadenopathy, chills, eye complaints, abdominal pain, loss of appetite, arthralgia, otitis, itching, vomiting, other rashes, constipation, lower respiratory illness, allergic reactions (including allergic rash, hives), contact rash, cold/canker sore.

Pet'r's Ex. 36 at 10; Tr. at 62.

The following colloquy between counsel and Dr. Rumans ensued:

> Q: So, Dr. Rumans, based on your reading of page 10 of the Varivax package insert, would you say that Mr. Coppola had a majority of those symptoms that you just read?
>
> A: Yes, sir. He certainly had a number of them.

Tr. at 62-63.

Dr. Rumans testified that the ongoing symptoms attributable to vaccination in Petitioner's case were chronic fatigue and respiratory tract complaints, although, he explained, Petitioner did not have the symptoms of chronic fatigue syndrome, per se. Tr. at 66. In addition, according to Dr. Rumans, Petitioner did not suffer from sepsis as

[21] Counsel confirmed that the record did not contain "anything" specifically concerning systemic inflammatory response syndrome. Tr. at 71.

[22] Dr. Rumans agreed that on October 20, 2006, when Petitioner was evaluated following his post-vaccination hospitalizations, he reported no problems with fever, chills, shortness of breath, or anxiety. Tr. at 78.

a result of his vaccination and was not immunosuppressed. Tr. at 67-68. Further, Dr. Rumans testified that he was "not able to state" that the Petitioner had myofascial pain as a result of his varicella vaccination, as he "[did not] have enough data upon which to substantiate" that the Petitioner suffered from myofascial pain. Tr. at 68-69.

In sum, Dr. Rumans testified that the only symptoms which he believed were attributable to the vaccination were fatigue (although not CFS), coughing, and shortness of breath, all of which he believed were "more likely than not" to have resulted from SIRS, caused by Petitioner's vaccination. Tr. at 69-74. Dr. Rumans acknowledged that there was nothing in the Petitioner's record regarding SIRS; further, Dr. Rumans stated that his opinions regarding SIRS were based on his experience as a medical practitioner, and that he "[did] not have any scientific data." Tr. at 71-73.

Dr. Rumans confirmed that Petitioner did not suffer symptoms consistent with zoster infection. Tr. at 74.[23]

b. Fred Depee

Mr. Depee testified as a long-time friend of Petitioner. Tr. at 82. He said that he had learned only a week or two prior to the hearing about Petitioner's alleged vaccine injury, when he was contacted by an employee of Petitioner's counsel "wanting some kind of statement or something." Tr. at 82-83. He recalled that Petitioner became ill in October 2006, but said he was unaware of the details surrounding that illness. Tr. at 85. He stated that he worked out with Petitioner and that in the last three to four years the quality of Petitioner's workouts had diminished: Petitioner was unable to lift as much weight and seemed lethargic. Tr. at 86-87, 92-93. Mr. Depee also testified that he does not see the Petitioner as often as in past years. When he has seen Petitioner, it has been his observation that Petitioner has less energy than in the past, and that Petitioner's memory and ability to carry on intelligent discussions has declined "over the last three, four years," as has his sense of humor. Tr. at 86-89.

Mr. Depee's testimony was vague about the observed time frame of the events on record and the Petitioner's observed changes in behavior. Tr. at 85-92. Further, in response to questioning by Petitioner's counsel Mr. Depee frequently qualified his answers by stating that he was unclear as to the events and/or didn't have personal knowledge of them, or that they were not particularly significant to him and therefore his memory was not clear. Id.

Mr. Depee's testimony was contradictory. For example, according to Mr. Depee, Petitioner had not informed Mr. Depee of an adverse vaccine reaction. Tr. at 91. Minutes later, the witness qualified his testimony, stating that Petitioner "probably mentioned it to me." Tr. at 96. Mr. Depee noted that "I don't hardly see him anymore."

[23] This testimony seemed to contradict his Supplemental Expert Report, in which Dr. Rumans opined that Petitioner suffered from post-infectious zoster symptoms. See Pet'r's Ex. 45 at 6; see also Discussion, infra.

Tr. at 86. On the other hand, on cross-examination, Mr. Depee testified, speaking of Petitioner, "he's one of my best friends." Tr. at 96.

He confirmed that Petitioner, as of the time of hearing, continued his term as mayor of Port Orchard, Washington, and still owned a publishing company there. Tr. at 94.

Mr. Depee had several explanations for why he did not know more about Petitioner's claimed health issues: Mr. Depee stated that Petitioner was not inclined to complain about his health because he was "macho," and had likely adopted a "persona" to impress the public "because you know if you're going to run again, you better be staying on your game to get those votes." Tr. at 95. Despite testifying that Petitioner is "one of [his] best friends," Mr. Depee explained that he and Petitioner "very seldom" discussed "personal" matters. Tr. at 97.

c. Jennifer Christine

Ms. Christine is an employee of Petitioner's publishing business, where she has worked since January 2002. Tr. at 100. She stated that Petitioner decided in January 2006, to run for Mayor of Port Orchard, but that his campaign did not really get under way until October of that year. Tr. at 101-02. She recalled Petitioner's hospitalization in October 2006, but stated that she did not know the details of his illness. Tr. at 104-05. Following his hospital stay, Petitioner was "less active." Tr. at 107. "[H]e tends to just back down a little bit more on being active . . . he goes to work, he does his job, and that's pretty all-consuming, but outside of that, he's not [doing] as much as he used to." Id.

She testified that being Mayor of Port Orchard started as a part-time job but was converted to a full-time job. Tr. at 108. When counsel asked "[w]hy would someone feeling so ill at that time undertake such a big responsibility," the witness testified that Petitioner "saw it as a civic duty." Tr. at 110. "He's the type of person who even though he's not feeling well, he still feels that there's a job to be done and he has to do it." Tr. at 111. She stated that Mr. Coppola goes on fewer "junkets," "because he just hasn't felt like he can do that, not just as in the job, but healthwise. . . . He's a lot less active." Tr. at 112. She confirmed that Petitioner is "much more sedentary" and no longer works out at the gym. Id.

d. Dee Coppola

Ms. Coppola, Petitioner's wife, testified that Petitioner started to feel ill somewhere between a day and a few days following his varicella vaccination. Tr. at 117-18. He complained of fatigue and had a temperature of 105 degrees. Id.

Petitioner was admitted to the hospital in Bremerton on October 9, 2006. Pet'r's Ex. 3. Ms. Coppola indicated that his temperature was fluctuating. Tr. at 119-20. After he was released, Petitioner was "tired" but had difficulty sleeping. Tr. at 120. He still

suffered from "the temperature thing. He couldn't get warm." Id. This continued to be a severe problem. Tr. at 120-23, 126-27. Ms. Coppola testified that Petitioner becomes winded easily and has much less energy than in the past. Tr. at 123.

Ms. Coppola testified that preparations for her husband's mayoral campaign were under way in the summer of 2006, and that "when he starts something, he likes to finish it." Tr. at 124. She stated that the mayor's job is full-time and that Petitioner no longer "comes to the office" of Wet Apple, the couple's publishing business, and that she has taken over the active management of the office. Tr. at 125.

e. Petitioner Lawrence Coppola

Petitioner testified that he reacted to his vaccination with fatigue and fever "[p]robably about 48 hours afterwards. Somewhere between 48 and 72 hours afterwards." Tr. at 132. He could not recall which day of the week he had gotten the vaccination – he believed it was either a Wednesday or a Thursday – but he was certain he had gone to the emergency room for the first time on the following Saturday because he remembered he "had a specific task" that he had to do. Tr. at 132; see Pet'r's Ex. 2 at 10 (recording the date of admission as October 8, 2006, which was a Sunday). He decided to visit the ER after he "started feeling really bad," and had fatigue and hot and cold sweats. Tr. at 132-33. He was discharged from the hospital and went home, but returned a few hours later with severe chills. Tr. at 133-34. He also was hyperventilating. Tr. at 134. He was again discharged and the following morning presented to the ER at the hospital in Bremerton. Tr. at 135. "Somebody" there asked, "I'm not sure what doctor it was . . . have you had anything unusual happen, and I told them about getting the vaccine, and he said, well, I think you're having a reaction to it." Tr. at 137.

Petitioner was admitted to the hospital in Bremerton, where he was seen by his family physician, Dr. Butler. Tr. at 137. Dr. Butler "was very noncommittal," Petitioner recalled. Tr. at 138. During this hospital stay, from October 9-11, Petitioner continued to experience "massive fatigue," hyperventilation and cold. Id. Petitioner testified that his fatigue diminished eventually but he was "still much fatigued over what I had been previously." Tr. at 139.

Petitioner did not recall a visit to Dr. Butler on October 20, 2006, for a hospital follow-up. The summary of the follow-up by Dr. Butler noted that since Petitioner's hospital visit "he has had no problems with fever or chills or episodes of shortness of breath or anxiety. Overall he is feeling much better since his hospitalization. The only big problem now is problems with sleeping as a direct consequence of his grandchild who he now has custody of." Pet'r's Ex. 7 at 2; Tr. at 140.

Petitioner testified that currently he sleeps well but needs to wear heavy clothing because he feels cold "all the time." Tr. at 141.

He testified that he decided to run for Mayor in early 2006 and began preparing for the race "early on in the year." Tr. at 141-42. He testified that he "is the kind of person" who "would not be happy not finishing something I start." Tr. at 143. He explained that, as a politician in his public appearances he believes it is part of his job to appear to believe his own speeches about "what a great city we have" and "be the person that, you know, the people think I am, and I have a duty to represent my city and I have to do it well." Tr. at 144. He answered in the strong affirmative to his attorney's question, "Would you put on that face even though you might be feeling unwell?" Id. ("Absolutely. That's my job.").

On cross-examination, Petitioner recalled that he had a urinary tract infection in October 2006, but did not remember exactly when it occurred, and stated that "it was not a major infection." Tr. at 149. As noted above, he denied any recollection of his October 20, 2006, visit with Dr. Butler, or of telling Dr. Butler that he "felt much better after the hospitalization." Tr. at 150; see Pet'r's Ex. 7 at 1. He did not contest the accuracy of the Secretary's assertion that he sought no medical care during the six months between October 20, 2006, and April 14, 2007. Tr. at 150.

Petitioner confirmed that he consulted Dr. Bennett, a pulmonologist, in June 2008, concerning a cough. Tr. at 151.[24] He acknowledged telling Dr. Bennett at that visit that he was still regularly working out; he had not divulged that while he was trying at that time to maintain his past workout regimen, he was going to the gym fewer days a week than in the past, and "didn't have the energy, really" to maintain his past regimen. Tr. at 151-52. Mr. Coppola was referred to an ear, nose and throat specialist. Id. He was told there were a number of possibilities concerning the source of his cough, including acid reflux. Tr. at 153. Petitioner acknowledged that at the time of the hearing he had been on acid reflux medication for a number of years. Id.

Petitioner recalled that in 2009 he successfully advocated for converting the office of mayor from a part-time to a full-time position. Tr. at 154.

On cross-examination, Petitioner stated that he did not recall whether he took Phenergan with codeine, as prescribed by Dr. Butler for Petitioner's sinus infection on September 13, 2006. Tr. at 156; see Pet'r's Ex. 7 at 4. But see Pet'r's Ex. 28 at 1 ("I received a prescription from Dr. [Butler] on September 13, 2006, for eight (8) ounces of phenergan with codeine for a sinus infection. . . . I followed my physician's directions and took the prescribed dosage."). Petitioner testified that he suffered from shortness of breath, diminished ability to lift weight, wheezing and congestion. Tr. at 157-58.

[24] The medical record of Petitioner's visit to Dr. Bennett states: "IMPRESSION: Left maxillary and sphenoid sinus disease evidence chronic in appearance" and "A/P 1. CHRONIC COUGH 2. CHRONIC BRONCHITIS 3. POSSIBLE CHRONIC SINUSITIS 4. GERD". The record also states: "ENT REFERRAL TO EVALUATE POSSIBLE ASSOCIATION OF COUGH AND RECENT FINDINGS ON SINUS CT AND PRIOR HISTORY OF UPPER AIRWAY SURGERY AND POSSIBLE RELATION TO CHRONIC COUGH. 2. RESUME NASAL STEROIDS. 3. FOLLOW UP AFTER COMPLETION OF ENT EVALUATION." Pet'r's Ex. 5 at 33-34. As noted in Respondent's Expert Report, the record also indicates that Petitioner had prior back surgery and "throat surgery for scar tissue, UPPP." Pet'r's Ex. 5 at 35.

On re-cross examination, Petitioner testified he had been coughing for "a long time" before he sought medical help for that complaint in October 2007. Tr. at 159; Pet'r's Ex. 5 at 7. He stated that a documented "coughing incident before vaccination," in September 2006 was "totally different." Tr. at 159.

On further re-cross examination, Petitioner testified that he is not a complainer and does not use sickness "as an excuse to not complete things, not perform at a high level." Tr. at 161. As a result, "I probably didn't go to the doctors as often as I should have or as soon as I should have." Id.

2. For Respondent

Dr. Raoul Wientzen

Dr. Wientzen is a specialist in pediatric infectious diseases. Tr. at 163. He has held an appointment in the pediatrics department at Georgetown University School of Medicine ("GUSM") since 1977, and was appointed a Professor in 1997, a position he held until 2009. Resp't's Ex. B at 1; Tr. at 166. Dr. Wientzen was Vice Chairman of the GUSM Department of Pediatrics from 1999 to 2002 and served as Associate Dean of the Georgetown University Medical Center from 2000 to 2002. Resp't's Ex. B at 1; Tr. at 166. He was board certified in pediatrics in 1978 and board certified in pediatric infectious diseases in 1995, allowing this latter certification (which is a seven-year certification) to lapse in 2008. Tr. at 206. He had decided to concentrate his activities at that point on his work at the Rostropovich Foundation, where he had accepted a full-time position in 2002. Tr. at 166-67, 206. Since 2002, Dr. Weintzen has served as Medical Director of the Rostropovich Foundation, which conducts large public health programs in the former Soviet Union and the West Bank of Palestine. Tr. at 164-66.[25]

He has treated many individuals over the age of 18 who had chicken pox or shingles. Tr. at 168. He has served on FDA panels on anti-infectious agents. Id. He has extensive experience with the childhood chicken pox vaccine, which is the vaccine Petitioner received. Tr. at 172.

Dr. Wientzen testified that Petitioner had a lingering sinus infection three weeks to a month before his vaccination, as well as a history of chest pain, "sometimes induced by anxiety," that went back to 2004. Tr. at 172-73; Pet'r's Ex. 2 at 34; Pet'r's Ex. 7 at 9. In addition, Dr. Wientzen testified that at the time of his vaccination Petitioner had a history of high blood pressure, hypertension, high cholesterol, and benign prostatic hypertrophy ("BPH") (enlarged prostate), which put him at risk for urinary tract infections. Tr. at 172-73; Pet'r. Ex. 7 at 3, 9-10. Dr. Wientzen testified that Phenergan with codeine, which had been prescribed for Petitioner's cough/sinus infection, does not cause any immune deficit, and there is no contraindication for vaccination in those individuals who are taking Phenergan with codeine. Tr. at 174. Dr.

[25] Petitioner's counsel elicited the information that Dr. Wientzen's CV lists his state licensures as Maryland, Virginia and Washington, D.C., but that Dr. Wientzen's license in the State of Maryland has lapsed. Tr. at 206-07.

Wientzen noted that both of those medications may decrease the ability to empty the bladder appropriately and fully, and that people with BPH are particularly susceptible to this effect, putting them at risk for UTIs. Tr. at 173-74.

Dr. Wientzen provided a detailed explanation of Petitioner's condition following his vaccination on October 3, 2006, based on Petitioner's medical records. Petitioner presented in the emergency room at Silverdale in the early morning hours of October 8, 2006, with "sort of nonspecific symptoms of fatigue, chills, headache . . . fever and burning on urination." Tr. at 175-76; Pet'r's Ex. 2. The medical record showed Petitioner had flank tenderness to percussion as well as elevated fever, a markedly elevated pulse rate, and a significantly elevated respiratory rate. Tr. at 176-77.

Laboratory results from this hospital admission showed that Petitioner had an abnormal number of white blood cells in the urine, blood in the urine, and a positive nitrite test, with "evidence of bacterial grown in the urine." Tr. at 177. He was diagnosed with pyelonephritis, a reaction to the varicella vaccine, and hypokalemia. Id.[26] He was treated in the ER with morphine for comfort, intravenous fluids and Bactrim, an oral antibiotic effective against urinary tract infections. Tr. at 178.

According to the medical records, Petitioner returned to the ER about 10 hours later, continuing to manifest fever, chills and persistent burning on urination. Pet'r's Ex. 2. A nursing note from this visit indicates that Petitioner had drunk 54 ounces of liquids since leaving the ER that morning, and had urinated five or six times in that 10-hour time period with slight burning, but without large amounts of urine. Tr. at 179. Dr. Wientzen explained, "this is a history of a person who has dysuria and urinary frequency, both of which are symptoms of urinary tract infection." Id. Dr. Wientzen strongly disagreed with Dr. Rumans' opinion that Petitioner's burning on urination was due to dehydration. Tr. at 179, 202-03. Dr. Wientzen explained that Petitioner's records show none of the signs of dehydration, namely dry mouth, sunken eyeballs, and doughy skin. Tr. at 202. In addition, Dr. Wientzen added, "the laboratory evaluation that was done, which is the BUN and the creatinine level, which is the function, which is the test for dehydration, was normal. . . . That laboratory evaluation, to me, closes the door on him having any significant level of dehydration that could theoretically explain th[e] symptoms of dysuria." Tr. at 202.

On his third trip to the emergency room, Petitioner went to the hospital in Bremerton; he had complained to the ambulance medical technicians that he was dissatisfied that the hospital in Silverdale had not admitted him as he requested, and "the ambulance, they said, well, we're not even going back to Silverdale, we're going to take you to Bremerton because Silverdale obviously isn't working." Tr. at 136. Petitioner, in addition to his previous symptoms, had shortness of breath; Dr. Wientzen attributed this symptom to hyperventilation due to stress, and pointed out that Petitioner

[26] "Pyelonephritis" is defined as "inflammation of the kidney and renal pelvis because of bacterial infection." Dorland's at 1559. "Hypokalemia," or hypokaliemia, is defined as "abnormally low potassium concentration in the blood." Id. at 903.

had testified earlier that during his third trip to the emergency room Petitioner was worried he was dying. Tr. at 179.[27] Dr. Wientzen noted that Petitioner was given an anti-anxiety medication, Ativan, to treat his hyperventilation and testified that based on the record that drug appeared to have been effective. Tr. at 180.

Dr. Wientzen agreed that several of the medications that Petitioner had been prescribed are known to have an effect on the immune system; for example, codeine has been shown to "cause a measurable decrease in some cellular functions that immune cells are known to produce," while morphine and Dilaudid (a drug in the same class as morphine), have been shown to be immunosuppressants. Tr. at 181-82.

Dr. Wientzen testified that the evidence in the record of abnormal levels of E. coli in Petitioner's urine was evidence of a urinary tract infection. Tr. at 182-83. In addition, Dr. Wientzen stated that the Petitioner had "a textbook case of urosepsis," based on the definition of that disorder, as follows: "a urinary tract infection [in an individual] who manifests" two of four criteria: (1) temperature abnormalities; (2) elevated pulse rate; (3) elevated respiratory rate; and (4) elevated white blood cell count. Tr. at 183-85. Dr. Wientzen further testified that it is notable that Petitioner need only have two of the above-listed criteria to be diagnosed with urosepsis, but in this case Petitioner met all four of the criteria. Tr. at 185.

Dr. Wientzen denied that Petitioner ever had serum sickness. Tr. at 185. Serum sickness, he explained, is an immunologic reaction that "tends to be quite delayed in time because it is a manifestation of antibody and antigen complexing in the serum, in the blood . . . and then is deposited typically in joints and in the skin." Tr. at 185-86. Petitioner did not have either joint swelling or a rash. Tr. at 186. Further, it would be "impossible for a man to get a vaccine and then two days later have produced so much antibody that he has serum sickness." Id. In addition, Petitioner's laboratory evaluations "do not match serum sickness." Id. "[T]his process, whatever it was, I think it was a urinary tract infection, caused Mr. Coppola to have a low white count, a diving white count, a low platelet count and a low hemoglobin, and serum sickness does not do that." Tr. at 187.

Dr. Wientzen rejected the allegation that Petitioner had an adverse reaction to the varicella vaccination. First, Petitioner's symptoms were completely consistent with "a serious kidney infection." Tr. at 187. Second, adverse reactions to varicella vaccination do not consist of 106 degree fevers "and really sick looking people and rigors that occur in the first 72 hours after the infection of the vaccine." Tr. at 188. He quoted Petitioner's Exhibit 18, a study of 200 vaccinated adults, age 55 and above, in which "there were exactly zero patients who developed fever in the first three days

[27] In his testimony, Petitioner recalled hyperventilating during his second trip to the Emergency Room at Silverdale. Tr. at 134.

postvaccination. . . . [T]his is not an expected reaction to somebody who has been vaccinated." Id.[28]

Dr. Wientzen also referred to the medical records of Petitioner's follow-up visit to his physician on October 20, 2006. At that visit, Petitioner reported doing well except for sleep disturbances caused by his grandson, who was living with him. Tr. at 188-89; see also Pet'r's Ex. 7 at 1. Dr. Wientzen noted that another six months passed before Petitioner again visited a physician (on April 14, 2007), at which time he complained of chest pain caused by an "emotional event" earlier that day that had "caused him to become 'very angry.'" Tr. at 189; Pet'r's Ex. 2 at 34, 37. Dr. Wientzen pointed out that at the time of that visit there were no "notations of ongoing cough, ongoing fatigue, things that he is complaining of now." Tr. at 189. Dr. Wientzen testified that, based on the medical records, he believed the onset of this cough occurred in the three weeks prior to Petitioner's visit to the doctor of October 11, 2007, in the wake of two respiratory illnesses in his family; this was a year after Petitioner received the varicella vaccination. Id.

Dr. Wientzen suggested that the cause of Petitioner's ongoing fatigue was chronic sinus disease. Tr. at 190-92. He rejected the notion that Petitioner was immunocompromised at the time of vaccination due to taking Phenergan with codeine. Tr. at 194. He noted that varicella vaccine is not contraindicated for individuals taking Phenergan with codeine. Tr. at 195. Further, Dr. Wientzen testified that an adverse reaction due to an inoculation in combination with Phenergan and codeine would be readily apparent, as an adverse reaction to varicella vaccine in an immunocompromised individual would produce a severe reaction requiring prolonged hospitalization and antiviral therapy. In contrast, "Mr. Coppola was treated with Bactrim, which has no antiviral activity whatsoever, and he was better in 48 hours. How could he have an immune deficiency and a reaction because of that by the vaccine strain of the varicella virus? I think it's impossible." Tr. at 198.

Similarly, Petitioner's respiratory symptoms were inconsistent with reaction to varicella. Tr. at 198-99. Varicella causes pneumonia, requiring treatment for days. "Varicella virus, varicella vaccine cannot cause a hyperventilation syndrome that's episodic and goes away with Ativan . . . It doesn't work that way. It's a disconnect from reality." Id. There is no medical theory "in any way, shape or form that would connect[] that hypothetical adverse reaction to someone who starts coughing a year later," Dr. Wientzen testified. Tr. at 200.

Dr. Wientzen stated that the Affidavit from Dr. Butler stating that Petitioner "suffered an adverse reaction to the Varicella vaccine" did not change his opinion. Tr. at 200-01; see Pet'r's Ex. 38.

[28] The virus strain from which the varicella vaccine for children was developed has a normal incubation period of 10 to 21 days. Tr. at 196. Even in individuals with a compromised immune system, not one had an adverse effect until the tenth post-vaccination day. Tr. at 197; Pet'r's Ex. 25.

On cross-examination, Dr. Wientzen conceded that there were two inaccuracies on his CV. He did not renew his board certification in pediatric infectious disease in 2009. Tr. at 206. He currently is licensed to practice medicine in only two states, not three. Tr. at 206-07. He also testified that despite his administrative duties, he continues to practice public health medicine for children internationally. Tr. at 207. On further cross-examination, counsel for Petitioner intimated that Dr. Wientzen was biased because Merck, which manufactures the Varivax vaccine, provided Dr. Wientzen's foundation with a $250,000 grant of vaccine in 1999 or 2000 to begin a hepatitis B vaccination program in a small part of Russia. Tr. at 209-10.

Dr. Wientzen conceded that the human immune system becomes less robust after age 60. Tr. at 213.[29]

Dr. Wientzen explained that there are many different types of upper airway illnesses – even the common cold is an upper airway illness – and the upper airway illnesses indicated on the Varivax package insert were not those described in Petitioner's medical records.

> [T]hat's not what Dr. Bennett had in mind when he was talking about the prior surgery that Mr. Coppola had had for sleep apnea, about his gastroesophageal reflux disease and his constant clearing of his throat to clear secretions or specifically about the finding on CAT scan of maxillary and sphenoid sinus changes. They were the upper airway issues Dr. Bennett was concerned with.

Tr. at 226. See Pet'r's Ex. 5; note 24, supra.

Dr. Wientzen conceded that it is possible someone could be "infected with a live varicella vaccine with varicella virus and not experience a rash." Tr. at 228-30. Dr. Wientzen explained that the symptoms that may be reported following vaccination, and included in the package insert, "are not necessarily adverse reaction to the varicella vaccine. . . they're just noted in the interval following the vaccine." Tr. at 231.[30] He testified that varicella vaccine reactions are not likely to differ as between "a four year old child who got the vaccine and a 24 year old, 34 year old, 44 year old man who got the vaccine." Tr. at 233. He conceded that he knew of "no placebo-controlled trials in adults." Id.

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[29] Dr. Wientzen noted that the Petition asserted erroneously that Petitioner was "perfectly healthy" before his vaccination. Tr. at 215; Resp't's Ex. A at 2; see Pet. at ¶ 27. Petitioner's counsel argued that the Petition "was an attorney document" and Petitioner "never said he was perfectly healthy." Tr. at 216. But see, e.g., Granite Const. Co. v. United States, 24 Cl. Ct. 735, 748 (1991) ("a client is bound by his attorneys authorized representations"), citing Fleming v. United States, 648 F.2d 1122, 1127 (7th Cir. 1981).

[30] Dr. Rumans, Petitioner's expert, agreed that conditions reported following vaccination are not necessarily causally related to the vaccination. See Tr. at 63.

Dr. Wientzen testified that Petitioner did have a systemic inflammatory response syndrome, but not as the result of vaccine reaction. Rather, Petitioner's syndrome was a consequence of his urinary tract infection. Tr. at 236. Such a syndrome would resolve within days, as it did in this case. Tr. at 237. Ongoing symptoms would indicate the possibility of other disorders. Id.[31]

E. Medical Literature

1. Petitioner's Medical Literature

Petitioner's Exhibit 10 is an article by a general practitioner in Leeds, U.K., clinically describing herpes zoster infection. There is no persuasive evidence that Petitioner was infected with herpes zoster. See Tr. at 74 (Dr. Rumans's testimony that there is no evidence in the record of a zoster infection), 199 (Dr. Wientzen's testimony that the record does not show a zoster infection).

Petitioner's Exhibit 11 is an article on the possible mechanisms to explain immunosuppressive effects of promethazine (i.e., Phenergan) in clinical and experimental organ transplantation. Pet'r's Ex. 11 at 1.[32] The article does not mention vaccinations, and does not indicate that otherwise healthy individuals taking Phenergan are at risk of vaccine reactions. Dr. Wientzen also gave his expert opinion in testimony that there is no such risk associated with the drug. Tr. at 174.[33]

Petitioner's Exhibit 12 is another article concerning pain from shingles (caused by herpes zoster). Petitioner did not have shingles or the symptoms of shingles. Tr. at 199.

Petitioner's Exhibit 13 is an article concerning the immune responses of adults four years after receiving a live attenuated varicella vaccine. The data concerned duration of the immune response in 202 individuals aged 55 to 87. Pet'r's Ex. 13 at 2. The described reactions did not include the symptoms complained of by the Petitioner in this case. Id. at 5, Table 1.

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[31] Petitioner's Post-Hearing Brief asserted that both sides agree Petitioner suffered SIRS after his vaccination. Pet'r's Post-Hr'g Br. at 6. This is true only if SIRS is construed very broadly to mean any sort of inflammatory response. Petitioner's expert testified that the SIRS resulted from vaccine-induced serum sickness. Respondent's expert testified that serum sickness was out of the question, and Petitioner's SIRS was solely the result of a urinary tract infection.

[32] The pharmaceutical company Wyeth markets promethazine under the brand name "Phenergan." Physician's Desk Reference 3440 (61st ed. 2007).

[33] As noted herein, Petitioner's testimony was inconsistent concerning whether he took the Phenergan that was prescribed. Petitioner affirmatively asserted in his Supplemental Affidavit that he did take the medication, yet during the hearing he stated that he did not remember whether or not he took it. See Pet'r's Ex. 28 at 1; Tr. at 156. However, based on the medical evidence in the record, this appears to be irrelevant, as there is no apparent link between Phenergan and a vaccine reaction. Even if Petitioner did take Phenergan as prescribed for his sinus infection, I find Dr. Wientzen's explanation persuasive, that this might be a factor explaining why Petitioner suffered a UTI. See Tr. at 173-74.

Petitioner's Exhibit 14 is an FDA report on the efficacy, immunogenicity, safety and use of the varicella vaccine. Among the subjects studied, the most common side effects reported were pain and fever. Pet'r's Ex. 14 at 4 (citing package insert). "No severe side effects attributable to vaccination were reported in healthy recipients of Varivax." Id.

Petitioner's Exhibit 15 is an article concerning the immunosuppressive effects of codeine generally. As noted above, there is no persuasive evidence that Petitioner was immunocompromised at the time of his vaccination.

Petitioner's Exhibit 16 is an article exploring the relationship of pain, allodynia and thermal sensation in post-herpetic neuralgia.[34] On the record before me, there is no evidence that Petitioner had herpes; even Petitioner's expert, Dr. Rumans, testified that there is no evidence in the record of zoster infection. See Tr. at 74; see also Pet'r's Ex. 45 at 6; Discussion, infra. As Dr. Wientzen testified, moreover, the sensations with which this article is concerned occur at the sites of nerve damage caused by herpes infection. There is no evident relationship, nor does the article even hint at a relationship, between Petitioner's generalized sensations of freezing and sweating and herpes infection.

Petitioner's Exhibit 17 reported that 10 percent of immunized adults may develop a vaccine-associated rash about a month after immunization, 20 percent may experience mild breakthrough varicella, and less than one percent is predicted to develop zoster. Pet'r's Ex. 17 at 1. None of these symptoms were reported by Petitioner.

Petitioner's Exhibit 18 reported a study of 200 adults ages 55 to 88 years who received the varicella vaccine. The study did not report fever in any of the subjects following vaccination. Pet'r's Ex. 18 at 3 ("No subject had a fever during the 72 h following vaccination."). None of the other conditions reported by the Petitioner were noted in the study.

Petitioner's Exhibit 19 is an update on the varicella vaccine from the American Academy of Pediatrics. The article reported that a temperature higher than 100 degrees Fahrenheit has been reported in 10 percent of adolescents and adults who are immunized with the vaccine. Pet'r's Ex. 19 at 4. No serious adverse events were causally associated with the vaccine, however. Id. Further, no systemic inflammatory response syndrome such as that alleged by Petitioner was reported. Id.

Petitioner's Exhibit 20 reviews the post-licensure safety surveillance for the varicella vaccine, based on data from the Vaccine Adverse Event Reporting System ("VAERS"). Petitioner's alleged inflammatory response syndrome is not described in the article, which also notes the well-established principle that "[m]ost reports cannot prove whether vaccination caused the subsequent symptoms." Pet'r's Ex. 20 at 7.

[34] "Allodynia" is defined as "pain resulting from non-noxious stimulus to normal skin." Dorland's at 51.

Petitioner's Exhibit 21 is another post-marketing safety review. It contained no report of a syndrome like that described by Petitioner and his expert.

Petitioner's Exhibit 22 is an editorial comment concerning "rare serious problems" of varicella vaccination. The commentary reports on cases of severe reactions in children with underlying immune disorders, which is inapplicable to the instant case. Pet'r's Ex. 22 at 1. There was no reliable evidence that Petitioner was immunocompromised.

Petitioner's Exhibit 23 is an article on opioid immunosuppression in the clinical setting. There is no evidence to support any contention that Petitioner was immunosuppressed or that Phenergan with codeine caused him to become immunosuppressed, assuming that Petitioner actually ingested the cough preparation, another fact that is not supported by a preponderance of the evidence.

Petitioner's Exhibit 24 is another article concerning opioids and the immune system. The most susceptible populations are individuals who already are immunosuppressed prior to receiving the vaccination. Pet'r's Ex. 24 at 4. There is no evidence of pre-vaccination immunosuppression in Petitioner's case.

Petitioner's Exhibit 25 is another review of the post-marketing adverse experience reports submitted to Merck, the manufacturer of the varicella vaccine. There was no report of a syndrome like that alleged by Petitioner and his expert.

Petitioner's Exhibit 26 is an article from the Dana Foundation advocating varicella vaccination. The article states that any medical condition that impairs an individual's immune system also predisposes that person to shingles. Pet'r's Ex. 26 at 2. There is no evidence that Petitioner had an impaired immune system or shingles.

Petitioner's Exhibit 27 contains general recommendations from the Centers for Disease Control and Prevention ("CDC") on immunization.

Petitioner's Exhibits 34-37, 39 and 40 are similarly general and provide no support for Petitioner's allegations.

2. Respondent's Literature

Respondent submitted literature supporting Dr. Wientzen's testimony that chronic sinus infection can cause fatigue. Resp't's Exs. A-Supp. 1-3. Respondent also submitted a portion of a chapter from a textbook supporting Dr. Wientzen's testimony that urinary obstruction can increase susceptibility to infection. Resp't's Ex. C at 9. The article identifies "fever (sometimes with chills), flank pain, and frequently lower tract symptoms (e.g., frequency, urgency, and dysuria)" as "classic clinical manifestations" of upper UTI. Id. at 12.

F. Parties' Arguments

1. Petitioner's Argument

After the hearing, Petitioner identified as the primary issue whether the varicella vaccine can cause SIRS 72 hours after its administration in a 56-year old man. Pet'r's Post-Hr'g Br. at 2. Petitioner stated that "[t]he only peer-reviewed literature available on the subject simply states that adverse reactions to the varicella vaccine have not been reported within seventy-two hours in petitioner's age group." Id.

Petitioner maintained that the opinion of Petitioner's expert, "in agreement with the medical record and three treating physicians," is sufficient to establish entitlement. Id. at 2.[35]

Petitioner stated that he presented to the ER in Silverdale five days after receiving the varicella vaccine. Id. at 2. He quoted the notes of Dr. Dahlgren, who indicated that Petitioner was suffering from a vaccine reaction. Id. Dr. Dahlgren also found that Petitioner had a UTI and prescribed Bactrim to treat it. Id. at 3. Dr. Dahlgren stated that he believed that the UTI had "very little to do with his symptoms." Id.

When Petitioner was seen the next day at the ER in Bremerton he was treated by Dr. Moore, who diagnosed flu syndrome, suspected systemic reaction to varicella vaccination, and leukopenia, "which I suspect is secondary to his systemic viral reaction to varicella vaccination." Id. at 3.

Petitioner notes Dr. Butler's diagnosis of "[a]dverse side effect to either varicella immune globulin or varicella immunization . . . ." Id. at 4. During his hospital stay, Petitioner suffered from shortness of breath, wheezing and rhonchi. Id.

Petitioner states that he continues to suffer from the ill effects of his vaccine reaction. Id. at 4. "Mr. Coppola continues to suffer from persistent fatigue, shortness of breath and variations in temperature sensation." Id.

Petitioner maintains that "varicella vaccinations are well known to cause febrile illness, shortness of breath and respiratory illness." Id. at 6 ("[t]he studies are legion"). He also relies on the "clinical experience of three treating physicians and petitioner's

[35] Petitioner disparaged Dr. Wientzen's qualifications. See, e.g., Pet'r's Post-Hr'g Br. at 2 ("Respondent's expert, with no serious clinical experience with adults, disagrees."), 7 ("Respondent submitted the expert report of a pediatrician who has not practiced full-time since 2000 (or at all since 2009), accepted money for speaking engagements from large pharmaceutical companies while maintaining an active practice of only testifying for respondent."). Based on all the evidence, I have assessed Dr. Wientzen's qualifications. I find that he has some experience treating adults, albeit not nearly as much as he has had over the course of a professional lifetime spent treating sick children. See Tr. at 163-68, 210-12. His most important qualification is that he knows expertly how the varicella vaccine Petitioner received affects the human body. See Tr. at 167, 171; Resp't's Ex. B. The record contains no persuasive evidence that the effects differ as between adults and children. See Tr. at 233.

expert." Id. at 5. He states that "the only peer reviewed medical article on the subject supports the timing of the onset of petitioner's fever." Id. at 6. He asserts that Respondent has offered no reliable medical or scientific evidence "to support its alternative causation theory." Id. at 5.

Petitioner relies on Dr. Rumans's testimony that Petitioner did not suffer from a "true urinary infection." Id. at 8. He states that his alleged urinary tract infection "resolved three days before he was well enough to leave the hospital" and that "there was absolutely no evidence in any of the medical record[s] of any systemic infection" due to E. coli. Id.

In further support of his argument that he has sufficiently demonstrated a causal link, Petitioner points out that "febrile illness, shortness of breath and respiratory illness are all clearly warned about in the prescription drug label for Varivax vaccine." Pet'r's Reply to Resp't's Post-Hr'g Br. at 1.

2. Respondent's Argument

Respondent reviewed Petitioner's medical records, including the evidence from Dr. Bennett, a treating physician Petitioner consulted for his history of respiratory ailments. Resp't's Post-Hr'g Br. 1-5, May 11, 2011, ECF No. 50. Respondent noted that Dr. Bennett believed the etiology of Petitioner's respiratory "symptoms was 'likely upper airway' in nature," and he scheduled a sinus scan "to rule out 'occult sinusitis.'" Id. at 5 (quoting Pet'r's Ex. 5 at 32, 36). The scan, conducted on July 11, 2008, showed evidence of "'left maxillary and sphenoid sinus disease,' which appeared to be chronic." Id. (quoting Pet'r's Ex. 5 at 25). Dr. Bennett planned to refer Petitioner to an ear, nose and throat specialist. Id. The record contains no evidence of treatment by an ENT specialist; thus it is unclear if Petitioner followed up on this medical finding.

Respondent maintained that Petitioner failed to establish any of the three elements of causation set forth in Althen. Respondent argued that the evidence established Petitioner was suffering from a UTI in the days following his vaccination. Respondent contended that Petitioner's expert, Dr. Rumans, was unable to establish a reliable medical theory explaining how the varicella vaccination could have caused Petitioner's symptoms.

Based on the lack of any link between Petitioner's initial and later symptoms, Respondent argued that the Vaccine Act's six-month durational requirement had not been met. Respondent maintained that there was no evidence of an appropriate temporal relationship between vaccination and the symptoms for which Petitioner eventually sought care in 2007, six months after vaccination. Respondent rejected the suggestion that those symptoms were attributable to post-herpetic neuralgia, since there is no evidence Petitioner had a herpes infection at the time of his symptoms.

Respondent argued that statements in the record by treating physicians theorizing that Petitioner's vaccination caused him illness do not offer any viable

medical theory or evidence of a "'logical sequence of cause and effect.'" Resp't's Post-Hr'g Br. at 16 (citing and quoting Althen, 418 F.3d at 1278). Instead, Respondent maintained, the physicians' opinions seemed to rely primarily on the temporal relationship between vaccination and the onset of Petitioner's symptoms. Respondent noted that such temporal proximity does not establish causation. Id. at 16 (citing Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983)).

III. DISCUSSION

A. Petitioner's Burden of Proof

To establish causation-in-fact, a petitioner must show by a preponderance of the evidence that but for the vaccination he would not have been injured, and that vaccination was a substantial factor in bringing about the injury. Cedillo v. Sec'y of Dep't of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Shyface v. Sec'y of Dep't of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir.1999).[36] Proof of actual causation must be supported by a sound and reliable "medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Moberly ex rel. Moberly v. Sec'y of Dep't of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)); see also Grant v. Sec'y of Dep't of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir.1992) (medical theory must support actual cause). "[A] petitioner must demonstrate the reliability of any scientific or other expert evidence put forth to carry this burden. . . . Expert testimony, in particular, must have some objective scientific basis in order to be credited by the Special Master." Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54-55 (2011) (citing Moberly, 592 F.3d at 1322; Cedillo, 617 F.3d at 1339; Terran ex rel. Terran v. Sec'y of Dep't of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999)).

Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." Knudsen, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove the case, and "close calls" regarding causation must be resolved in favor of the petitioner. Althen, 418 F.3d at 1280.

Petitioner's burden is to show that the vaccination brought about his 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

[36] Petitioner does not allege a "Table" injury. Pet'r's Post-Hr'g Br. at 1; "The Table lists symptoms and injuries associated with each listed vaccine and a timeframe for each symptom or injury." de Bazan v. Sec'y of Dep't of Health & Human Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008). If a listed symptom occurs after vaccination within the times specified, causation is presumed. Id. Injuries not listed on the Table or injuries suffered outside the specified times following vaccination are deemed off-Table injuries, and causation is not presumed. Id.

and injury. Althen, 418 F.3d at 1278. If Petitioner succeeds in establishing a prima facie case of causation, the burden then shifts to Respondent to prove alternative causation by a preponderance of the evidence. Id.; see Cedillo, 617 F.3d at 1335 (citing Walther v. Sec'y of Dep't of Health & Human Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007)). If Petitioner fails to establish a prima facie case of causation, the burden does not shift. Doe 11 v. Sec'y of Dep't of Health & Human Servs., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010).

In evaluating whether a petitioner has presented a legally probable medical theory, "the special master is entitled to require some indicia of reliability to support the assertion of the expert witness." Cedillo, 617 F.3d at 1339 n.3 (quoting Moberly, 592 F.3d at 1324). A special master is not required to rely on a speculative opinion that "'is connected to existing data only by the ipse dixit of the expert.'" Snyder ex rel. Snyder v. Sec'y of Dep't of Health & Human Servs., 88 Fed. Cl. 706, 745 n.66 (2009) (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)); accord, e.g., Cedillo, 617 F.3d at 1339 n.3 ("'[a]n expert opinion is no better than the soundness of the reasons supporting it'") (citing and quoting Perreira v. Sec'y of Dep't of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994)).

Assessing the reliability of an expert opinion in Vaccine Act cases can be challenging, because often there is little supporting evidence for the expert's opinion. See Althen, 418 F.3d at 1280 (noting that the "field [is] bereft of complete and direct proof of how vaccines affect the human body"). Consequently, most expert opinions extrapolate from existing data and knowledge. The weight to be given to an expert's opinion is based in part on the size of the gap between the science and the opinion proffered. Cedillo, 617 F.3d at 1339. Evidence should be viewed under the preponderance standard as it is understood in civil courts and "not through the lens of the laboratorian." Andreu ex rel. Andreu v. Sec'y of Dep't of Health and Human Servs., 569 F.3d 1367, 1380 (Fed. Cir. 2009).

With respect to the existence of non-vaccine related medical conditions, Respondent need not establish "alternative causation" to prevail. See 42 U.S.C. § 300aa-13(a)(1)(A)-(B). A special master, however, may consider evidence of factors unrelated to vaccination in deciding whether the petitioner has established a prima facie case. Doe 11, 601 F.3d at 1351-52; see Cedillo, 617 F.3d at 1335 (citing Walther, 485 F.3d at 1151).

By the same token, a Petitioner is not required to negate the existence of an alternative cause as part of the prima facie case. Doe 11, 601 F.3d at 1358 ("A petitioner's failure to meet his burden of proof as to the cause of an injury or condition is different from a requirement that he affirmatively disprove an alternative cause." (citing de Bazan, 539 F.3d at 1353-54)). Here, Respondent need not establish that Petitioner's acute injuries were caused by his UTI; she may present evidence, however, to establish that the record concerning a serious UTI weakens Petitioner's attempt to establish a prima facie case of vaccine injury.

B. Analysis

1. Althen Prong 1

Under Althen prong 1, a petitioner must set forth a reliable theory explaining how the vaccine could cause the injury of which the petitioner complains. This requirement has been interpreted as "'can [the] vaccine(s) at issue cause the type of injury alleged?'" Pafford v. Sec'y of Dep't of Health & Human Servs., 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (quoting Pafford v. Sec'y of Dep't of Health & Human Servs., No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004)). Although the theory of causation need not be corroborated by medical literature or epidemiological evidence, the theory must be sound, reliable, and reputable – in other words, the theory need not be scientifically certain, but it must have a scientific basis. See id. at 1379-80.

The record in this case discloses no coherent theory of vaccine injury. Certainly, there is no evidence of a reliable theory of vaccine injury. When asked how the varicella vaccination would result in fatigue on an ongoing basis, Petitioner's expert responded, "I'm afraid I don't have a theory . . . ." Tr. at 69.[37] He identified Petitioner's post-vaccination injury as the result of "systemic inflammatory syndrome," but admitted that it "resolved in Mr. Coppola in several days." Tr. at 71-72. Nor could he explain how the alleged effects of the syndrome could result in symptoms long after its resolution. "I do not know, ma'am. I'd have to honestly say I don't know." Tr. at 72-73.[38]

Dr. Rumans acknowledged that there is no medical literature in the record to support the theory that the varicella vaccination can cause SIRS, and Dr. Rumans further acknowledged that he "do[es] not have any scientific data." Tr. at 71-73. Further, Dr. Rumans acknowledged that serum sickness is an illness of limited duration, as illuminated in the following exchange at the hearing:

> Q: Okay. Getting back to serum sickness for a minute, isn't serum sickness self-limited and benign, generally, with allergic and immunologic reaction?
>
> A: It is generally felt that people recover from that, and I'm not attempting to suggest that Mr. Coppola has ongoing evidence of serum sickness.

Tr. at 59.

[37] Indeed, Petitioner's expert testified that "fatigue can be, it can be a symptom of so many conditions, you wouldn't believe it." Tr. at 59.

[38] Dr. Rumans also declined to diagnose Petitioner as suffering from chronic fatigue syndrome and myofascial pain, both of which the Petitioner claimed and argued were caused-in-fact by his varicella vaccination. See supra; see also Tr. at 66, 68-69; Pet. at ¶¶ 2, 28.

Petitioner's personal physician, Dr. Butler, submitted a skeletal Affidavit that is silent concerning a theory of vaccine causation. Pet'r's Ex. 38.[39] Dr. Butler's Affidavit does not describe in any way the nature of the alleged vaccine reaction, or a theory concerning how the vaccine could have caused the symptoms of which Petitioner complains. It therefore provides no support for Petitioner's allegations of long-term fatigue, weakness, temperature spikes, generalized aching, cough, and other ailments due to vaccination.

Nor is there anything in the notes of the ER physicians who treated Petitioner that could be construed as a theory of vaccine causation, much less a reliable theory. See, e.g., Moberly, 592 F.3d at 1323-24 (upholding Special Master's finding that acknowledgment by treating physicians of a temporal relationship between petitioner's symptoms and her DPT vaccination, along with their notes that the DPT vaccination could be a possible cause of these symptoms, did not amount to a theory of causation such that an award was reasonable).

The medical literature also does not present a cognizable theory. None of the literature identifies an inflammatory syndrome such as Petitioner alleges as a consequence of varicella vaccination.

Petitioner relies on the Varivax package insert, as well as "a number of studies" to maintain that "febrile illness, shortness of breath and respiratory illness are all clearly . . . side effects of varicella vaccination." See Pet'r's Post-Hr'g Br. at 1-2. The most frequently reported adverse experiences listed on the package insert on which Petitioner relies, however, are not causally linked. See Tr. at 63; see also Pet'r's Ex. 36.[40] Further, the events listed on the package insert do not include the inflammatory syndrome alleged by Petitioner. Petitioner's expert forthrightly acknowledged as much. Tr. at 71.

Petitioner cites several of his exhibits as supporting the proposition that "Varicella vaccines are well known to cause febrile illness, shortness of breath and respiratory illness." Pet'r's Post-Hr'g Br. at 6 (citing Pet'r's Exs. 8, 16-19, 21 and 25). This is a mischaracterization of the literature contained in these exhibits. The literature cited is clear that no causal association has been demonstrated between vaccination and any of the observed conditions. See, e.g., Pet'r's Ex. 19 at 4 ("In most cases, data are

[39] The Affidavit states in its entirety:

> "I, Michael J. Butler, M.D., do swear and affirm as follows:
> 1. I am over the age of 18.
> 2. I am a physician that has and does provide medical treatment to Mr. Lawrence Coppola. As a result I am fully knowledge[e]able about the facts and circumstances surrounding Mr. Coppola's health and well-being.
> 3. I hold the opinion to a reasonable degree of medical certainty that Mr. Coppola suffered an adverse reaction to the Varicella vaccine."

[40] "[T]he most frequently (≥1%) reported adverse experiences, without regard to causality, are listed in decreasing order of frequency . . ."

insufficient to determine a causal connection."). The literature cited by Petitioner reports short-term symptoms of fever and/or rash, or symptoms in individuals who were infected with a strain of VZV (varicella zoster virus), or who had unrelated serious health issues at the time of vaccination. See Pet'r's Exs. 8, 16-19, 21, 25.[41, 42] These reports on their face furnish no support for the enduring symptoms Petitioner ascribes to his alleged vaccine reaction. As discussed by Dr. Wientzen, they simply do not fit the facts of this case.

Dr. Wientzen explained that although the vaccine package insert "talks about certain upper airway conditions potentially following in the wake of the varicella vaccine," the manufacturers were likely referencing "an entire range of . . . upper airway illnesses." Tr. at 226. For example, "the common cold is an upper airway illness. People who get the Varivax vaccine can go on to get a common cold five days later. It's well-recognized in the package insert, and well-recognized by practicing physicians." Id. Petitioner's symptoms, as described by his personal physician, were decidedly different. In Petitioner's case, Dr. Wientzen testified, "that's not what Dr. Bennett had in mind." Id. Dr. Bennett "was talking about the prior surgery that Mr. Coppola had had for sleep apnea, about his gastroesophageal reflux disease and his constant clearing of his throat to clear secretions or specifically about the finding on CAT scan of maxillary and sphenoid sinus changes." Id. It was these "upper airway issues Dr. Bennett was concerned with." Id.

A thorough review of the record, in sum, reveals no reliable theory explaining how varicella vaccination could have caused the symptoms of which Petitioner complains. Petitioner's belief, without more, does not satisfy the required showing. See 42 U.S.C. § 300aa-13; see also Keith v. Sec'y of Dep't of Health & Human Servs., 55 Fed. Cl. 791, 792 (2003) ("unsubstantiated claims of a petitioner, without more, do not entitle a person to compensation").

Acknowledging the absence of probative evidence in the medical literature, Petitioner contends that "this case rests on the clinical experience of the experts." Pet'r's Post-Hr'g Br. at 2. Petitioner's argument misapprehends the requirements for proving vaccine causation.

Absence of medical literature does not preclude a finding of vaccine causation, but it is evidence that must be considered, along with all the other evidence in the case. If a petitioner can present a scientifically reliable theory supporting vaccine causation without medical literature then, to be sure, no supporting medical literature is required. See Andreu, 569 F.3d at 1379; Capizzano v. Sec'y of Dep't of Health & Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006). In the absence of medical literature, however, there still must be some reliable scientific basis to support causation. See Moberly, 592 F.3d at 1322; see also Cedillo, 617 F.3d at 1339. There is none in this case.

[41] See Medical Abbreviations at 342.

[42] Petitioner has not been found to be infected with zoster virus. See Discussion, supra.

2. Althen Prong 2

a. Evidentiary standards

The second prong of Althen requires a petitioner to prove "'a logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" Andreu, 569 F.3d at 1374 (quoting Althen, 418 F.3d at 1278). The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." Knudsen, 35 F.3d at 548-49. Along those lines, a petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathologic markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second Althen factor. Id. at 1325-26; see Andreu, 569 F.3d at 1375-77.

"[T]reating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect shows[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280); see Andreu, 569 F.3d at 1375-76. The testimony of treating physicians concerning vaccine injury therefore is afforded extra weight when balancing the evidence. See Andreu, 569 F.3d at 1375-76. A special master may find that a petitioner has established causation based solely on a treating physician's opinion that a vaccination was causally linked to the vaccinee's injury, if the special master finds the opinion to be both reliable and persuasive. Moberly, 592 F.3d at 1324-25; Andreu, 569 F.3d at 1375-76. The opinions of treating physicians are not conclusive of the issue, however. See 42 U.S.C. §300aa-13(b)(1) ("Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court."); Broekelschen v. Sec'y of Dep't of Health & Human Servs., 618 F.3d 1339, 1346-49 (Fed. Cir. 2010) (affirming special master's finding that Petitioner's injury was not transverse myelitis, notwithstanding the diagnosis of treating physician); Cedillo, 617 F.3d at 1348.

In Andreu, the Federal Circuit found that treating physician testimony was sufficient to establish a logical sequence of cause and effect. The physician in that case, a pediatric neurologist, testified "unequivocally" that he believed the vaccination caused the injury alleged – a seizure disorder – and he explained the rationale for his conclusion: he could identify the cause of seizures in 70 to 75 percent of his patients, but he was unable to find a cause for the vaccinee's seizures. Andreu, 569 F.3d at 1375-76. He further explained that the timing was consistent with a vaccine-caused seizure, which led him to conclude that the vaccine caused the seizure. Id. at 1376. His testimony was supported by the testimony of another treating physician. A second treating physician explained that some evidence supported finding that the vaccine caused the seizure, but he was reluctant to attribute causation to the vaccine. Id. at 1376-77.

The underlying facts in Moberly were very similar to Andreu. In Moberly, however, the Federal Circuit found the treating physicians' opinions were insufficient to establish causation. The Federal Circuit upheld the lower courts' findings that none of the vaccinee's treating physicians offered a reliable statement that the vaccine caused the injury. The Moberly court contrasted Andreu, stating that "there was direct testimony from Andreu's treating physicians stating 'unequivocally' that the [vaccination] caused his seizures," whereas in this case "there was no treating physician evidence that supported the claim of causation." Moberly, 592 F.3d at 1324-25. Instead, the notations in the "medical records regarding the temporal proximity of the [vaccination] to the seizures were all speculative." Id. at 1323.

In Broekelschen, the medical records contained conflicting diagnoses. The Federal Circuit upheld the special master's finding that "certain evidence, such as the medical records and doctors' notes, were not as persuasive as other evidence because the treating doctors were 'not consistent in their diagnoses.'" Broekelschen, 618 F.3d at 1347 (quoting Broekelschen v. Sec'y of Dep't of Health & Human Servs., No. 07-137V, 2009 WL 440624, at *43 (Fed. Cl. Spec. Mstr. Feb. 4, 2009). The Federal Circuit also upheld the special master's finding that a detailed discharge summary by one doctor was more persuasive than notes by other doctors that did "'not provide any reasoning for their statements.'" Broekelschen, 618 F.3d at 1347 (quoting Broekelschen, 2009 WL 440624, at *11).[43]

In light of on Andreu and subsequent Circuit decisions, it appears that the weight to be afforded the opinion of a treating physician varies according to the nature of the views expressed and the facts of the particular case. Consistent with the flexible practice under the Vaccine Act, such opinions are not dispositive. See 42 U.S.C. §§ 300aa-13 (a)(1) (requiring an award based "on the record as a whole"); 13(b)(2) (stating that conclusions in the medical record as to vaccine causation "shall not be binding on the special master or court"). Such opinions may be more or less persuasive, depending on the circumstances of the case. A variety of circumstances bears on a special master's decision with respect to treating physicians' opinions.

Among the circumstances that might be considered: firmness of the treating physician's opinion; extent of the treating physician's experience with the vaccinee; pertinence of the treating physician's specialty; standing of the treating physician in the medical profession; and consistency of the treating physician's opinion with the medical record. Also pertinent, according to the Federal Circuit, is the strength of petitioner's showing on the other Althen prongs. For example, where a petitioner produces evidence sufficient to meet the requirements of prongs 1 and 3, a court may rely solely

[43] But see Campbell v. Sec'y of Dep't of Health & Human Servs., 97 Fed. Cl. 650, 667 (2011) ("Any expectation that treating physicians will record the precise biological theories behind their belief that a patient's condition was caused by a particular trigger is discordant with the reality of medical treatment. Doctors are and must be concerned with treating patients, not with articulating the precise biological theories upon which they base their diagnoses.").

on the testimony of a treating physician to establish prong 2. See Moberly, 592 F.3d at 1324-25. See also Andreu, 569 F.3d at 1377 n.4 (petitioners presented evidence from a well-qualified medical expert in support of prong 1).

For the reasons discussed below, I am not persuaded by the notations of treating physicians in this medical record that there is a logical sequence of cause and effect between Petitioner's vaccination and his medical complaints.

b. Treating Physician Notations

(1) Petitioner's Emergent Symptoms

It follows from the preceding discussion that the notations of the physicians who treated Petitioner on an emergent basis require careful consideration under this element of the Althen test for causation-in-fact. The treating physicians' opinions in this instance do indeed provide some reliable evidence of logical cause and effect. Examination of these opinions in light of all the facts and circumstances demonstrated in this case indicates, however, that the physicians who saw Petitioner at the Silverdale and Bremerton facilities relied principally on the temporal relationship between the vaccination and Petitioner's illness. See Pet'r's Exs. 2, 3. Such a temporal relationship exists in most cases in the Vaccine Program but is insufficient, without more, to provide preponderant evidence of causation.[44]

In his Emergency Department Report – which was excerpted in Petitioner's Post-Hearing Brief – Dr. Dahlgren, the physician who first treated Petitioner at the emergency room for his acute symptoms, stated:

> I discussed with [Petitioner] that I think he is probably dehydrated and I would assume that his myalgias and fever, shakes and chills are febrile illness because of the varicella vaccine. However, when he urinated his urine shows 2+ leukocytes, positive nitrites and positive blood. I then ordered a urine culture and sensitivity, CBC, basic metabolic panel and a blood culture.
>
> I discussed with him that it is possible this fever is purely from a urinary tract infection and pyelonephritis, but that would be an awfully significant coincidence for that to come on after a varicella vaccine when he has never had a urinary tract infection in the past. I think a more likely explanation is that the myalgias, fever and chills, and essentially all of his

[44] In Capizzano the Federal Circuit cautioned that the fact that a physician's diagnosis "may have relied in part on the temporal proximity" of a vaccinee's "injuries to the administration of the vaccine is not disqualifying." 440 F.3d at 1326. It appears nevertheless that temporal proximity, without more, even when relied upon by a treating physician, does not provide conclusive evidence of causation. The fact of temporal proximity must be considered in the overall, careful assessment of a treating physician's opinion.

> symptoms are probably from the varicella vaccine, but because of feeling ill he is eating and drinking poorly, he is somewhat dehydrated, there is lessened urine flow, some stagnation of urine, and because of that he has a urinary tract infection which has nothing to do with the rest of his symptoms. If his white count comes back very high, then I will change my opinion and think that it may be more from the kidney infection, but if his white count comes back normal, then I would be that much more suspicious that it is from the varicella.

Pet'r's Ex. 2 at 11.[45] In context, it appears that Dr. Dahlgren recognized the possibility that Petitioner's symptoms were caused entirely by a UTI, but he was swayed by the temporal connection with vaccination to conclude that a vaccine reaction was more likely. In addition, Dr. Dahlgren's notes indicate that Petitioner, in his initial interview, explained his symptoms to Dr. Dahlgren in the context of his recent vaccination. See Pet'r's Ex. 2 at 10. Petitioner himself seems to have associated the onset of his symptoms with the recent event of his vaccination.[46]

Dr. Moore, the second physician to treat Petitioner, also was apparently without special competence in immunology or infectious disease. The Emergency Department Report by Dr. Moore states: "He has taken Vicodin and has taken Bactrim for a presumed urinary tract infection, as diagnosed a few days at Silverdale." Pet'r's Ex. 3 at 15.

During his Bremerton admission, Petitioner also was seen by his primary care physician, Dr. Butler, whose notes state similarly: "Final Diagnoses: 1. Flu Syndrome, 2. Systemic Reaction to varicella Vaccination." Pet'r's Ex. 3 at 11.

The comments of the three doctors, in context, do not merit the same weight as the "unequivocal" testimony of vaccine causation from the experts in Andreu. The treating doctors' notations were somewhat equivocal. The doctors recognized that Petitioner had a UTI, for which they treated him. Dr. Dahlgren, in particular, confirmed that all of Petitioner's symptoms could have been caused by his UTI, and the only reason Dr. Dahlgren doubted that they were attributable to Petitioner's UTI is the coincidence of his recent vaccination. This is a conclusion based on the post hoc ergo propter hoc line of reasoning that has been held not to be persuasive in vaccine injury cases. See Pafford v. Sec'y of Dep't of Health & Human Servs., No. 01-0165V, 2004 WL 1717359, at *9 (2004), aff'd, 451 F.3d 1352 (Fed. Cir. 2006).

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[45] Petitioner's white blood count was abnormal, confirming a UTI. See Tr. at 177; Resp't Ex. A at 3.

[46] In Shyface, the Federal Circuit held that vaccination was a substantial factor in causing the vaccinee's high fever and death. The Court held that where both vaccination-related and non-vaccination-related factors caused injury, petitioners were entitled to compensation. 165 F.3d at 1353. In this case I find that, based on a preponderance of the evidence, Petitioner's UTI was the sole substantial cause of his acute symptoms. There is no persuasive evidence that vaccination played any role in his acute symptoms. Petitioner has failed, moreover, to establish any relationship between vaccination and his symptoms in later years. Accordingly, there is no occasion here to apply the holding in Shyface.

The doctors characterized Petitioner's illness as a "flu syndrome," not a hypersensitivity reaction, as proposed by Dr. Rumans. "Flu syndrome" does not fit either of the theories proposed by Petitioner's expert to explain the alleged vaccine reaction. The diagnosis therefore lends no additional weight to the case for vaccine causation.

None of the treating physicians were specialists in immunology or infectious diseases. Notwithstanding that they were treating physicians, they were not treating specialists, to whose opinions I would assign much greater weight. In addition, two of the three doctors had no ongoing relationship with Petitioner. They did not treat him on a regular basis and were not familiar with his overall medical condition. Consequently, there is less reason to give special weight to their statements concerning Petitioner's alleged vaccine injury.

The doctors' notes reflect working diagnoses for the purpose of emergency treatment of Petitioner's serious, acute symptoms. In an emergent treatment setting, the doctors recognized the possibility of a vaccine reaction because of the proximity in time to vaccination, but they also recognized, based on his symptoms and his test results, that Petitioner was suffering from a UTI. The doctors treated him appropriately and effectively for the infection, confirming the existence of a non-vaccine related condition that could explain all of Petitioner's symptoms.[47]

Petitioner's personal physician, Dr. Butler, also prescribed medication for symptoms that actually pre-existed Petitioner's emergency hospital admissions. Pet'r's Ex. 3 at 2. Pre-existing symptoms cannot logically have been caused by vaccination. Dr. Dahlgren and Dr. Moore apparently were unaware of Petitioner's pre-existing disorders and the medications he had been taking before his vaccination. In Dr. Wientzen's opinion, these facts made it less likely that Petitioner's symptoms were caused by a vaccine reaction. See Resp't's Ex. A at 5 (noting 10 different medical conditions).

For all these reasons, the evidence regarding Petitioner's treating physicians, while providing some reliable evidence of vaccine causation, ultimately is unpersuasive.

(2) Petitioner's Long-term symptoms

Beyond the issue of causation of Petitioner's acute symptoms, the ER physicians' diagnoses furnish no support for the ongoing ailments Petitioner alleges as grounds for compensation. Significantly, the diagnoses by Dr. Dahlgren on Petitioner's

[47] Dr. Wientzen noted that Petitioner "showed flank tenderness to percussion" when he was examined on October 8, 2006, a symptom consistent with a UTI. Resp't's Ex. A at 3. Dr. Rumans confirmed that Petitioner showed flank tenderness to percussion. Tr. at 26. Dr. Dahlgren, too, noted Petitioner "is slightly tender over the flanks to percussion" even though there was [n]o flank tenderness to palpation." Pet'r's Ex. 2 at 11. Petitioner's Post Hearing Brief, however, ignores this medical evidence, stating flatly that Petitioner had "no . . . flank pain." Pet'r's Post-Hr'g Br. at 8.

first two trips to the emergency room indicated that any reaction to the varicella vaccine was presumed to be of limited duration. Under the category "Diagnoses" on the Silverdale "Emergency Department Report" from Petitioner's first ER visit, Dr. Dahlgren lists "Acute febrile illness secondary to varicella vaccine." Pet'r's Ex. 2 at 11 (emphasis added).[48] Under the category "Diagnoses" on the Silverdale "Emergency Department Report" from Petitioner's second ER visit, Dr. Dahlgren lists "Acute and severe fever and myalgias secondary to varicella vaccine." Pet'r's Ex. 2 at 30 (emphasis added). In accordance with these diagnoses, Petitioner's emergent symptoms resolved within a few days.

Similarly, the record discloses no notations from Dr. Moore or Dr. Butler that connect the acute events in October 2006 with the symptoms Petitioner experienced years later. Dr. Butler's notes from subsequent visits actually disprove such a connection. Pet'r's Ex. 7 at 1.[49]

Petitioner asserts that his case rests on the "opinion[s] of three treating physicians." See Pet'r's Reply to Resp't's Post-Hr'g Br. at 3. It is a shaky foundation, even with the added evidentiary boost that is provided by Andreu and Capizzano. The medical record suggests that the treating physicians' identification of a causative link was based on little more than the temporal proximity between the vaccine and Petitioner's acute symptoms. See Tr. at 137 ("I told them about getting the vaccine, and he said, well, I think you're having a reaction to it. I'm not sure what doctor it was, but somebody there told me that.")

Neither the treating physicians' notes nor Dr. Butler's Affidavit furnish persuasive evidence that vaccination caused the various ailments and syndromes Petitioner has alleged. In essence, Dr. Rumans's opinion stands as the only medical support for those allegations.

c. Dr. Rumans's Opinion

(1) Petitioner's Emergent Symptoms

Dr. Rumans testified that in the days following vaccination Petitioner

> likely . . . experienced a type of what we call serum sickness-like reaction in which people do, in fact, develop significant fever, . . . prominent arthralgias, . . . myalgias, . . . leukopenia, thrombocytopenia, and . . . an inflammatory response that we refer to, really which Mr. Coppola clearly

[48] "Acute" is defined as "having a short and relatively severe course." Dorland's at 24.

[49] See, e.g., Pet'r's Ex. 3 at 2 ("He remained afebrile after the first 24 hours and had no other real complications. Developed no rash, nausea or vomiting."); see also Pet'r's Ex. 7 (a "Hospital follow up" written by Dr. Butler on October 20, 2006: "[H]e has had no problems with fever or chills or episodes of shortness of breath or anxiety. Overall he is feeling much better since his hospitalization."). Dr. Rumans agreed that on October 20, 2006, when Petitioner was evaluated following his post-vaccination hospitalizations, he reported no problems with fever, chills, shortness of breath or anxiety. Tr. at 78-79.

> exhibited, and that is he had what's called systemic inflammatory response syndrome.

Tr. at 36. Dr. Rumans seemed to conflate the terms "serum sickness" and "systemic inflammatory response syndrome" throughout his testimony, and seemed generally to be averring that the former can lead to a development of the latter, without providing any explanation or scientific data in support of this link. See Tr. at 36-37. Dr. Rumans characterized serum sickness as a "hypersensitivity reaction," without indicating how the Petitioner's medical condition provided evidence of such a reaction. Id. at 37. See Moberly, 592 F.3d at 1322 (requiring "a reputable medical or scientific explanation that pertains specifically to the petitioner's case").

Dr. Rumans's opinion is not supported by the actual medical record and, in some ways, conflicts with known principles of medical science.[50] There were large gaps in Dr. Rumans's testimony. For example, he could not explain why Petitioner, who allegedly suffered an ongoing systemic inflammatory syndrome resulting from vaccination, displayed no symptoms of that syndrome for six months after he recovered from his serious urinary tract infection. Tr. at 72-73.

As discussed above, Dr. Rumans was unable to answer many of the questions raised by the medical record and candidly testified that he simply did not have an answer. Additionally, he contradicted himself several times, which perhaps was indicative of his difficulty in diagnosing the Petitioner, but in any event such contradictions and expressions of uncertainty make his testimony less persuasive than that of Dr. Wientzen. See, e.g., Tr. at 74 (Petitioner's illness was inconsistent with zoster infection); Pet'r's Ex. 45 at 6 (Petitioner suffered from post-infection zoster symptoms).

As Dr. Wientzen pointed out, Petitioner's symptoms were not consistent with serum sickness. Serum sickness, he explained, is an immunologic reaction that "tends to be quite delayed in time because it is a manifestation of antibody and antigen complexing in the serum, in the blood . . . and then is deposited typically in joints and in the skin." Tr. at 185-86. Petitioner did not have either joint swelling or a rash. Tr. at 186. Further, it would be "impossible for a man to get a vaccine and then two days later have produced so much antibody that he has serum sickness." Id. In addition, Petitioner's laboratory evaluations "do not match serum sickness." Id.

Dr. Wientzen testified that the scenario depicted by Dr. Rumans was not only improbable – it was impossible. Tr. at 179-80, 186, 198-99. Dr. Wientzen testified that

> Varicella virus, varicella vaccine cannot cause a hyperventilation syndrome that's episodic and goes away with Ativan . . . only to return six hours later, 10 hours later when the patient has another chill and

[50] I respect Dr. Rumans's qualifications and his sincerity, and I appreciate his participation in the Vaccine Program. I simply conclude that his opinions are not supported by the record.

> hyperventilates again and gets another dose of Ativan and then goes away for good. It doesn't work that way. It's a disconnect from reality.

Tr. at 199. See Tr. at 198 ("Mr. Coppola was treated with Bactrim, which has no antiviral activity whatsoever, and he was better in 48 hours.").

Dr. Wientzen's cogent testimony stands without persuasive refutation in the record before me. [51]

(2) Petitioner's Long-Term Symptoms

Dr. Rumans did not explain how Petitioner's complaints following vaccination logically added up to SIRS. His testimony on this point was vague and conclusory. See Tr. at 37-40, 70-73. There was no information in his expert report regarding the condition of SIRS, not even a mention of the term. See Tr. at 71 (Petitioner acknowledged that he presented "nothing specific on inflammatory response."). Further, there is nothing in the record that defines the term 'systemic inflammatory response syndrome' or otherwise explains it. Tr. at 71 (Court: "[I]s there anything in the record in this case concerning systemic inflammatory response syndrome?" Counsel: "No, Ma'am."). This is a failure of proof.

As a further consequence of the absence of information in the record concerning SIRS, Dr. Rumans offered no evidence, beyond his unadorned opinion, to link Petitioner's clinical course with this theory of vaccine injury. This is a further failure of proof. Indeed, Dr. Rumans was unable to concur with several of Petitioner's claims, further undermining Petitioner's case. Dr. Rumans stated that while he does believe that Petitioner has chronic fatigue, he does not believe that Petitioner has CFS. Pet'r's Ex. 8 at 3. Dr. Rumans also was unable to state whether Petitioner had mysofascial pain, as alleged in the Petition. Pet. at ¶ 23 (Petitioner "has continued to suffer from myofascial pain and chronic fatigue syndrome").

Dr. Rumans' testimony did not support a logical sequence of cause and effect, even by a mere preponderance standard. The evidence taken as a whole preponderates against the conclusion that the long-term symptoms alleged were in any way related to the varicella vaccine.[52]

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[51] Based on the entire record, I find Dr. Wientzen's testimony concerning Petitioner's UTI to be much more consistent with the medical evidence than Dr. Rumans's interpretation. For example, Dr. Rumans's view ignores Petitioner's history of BPH. It ignores as well the possibility that medications Petitioner was taking made him more susceptible to urinary retention, and therefore to urinary tract infection. Dr. Wientzen's testimony also casts doubt on the impressions of the treating physicians who diagnosed a possible vaccine reaction. Similarly, Dr. Wientzen's observations concerning the manifestations of a true zoster infection refuted persuasively the assertion that Petitioner's generalized body temperature fluctuations were indicative of such an event. See Resp't's Ex. D at 3 (recurring variation in temperature sensation due to zoster infection can occur in "a localized area of the body innervated by nerves arising from an infected dorsal root ganglion," such as "a small area of the chest wall or face or back.").

[52] When Prong 1 has not been established, Prong 2 fails as a result. See Moberly, 592 F.3d at 1324 (proposed mechanism of causation must be shown to be "at work" in the case at hand); Broekelschen,

3. Althen Prong 3

To show causation, a petitioner must establish that the injury occurred within a time frame that is consistent with the theory of causation set forth. Pafford, 451 F.3d at 1358. As discussed, the record with respect to the onset of Petitioner's illness following vaccination is inconsistent. See, e.g., Tr. at 20, 117-18, 132; Pet'r's Exs. 4, 28; Pet'r's Ex. 3 at 2. What is more important is the lack of support for the allegation that serum sickness commences within hours or days of vaccination. The literature submitted by Petitioner discusses adverse events occurring tens of days following vaccination, not in a matter of hours or a few days. Dr. Wientzen testified persuasively that a serum sickness reaction takes place over a period of time longer than a few days. Tr. at 185-86 (describing serum sickness as an immunologic reaction that "tends to be quite delayed in time because it is a manifestation of antibody and antigen complexing in the serum, in the blood").

An additional obstacle to establishing appropriate timing in this case is the vagueness of the injury alleged. Without clear identification of the injury and a logical connection to vaccination, it is impossible for Petitioner to establish that the timing of onset was appropriate. See Lombardi v. Sec'y of Dep't of Health & Human Servs., 656 F.3d 1343, 1352 (Fed. Cir. 2011) ("[T]he statute places the burden on the petitioner to make a showing of at least one defined and recognized injury.") It is not apparent when the alleged SIRS commenced, much less whether its onset and duration were consistent with vaccine causation.

The short duration of Petitioner's symptoms following vaccination also undermines the allegation of vaccine causation. Those symptoms cleared promptly following treatment for Petitioner's UTI, and he had no further complaints until six months later, when he presented with chest pains due to an emotional event. Pet'r's Ex. 2 at 34, 37. Thereafter he suffered a variety of ailments, some of which antedated his vaccination. None of these facts favors a finding of timing consistent with vaccine causation.

4. Failure to Prove Duration of Six Months Or More

I find in addition that Petitioner's symptoms did not last the requisite six months: after Petitioner's discharge from the Bremerton facility on October 11, 2006, the next medical record is that of his primary care physician, Dr. Butler, who noted that the Petitioner had recovered from his "reaction." Pet'r's Ex. 7 at 1.[53] After that entry, there is no record that the Petitioner was seen again for any symptoms until April 14, 2007, six months after his claimed first reaction, for chest pains precipitated by "an emotional event earlier [that] day that caused him to become 'very angry.'" Pet'r's Ex. 2 at 37. Thus, an alternative ground for dismissal in this case is Petitioner's failure to establish

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618 F.3d at 1345-46 ("causation is relative to the injury," and the theory must pertain specifically to the petitioner's case). For the sake of completeness, I have analyzed all the Althen prongs herein.

[53] See note 49, supra.

that he suffered the residual effects or complications of his injury for more than six months after administration of the vaccine. 42 U.S.C. §300aa-11(c)(1)(D)(i). See Song v. Sec'y of Dep't of Health & Human Servs., No. 92-279V, 1993 WL 534746 (Fed. Cl. Spec. Mstr. Dec. 15, 1993), aff'd 41 F.3d 1520 (Table) (Fed. Cir. 1994).

IV. CONCLUSION

Petitioner has not demonstrated the existence any of the elements required to establish a prima facie case of causation by a preponderance of the evidence. The Petition must therefore be **DISMISSED**. In the absence of a timely motion for review filed pursuant to Vaccine Rule 23, the Clerk is directed to enter judgment according to this decision.

IT IS SO ORDERED.

s/ Dee Lord
Dee Lord
Special Master