In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-653V

Filed: May 31, 2013

**********		**TO BE PUBLISHED**
KATEA D. STITT, as Personal Representative of the Estate of PAMELA WANGA STITT,	*	Special Master Zane
Petitioner,	*	Entitlement; trivalent influenza vaccine; Guillain-Barré Syndrome (GBS); Campylobacter jejuni; death.
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
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Franklin John Caldwell, Jr., Maglio, Christopher & Toale, Sarasota, FL, for Petitioner
Glenn A. MacLeod, United States Dep't of Justice, Washington, DC, for Respondent

RULING ON ENTITLEMENT[1]

This matter is before the undersigned on the issue of entitlement following a hearing. Petitioner, Katea D. Stitt ("Petitioner"), as the personal representative of the estate of her mother, Pamela Wanga Stitt ("Mrs. Stitt"), filed this petition alleging that the trivalent influenza ("flu")

[1] Because this decision contains a reasoned explanation for the Special Master's action in this case, the Special Master intends to post it on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 113 Stat. 2899, 2913 (Dec. 17, 2002). All decisions of the Special Master will be made available to the public unless they contain trade secret or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, a party has 14 days to identify and to move to redact such information before the document's disclosure. Absent a timely motion to redact, the decision will be made available to the public in its entirety. If the Special Master, upon review of a timely-filed motion, agrees that the identified material fits within the categories listed above, the Special Master shall redact such material from the decision made available to the public. 42 U.S.C. § 300aa-12(d)(4); Vaccine Rule 18(b).

vaccination Mrs. Stitt received on September 25, 2008, caused Mrs. Stitt to develop Guillain-Barré syndrome ("GBS"),[2] which then caused her death. Petition ¶ 8. Petitioner seeks compensation pursuant to the National Childhood Vaccine Injury Act ("Vaccine Act"), as amended, 42 U.S.C. § 300aa-1, *et seq.* [3]

Petitioner contends that the evidence shows that it is more probable than not that the flu vaccine was a substantial factor in causing Mrs. Stitt's GBS and subsequent death. Petitioner relies on molecular mimicry as the medical theory that causally connects the flu vaccine to GBS. *Id.* Petitioner argues that Mrs. Stitt's clinical picture and the results of diagnostic tests demonstrate a logical sequence of cause and effect showing the flu vaccine caused Mrs. Stitt's GBS. *Id.* Finally, Petitioner maintains that the 5-1/2 weeks between the vaccine and Mrs. Stitt's hospitalization are within the standard, medically acceptable time frame of six weeks between infection and onset of symptoms. *Id.* Petitioner argues that she has satisfied her burden and shown by preponderant evidence that the flu vaccine caused her GBS, which, in turn, caused her death.

Respondent argues that Petitioner has not satisfied her burden of proof. Although Respondent acknowledges that Mrs. Stitt's GBS was one of the causes of her death, Respondent claims that Petitioner has failed to satisfy her burden of showing the flu vaccine caused Mrs. Stitt's GBS. Respondent contends that Petitioner's presentation of molecular mimicry as a theory is inadequate because Petitioner has failed to identify a specific protein in the peripheral myelin as being similar to the antigen in the flu vaccine as evidence that molecular mimicry could occur. Respondent also contends that because Petitioner could not point to any direct evidence that would specifically identify the vaccine as the cause, Petitioner did not present sufficient evidence to show a logical sequence of cause and effect. Respondent further claims that Petitioner also failed to show a logical sequence because epidemiological evidence indicates that in a majority of GBS cases, the cause is an infection, most likely a *Campylobacter jejuni*, or *C. jejuni*, infection.[4] As a result, Respondent claims that the cause of Mrs. Stitt's GBS is more likely to be something other than the vaccine. Thus, according to Respondent, Petitioner fails to

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[2] Guillain-Barré syndrome, or GBS is defined as a rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated. It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face; other characteristics include slight fever, bulbar palsy, absent or lessened tendon reflexes, and increased protein in the cerebrospinal fluid without a corresponding increase in cells. Variant forms include acute autonomic neuropathy, Miller-Fisher syndrome, acute motor axonal neuropathy, and acute motor-sensory axonal neuropathy. *Dorland's Illustrated Medical Dictionary* 1832 (32d ed. 2012).

[3] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. § 300aa-10 through § 300aa-34 (2006).

[4] *Campylobacter jejuni* or *C. jejuni* has been defined as an acute diarrheal disease or infection with clinical manifestations like those of other acute bacterial gut infections of the intestinal tract such as salmonellosis or shigellosis. Blaser, et al., *Clinical Aspects of Campylobacter jejuni and Campylobacter coli Infections*, Campylobacter 99 (3d ed. 2008). R's Ex. G-1.

present sufficient evidence that the vaccine was a substantial factor in causing Mrs. Stitt's GBS and subsequent death.

For the reasons set forth below, upon review of the record as a whole, the undersigned concludes that Petitioner has satisfied her burden. She has shown by preponderant evidence that the vaccine was a substantial factor in bringing about Mrs. Stitt's GBS. And Mrs. Stitt's GBS was a substantial factor in bringing about her death. Petitioner is entitled to compensation.

I. PROCEDURAL BACKGROUND

Petitioner, Katea D. Stitt, filed a petition for vaccine injury compensation on October 2, 2009. In her petition, Petitioner alleges that her mother, Mrs. Stitt, died on November 20, 2008, from GBS, which was caused by the flu vaccine she received on September 25, 2008. Petition.

Following the submission of medical records and expert reports, an entitlement hearing was held on July 26, 2011, in Washington, DC.[5] Petitioner, Ms. Katea Stitt, and Petitioner's expert witness, Dr. Thomas Morgan, testified for Petitioner. Respondent relied on one witness, her expert witness, Dr. Winfried Raabe. Post-hearing briefing was conducted following the hearing. This case is now ready for ruling.

II. FACTS

The facts as evidenced by the records and testimony are as follows:[6]

Mrs. Stitt received an influenza ("flu") vaccination on September 25, 2008, at her local Safeway store. Petitioner's Exhibit ("P's Ex") 10. She was 74. P's Ex. 6. At that time, Mrs. Stitt's medical condition was generally healthy, although she did have hypertension. P's Ex. 2 at 13-16, 19; Transcript of July 26, 2011 hearing ("Tr.") at 16. Mrs. Stitt's medical history indicated that she had had gall bladder surgery and intermittent lower back pain over the last few years. P's Ex. 2 at 13-16, 19. Mrs. Stitt had also had some specific orthopedic issues, *i.e.*, rotator cuff problems and a twisted ankle. P's Ex. 2 at 7, 8-13.

Approximately a week after she received the flu vaccine, on October 2, 2008, Mrs. Stitt went to her orthopedist, Dr. Moskovitz, for a follow-up on her right knee and left shoulder pain (Rotator Cuff Syndrome). P's Ex. 2 at 1. At that time, Mrs. Stitt mentioned a new complaint, *i.e.*, stiffness and pain in both her hands and in her fingers, with the symptoms being greater in her right versus her left hand and fingers. *Id.*

[5] This case was originally assigned to another Special Master, who presided over it while records were submitted, expert reports prepared and settlement discussions occurred. It was transferred to the undersigned in May 2011, approximately 60 days before the hearing.

[6] The facts as set forth herein are derived from the medical records, Petitioner's testimony and the parties' Joint Submission of Uncontested Facts ("Stip."), all of which are consistent. There were no identified disputes as to the material facts.

Approximately two weeks later, on October 17, 2008, Mrs. Stitt traveled to New York City for an awards ceremony and concert. P's Ex. 15 at 1; Tr. at 13. After returning from her trip, Mrs. Stitt suffered a bout of gastroenteritis (non-diarrheal illness), *i.e.*, she had a bit of a "stomach upset." P's Ex. 6 at 6, 36, 39; Tr. at 14, 18. Petitioner, who spoke to her mother nearly every other day, explained that this was nothing more than a passing stomach upset for which Mrs. Stitt took some ginger ale to settle her stomach. Tr. at 18, 19, 23. Knowing her mother, had it been more than some mild stomach upset, Mrs. Stitt would have described the illness in great detail to Petitioner, her daughter. Tr. at 23.

On October 30, 2008, Mrs. Stitt visited her primary care physician/internist, Dr. George Graves, for a follow-up on her hypertension. P's Ex. 4 at 19. Mrs. Stitt reiterated the complaint she had made to her orthopedist of tingling in her hand up to her elbow for the past month. *Id*. She denied complaints of chest pain, shortness of breath, and cough. *Id.* There was no indication of any complaints of stomach problems, nausea, diarrhea or vomiting. *Id.*

A few days later, on November 3, 2008, Mrs. Stitt telephoned her doctor complaining of tingling in her hands and feet. P's Ex. 4 at 19; P's Ex. 6 at 16-17. Later that same day, Mrs. Stitt was admitted to Sibley Hospital due to leg weakness. P's Ex. 6 at 21. At the time of her admission, Mrs. Stitt told the admitting personnel that she had had leg weakness since the morning, that her knees buckled twice, and that she experienced shortness of breath and polyuria.[7] P's Ex. 6 at 21; Tr. at 26-27.

Upon admission, Dr. Mahgoub, a neurologist, provided a consult. P's Ex. 6 at 36-38. He specifically noted that Mrs. Stitt had received a flu vaccine four weeks before admission and that the differential diagnosis, which included GBS, was well described. P's Ex. 6 at 36-37. Having noted the receipt of the flu vaccine and possible GBS diagnosis, Dr. Mahgoub noted that the Centers for Disease Control ("CDC") and Food and Drug Administration ("FDA") had not issued an alert in connection with the flu vaccine. *Id.* Nonetheless, Dr. Mahgoub made a note to contact the CDC out of concern regarding the vaccine being a possible cause. P's Ex. 6 at 36-38. Dr. Mahgoub also noted Mrs. Stitt's trip to New York and a possibility of West Nile Virus. *Id.* Dr. Mahgoub eliminated that as a potential cause because Mrs. Stitt's cerebral spinal fluid ("CSF") and serum loads were the same. P's Ex. 6 at 37. Finally, he considered botulism but rejected that as Mrs. Stitt had not consumed fish in New York. *Id.* Mrs. Stitt's laboratory tests showed an elevated glucose level and elevated liver enzymes with otherwise normal results. P's Ex. 6 at 23.[8] Her urinalysis was positive for erythrocytes, bilirubin, ketones and protein. *Id.*

After being admitted to Sibley Hospital, Mrs. Stitt continued to experience leg weakness, as well as weakness in her arms. P's Ex. 6 at 17. Tests on Mrs. Stitt's blood, spinal fluid, and stool samples were ordered for routine cultures as well as for *C. jejuni*.[9] P's Ex. 6 at 144.

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[7] Polyuria is defined as the passage of a large volume of urine in a given period, as in diabetes mellitus. *Dorland's Illustrated Medical Dictionary* 1494 (32d ed. 2012).

[8] Mrs. Stitt learned she had diabetes this same day. P's Ex. 6 at 16-17; Tr. at 21-22.

[9] Progress notes from other parts of the record seemed to indicate that there may have been other laboratory tests performed although the laboratory test results were not in the record. Undersigned raised this with the parties at the time this matter was transferred to the

Results from her CSF and fungal culture tests were normal. P's Ex. 6 at 179, 181. On November 9, 2008, the results of her culture noted there was no *Campylobacter* (*C. jejuni*), *Salmonella*, *Shigella* or *E. coli* isolated. P's Ex. 6 at 178.

On November 6, 2008, the results from an electrodiagnostic study confirmed that Mrs. Stitt's presentation was consistent with GBS. P's Ex. 7 at 2. Mrs. Stitt was treated with a two-day course of IVIG. P's Ex. 6 at 52; P's Ex. 5 at 2. Because she developed shallow breathing and an increased respiratory rate on that day, Mrs. Stitt was intubated. P's Ex. 6 at 53-54; Tr. at 32. Within a day, Mrs. Stitt developed what was diagnosed as staphylococcus pneumonia. *Id.* She was treated with antibiotics. *Id*. Mrs. Stitt also developed a fever and an elevated white blood cell count. P's Ex. 6 at 67.

Beginning November 10, 2008, Mrs. Stitt's strength in her extremities began to return and her breathing improved. P's Ex. 6 at 7. However, it was also determined that Mrs. Stitt had developed hemolytic anemia due to her IVIG treatment. *Id.* As a result, her IVIG treatment was stopped after just two courses. *Id*.

By November 12, 2008, Mrs. Stitt's pneumonia had resolved. *Id*. Later that day, Mrs. Stitt was removed from the ventilator. P's Ex. 6 at 100. Mrs. Stitt was noted to be "doing quite well" and to have a good voice. *Id.* On November 13, 2008, Mrs. Stitt was again noted to be "doing well," "breathing easily," and "swallowing without difficulty," and her pneumonia had resolved. P's Ex. 6 at 105-06. Plans were made to transfer Mrs. Stitt to the National Rehabilitation Hospital. *Id*.

On November 14, 2008, Mrs. Stitt was discharged from Sibley Hospital to the National Rehabilitation Hospital. P's Ex. 6 at 6. The discharge summary indicated that Mrs. Stitt was diagnosed with, *inter alia*, GBS. P's Ex. 6 at 6. The doctors told Petitioner that Mrs. Stitt's GBS was caused either by the flu vaccine or some other unidentified infection. Tr. at 76.

On November 16, 2008, while at the National Rehabilitation Hospital, Mrs. Stitt experienced severe respiratory distress and was transported to Washington Hospital Center. P's Ex. 5 at 2. Mrs. Stitt was intubated. P's Ex. 5 at 8. Because her blood pressure dropped, Mrs. Stitt was placed on medication to raise her blood pressure. *Id*. A chest X-ray revealed bibasal infiltrates and an echocardiography demonstrated a nearly collapsed ventricle suggestive of hypovolemia.[10] P's Ex. 8 at 8, 13; Ex. 5 at 225. An evaluation for cardiac arrest revealed that Ms. Stitt had a cardiomyopathy.[11] P's Ex. 5 at 2; Tr. at 65.

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undersigned. July 14, 2011 Order. After inquiry, Petitioner represented that she made inquiry to the health care providers and verified that she had filed all the pertinent medical records. Tr. at 5-8. Respondent acquiesced in Petitioner's representation that all pertinent records had been filed. Tr. at 8.

[10] Hypovolemia is defined as an abnormally decreased volume of circulating blood in the body; the most common cause is hemorrhage. *Dorland's Illustrated Medical Dictionary* 908 (32d ed. 2012).

[11] Cardiomyopathy is a general diagnostic term designating primary noninflammatory disease of the heart muscle, often of obscure or unknown etiology and not the result of ischemic,

On the following day, November 17, 2008, Mrs. Stitt's EKG tests revealed changes in her ST-elevation and increased enzymes. P's Ex. 5 at 288. She received cardiac catherization, which revealed non-obstructive coronary artery disease, elevated right heart filling pressures, and takotsubo[12] with severe liver dysfunction. P's Ex. 8 at 4. Mrs. Stitt's lab results revealed no abnormalities in her stool cultures. P's Ex. 5 at 277.

Mrs. Stitt was placed on a ventilator, and on November 18, 2008, she suffered hypoxic respiratory failure while on the ventilator. P's Ex. 5 at 74. Mrs. Stitt was determined to have takotsubo syndrome with functional obstruction of liver outflow. *Id*. There was no change in Mrs. Stitt's status the next day, November 19, 2008. P's Ex. 5 at 84. Later on November 19, 2008, Mrs. Stitt began to experience worsening hypotension due to sepsis versus takotsubo cardiomyopathy. P's Ex. 5 at 85-86; Stip. ¶ 15. Mrs. Stitt's mental status worsened and her family decided that she should not be resuscitated. P's Ex. 5 at 2-3.

Ms. Stitt died on November 20, 2008. P's Ex. 11 at 1; P's Ex. 5 at 3, 91. Her causes of death were listed as: (A) Cardiogenic shock; (B) Cardiomyopathy; (C) GBS; and (D) Pneumonia. P's Ex. 11 at 1; P's Ex. 5 at 3, 91; Stip. ¶ 16. An autopsy was performed on January 12, 2009. P's Ex. 5 at 292-96. The autopsy report listed the causes of death as, *inter alia,* (1) Septic shock with respiratory failure (clinical) and (2) GBS (clinical). P's Ex. 5 at 292; Stip. ¶ 17.

The parties stipulated that Mrs. Stitt had been diagnosed with GBS at the time of her discharge from Sibley Hospital to the National Rehabilitation Hospital. Stip. ¶ 10. The parties also stipulated that the medical records listed GBS as a cause of her death. Stip. ¶ 16. Finally, the parties stipulated that the autopsy report identified GBS as one of the causes of Mrs. Stitt's death. Stip. ¶ 17.

III. PETITIONER'S CASE

In support of her case, Petitioner relied on the expert report and testimony of Dr. Thomas Morgan. Dr. Morgan is a neurologist. P's Ex. 13. Since 1978, he has been an Assistant Professor in the Department of Clinical Neuroscience at the School of Medicine of Brown University. P's Ex. 13. Prior to his appointment with Brown University, he was a Clinical Instructor in Neurology at Boston University's Medical School. *Id.* He is board certified in neurology. P's Ex. 12. During his training, as a result of electives taken, he developed a good understanding of peripheral nervous system disorders. Tr. at 36. Additionally, in 1976, he

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hypertensive, congenital, valvular, or pericardial disease. *Dorland's Illustrated Medical Dictionary* 294 (32d ed. 2012).

[12] Takotsubo cardiomyopathy is defined as a syndrome characterized by transient apical and midventricular akinesis that is typically precipitated by acute stress. Manzanal, et al., *Inverted Takotsubo Cardiomyopathy,* Tex. Heart Inst. J. 2013; 40(1):56-9. It is also defined simply as a weakening of the left ventricle, the heart's main pumping chamber, usually as the result of severe emotional or physical stress, such as a sudden illness, the loss of a loved one, a serious accident, or a natural disaster such as an earthquake. *Harvard Women's Health Watch*, November 2010.

treated patients who had received the swine flu vaccine and then developed GBS, which was determined to have a causal relationship. Tr. at 37. He is on the clinical track of the school, where they work with patients and teach residents to extract information from patients to try to formulate a diagnosis. Tr. at 39-40. The last patient he treated with GBS was a few years ago. Tr. at 107.

Dr. Morgan opined that Mrs. Stitt had suffered from GBS, an acute inflammatory demyelinative polyneuropathy, causally related to her vaccination. Tr. at 51. The mechanism that he believes could have caused this injury is molecular mimicry. Tr. at 91-92; P's Ex. 12 at 4. As to timing, Dr. Morgan explained that a medically appropriate temporal relation would be between two and six weeks after vaccination so that the timing here, 5-1/2 weeks between vaccination and hospitalization, was appropriate. P's Ex. 14.

Dr. Morgan explained that to determine the actual cause, as a clinician, he would apply a multi-step process as set forth in the neurology textbook, Adams & Victor's *Principles of Neurology*. Tr. at 46, 96; P's Ex. 12 at 6. As a clinician, Dr. Morgan looked at the various possible etiologies of Mrs. Stitt's GBS and used the symptoms displayed and other information to eliminate potential causes and to determine the cause of Mrs. Stitt's GBS, in essence using a differential diagnosis method. Tr. at 46, 96. Dr. Morgan testified that because GBS is an inflammatory immune disorder, the possible causes would be bacterial, viral or vaccinal. Tr. at 84. Dr. Morgan testified that the records, in his view, excluded bacterial and viral causes because the tests for bacterial and viral illnesses had been negative, and Mrs. Stitt did not have any clinical signs of bacterial or viral illnesses. Tr. at 86-87. Based on the records excluding other potential causes and her clinical symptoms (and lack thereof) as well as the temporal relation, Dr. Morgan concluded, as a matter of medical probability, that Mrs. Stitt's GBS was caused by the influenza vaccine she had received. P's Ex. 12; Tr. at 51.

IV. RESPONDENT'S CASE

Respondent relied on the expert report and testimony of Dr. Winfried Raabe. Dr. Raabe is a board-certified neurologist who is a Clinical (Adjunct) Associate Professor of Neurology at the University of Minnesota's Medical School. R's Ex. B; Tr. at 162. He is also a certified member of the American Association of Neuromuscular Electro-diagnostic Medicine. Tr. at 162. His area of expertise is electro-diagnostics, and he was the director of the EMG (electromyography) lab until 2007. Tr. at 163. He is semi-retired. *Id.*

Dr. Raabe opined that Mrs. Stitt's influenza vaccination was coincidental to her developing GBS. Tr. at 167. Dr. Raabe relied on the literature that indicated that there has been no epidemiological evidence connecting the flu vaccine and GBS since 1976-77 to conclude that there was no evidence of a causal connection between the flu vaccine and GBS. Tr. at 172, 175; R's Ex. A at 4. Again, relying on literature, Dr. Raabe noted that because 60% of the time where the cause of GBS is identified as being infectious, half of the infections are *C. jejuni.* R's Ex. D at 4. Thus, he concluded that *C. jejuni* was the likely cause of Mrs. Stitt's gastrointestinal illness, which in turn was the likely cause of Mrs. Stitt's GBS. R's Ex. D at 3-4. In his expert report, Dr. Raabe noted that one study reflected in the literature discussed the onset of GBS as generally occurring two weeks after infection. R's Ex. A at 4. Based on this, in his expert report, Dr.

Raabe stated that the timing between the vaccine and Mrs. Stitt's hospitalization, some 5-1/2 weeks, tended to make it a less medically appropriate temporal relation. R's Ex. A at 4.

Following the hearing, Dr. Raabe submitted a supplemental report.[13] R's Ex. F. That report consisted of the results of his further literature search on the following questions: (1) how *C. jejuni* is diagnosed; and (2) whether the test results indicating that Mrs. Stitt's stool sample tested negative for *C. jejuni* are conclusive. R's Ex. F. Dr. Raabe's search of the literature revealed that the definitive test for *C. jejuni* is a stool sample. *Id.* His search also revealed that some percentage of individuals with GBS do not show signs of *C. jejuni*. *Id.* Dr. Raabe concluded that the negative stool culture for *C. jejuni* is not dispositive as to whether Mrs. Stitt actually had *C. jejuni*. *Id.*

V. APPLICABLE LEGAL STANDARDS

The Vaccine Act provides for two means of recovery: Table claims and off-Table claims.[14] In an off-Table, or causation-in-fact case, such as this one, a petitioner must prove actual causation by a preponderance of the evidence. *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010). To prove actual causation, a petitioner must "show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.' " *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed.Cir.1999)). Causation is determined on a case-by-case basis. *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994).

A petitioner satisfies this burden if she provides: (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 proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). A petitioner must satisfy the three *Althen* prongs by preponderant evidence. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). This preponderant-evidence standard "simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence." *Moberly*, 592 F.3d at 1322 n.2; *Althen*, 418 F.3d at 1279 (citing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572–73 (Fed. Cir. 1993)) (noting the standard requires that a petitioner demonstrate the existence of the element is "more probable than not."). Evidence used to satisfy one of the *Althen* prongs can overlap and be used to satisfy another prong. *Capizzano*, 440 F.3d at 1326.

There are no "hard and fast *per se* scientific or medical rules" for finding causation under the Vaccine Act. *Knudsen*, 35 F.3d at 548. The Vaccine Act does provide that a claimant may satisfy the preponderant evidence standard by producing "medical records or a medical opinion."

[13] The report submitted post-hearing was actually Dr. Raabe's third report, or second supplemental report. R's Ex. F; *see also* R's Ex. A and D.

[14] In a Table case, a claimant who shows that he or she received a vaccination listed in the Vaccine Injury Table, 42 U.S.C. § 300aa–14, and suffered an injury listed in the Table within a prescribed period is afforded a presumption of causation. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009).

42 U.S.C. § 300aa-13(a)(1). A petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case. *Moberly,* 592 F.3d at 1322. However, the explanation need only be "legally probable, not medically or scientifically certain." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345-46 (Fed. Cir. 2010); *Moberly,* 592 F.3d at 1322 (quoting *Knudsen,* 35 F.3d at 548-49). Along these lines, a special master may not require "epidemiologic studies. . .or general acceptance in the scientific or medical communities. . . ." *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009).

At the same time, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly,* 592 F.3d at 1324; *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010). In determining reliability, a special master may appropriately rely on the standards set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-94 (1993); *see Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (finding that special masters' use of the *Daubert* factors reasonable); *Cedillo,* 617 F.3d at 1338-39 (finding no legal error in the standards applied by the special master in utilizing *Daubert).* When a party relies upon expert testimony, that testimony must have a reliable scientific basis. *Cedillo,* 617 F.3d at 1339. Although a party need not produce medical literature to establish causation, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury. *Andreu,* 569 F.3d at 1379; *Althen,* 418 F.3d at 1281; *see also Daubert,* 509 U.S. at 593-94.

With regard to alternative causes, the respondent bears the burden of proving by preponderant evidence that an alternative cause, or factor unrelated, was the sole cause of the injury. 42 U.S.C. § 300aa-13; *de Bazan v. Sec'y of Health & Human Servs.,* 539 F.3d 1347, 1354 (Fed. Cir. 2008); *Knudsen*, 35 F.3d at 549. But, neither 42 U.S.C. § 300aa-13 nor the decisions limit what evidence the special master may consider in deciding whether a prima facie case has been established. *Doe 11,* 601 F.3d at 1358 (citing *de Bazan,* 539 F.3d at 1353); *see also Walther v. Sec'y of Health & Human Servs.*, 85 F.3d 1146, 1151 (Fed. Cir. 2007). As a result, the government may also present and the special master may consider evidence of alternative causes on the issue of the adequacy of the petitioner's evidence regarding the petitioner's case-in-chief. *Doe 11 v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010) (quoting *de Bazan,* 539 F.3d at 1354).

In this regard, there are two particular points that the decisions make clear. First, a special master may not require the petitioner to shoulder the burden of eliminating all possible alternative causes in order to establish a *prima facie* case. *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379-80 (Fed. Cir. 2012). *S*econd, a special master may find that a factor other than a vaccine caused the injury in question only if that finding is supported by a preponderance of the evidence. *Stone,* 676 F.3d at 1379-80 (citing *Doe 11,* 601 F.3d at 1356–57); *see Walther*, 485 F.3d at 1151-52 (the petitioner does not bear the burden of eliminating alternative independent potential causes, and the respondent has the burden of proving an alternative cause as the sole, unrelated factor that caused the injury by a preponderance of evidence).

It is established that a special master is entitled to, and should, consider the record as a whole in determining causation. 42 U.S.C. § 300aa-13(a)(1)(A). This is especially true in a case involving multiple potential causes acting in concert. *Stone,* 676 F.3d at 1379-80; *see also Doe 11,* 601 F.3d at 1356–58; *de Bazan,* 539 F.3d at 1353; *Shyface,* 165 F.3d at 1352. In considering the record, the Vaccine Act does not contemplate full blown tort litigation. *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. Indeed, "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen,* 418 F.3d at 1280); *Capizzano,* 440 F.3d at 1324.

VI. DISCUSSION

The issue to resolve here is whether the influenza vaccine Mrs. Stitt received on September 25, 2008 was a substantial factor in causing Mrs. Stitt's GBS. The parties agree on other material issues. Specifically, Petitioner and Respondent agree that Mrs. Stitt was diagnosed with and had GBS. P's Ex. 14; R's Ex. A at 4. The parties also agree that Mrs. Stitt's GBS was one of the causes of her death. Stip. ¶ 17(2); Tr. at 66-67; Tr. at 149; Tr. at 167; Tr. at 231-32.[15] As explained below, Petitioner has satisfied her burden.

A. Petitioner Has Presented Sufficient Proof of a Medical Theory Causally Connecting the Flu Vaccine to Mrs. Stitt's GBS, Satisfying *Althen's* Prong One.

To satisfy *Althen's* prong one, Petitioner presented evidence that the flu vaccine could cause GBS through the biological mechanism of molecular mimicry. P's Ex. 12; Tr. at 92-94; 123.[16] As Dr. Morgan explained, molecular mimicry occurs when the immune system is stimulated, such as when an individual receives a vaccine. Tr. at 92. With molecular mimicry, antibodies stimulated to fight the flu, due to chemical similarity, mimic or cross react with normal tissue of the nerve roots or of the peripheral nerves and attack normal myelin or swan cells or axons. Tr. at 92-94. By the molecular mimicry process, the immune system "mistakes" myelin in the peripheral nervous system for parts of the antigen it has been "taught" to recognize

[15]By virtue of their stipulating that the cause of Mrs. Stitt's death was GBS, the parties are in agreement that Mrs. Stitt's GBS was the cause and, thus, a substantial factor in bringing about her death. Stip. ¶¶ 16, 17. *See supra* VI.B.

[16] As recently recognized by the Federal Circuit, despite GBS not being listed on the Vaccine Injury Table, there certainly are many flu vaccine causing GBS cases that have been compensated under the Program. *Figueroa v. Sec'y of Health & Human Servs.,* ____F.3d, ____, 2012 WL 1811018 *1 (Fed. Cir. May 1, 2013) (citing cases); *see generally Isaac v. Sec'y of Health & Human Servs.,* 2012 WL 3609993 *4 (Fed. Cl. Spec. Mstr. July 30, 2012) (in a case in which the influenza vaccine is alleged to have caused GBS by a process of molecular mimicry, there would be at least some indication from the swine flu experience that the influenza vaccine can cause GBS). Although these cases certainly indicate outcomes of cases involving the same or similar vaccines and the same alleged injury, as Congress recognized, rulings on entitlement in the Vaccine Program are decided on the record as a whole in the particular case. 42 U.S.C. § 300aa-13(a)(1).

as the flu vaccine, and attacks the myelin, which can then cause GBS. Tr. at 94; P's Ex. 18; *see also* Court Exhibit 1005. Respondent's expert, Dr. Raabe, agreed that the biological mechanism for GBS was some form of immune-mediated molecular mimicry. Tr. at 199. In fact, literature relied on by Respondent's expert noted that molecular mimicry has emerged as the leading hypothesis for the pathogenesis of GBS. R's Ex. E-3 at 2 (p. 644 of actual article).

The record further contains evidence that the flu vaccine, a stimuli of the immune system, could trigger molecular mimicry and lead to GBS. Respondent's expert's article, Lehmann, et al., *GBS after Exposure to Influenza Virus*, Lancet Infect. Dis. 2010; 10:643-51, indicates that there was epidemiological evidence of the swine flu vaccine in 1976-77 being causally connected with GBS. R's Ex. E-3 at 2. That article is evidence that there is a causal connection between at least one type of flu vaccine and GBS. That article also acknowledges that molecular mimicry is the mechanism that would likely cause GBS. R's Ex. E-3 at 2. Finally, the article summarizes the results of other studies and indicates that two of these studies suggest a causal connection between the flu vaccine and GBS. R's Ex. E-3 at 5 Table 2.

The articles regarding those two studies, also submitted in the record, provide further evidence of a flu vaccine causal connection with GBS. The 2010 Juurlink study, *GBS after Influenza Vaccination in Adults*, indicated a 1.7-fold adjusted relative risk for GBS associated with vaccination. R's Ex. C-4 at 3. The Laskey study also indicated a slightly greater risk of GBS after receipt of the flu vaccine. R's Ex. C-3 at 4; *see also* Court Exhibit 1008. Respondent's expert, Dr. Raabe, acknowledged that these studies did suggest a possible causal connection between the flu vaccine and GBS. Tr. at 253.

In addition to these studies, the Vaccination Information Statement ("VIS") provided by the Centers for Disease Control ("CDC") for the influenza vaccine also points to a causal connection. Court Exhibit 1001.[17] Under the heading "severe problems," the VIS states that in 1976 a type of influenza vaccine was associated with GBS. *Id.* That warning goes on to state that if there is a risk of GBS from the current flu vaccine, it is very rare. *Id.* When asked about this, Respondent's expert, Dr. Raabe, acknowledged this statement and referenced the Laskey and Juurlink studies as a possible reason for this warning. Tr. at 252.

Despite this evidence, Respondent argues that Petitioner has failed to satisfy prong one because Petitioner's expert has failed to prove that a particular protein in the human peripheral myelin that gets attacked under the molecular mimicry theory is sufficiently similar to the antigen found in the flu vaccine and that this is necessary to show that molecular mimicry has taken place. R's Post-Hearing Brief at 11-12. In essence, Respondent argues that Petitioner must show the exact biologic mechanism that could have caused Petitioner's injury.

Contrary to Respondent's argument, Petitioner is not required to demonstrate the exact biologic mechanism by which the flu vaccine could cause GBS. As the Federal Circuit observed in *Knudsen*, "to require identification and proof of specific biological mechanisms would be

[17] Court Exhibits were placed into the record in advance of the hearing. July 14, 2011 Hearing Order. The parties were advised to provide their experts these exhibits for comment and consideration and that inquiry might be made of their experts at hearing regarding these exhibits.

inconsistent with the purpose and nature of the vaccine compensation program." *Knudsen*, 35 F.3d at 551 (quoting House Report 99-908 at 3, 1986 U.S. Code Cong. &. Admin. News at 6344). The Vaccine Program "is therefore not to be seen as a vehicle for ascertaining precisely how and why vaccines sometimes destroy the health and lives of certain individuals while safely immunizing most others." *Knudsen*, 35 F.3d at 549. Indeed, "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280. Thus, Petitioner is only required to establish that the medical theory upon which she relies shows that it is more likely than not that the flu vaccine could cause GBS.

Respondent also argues that Petitioner's evidence is insufficient due to the lack of epidemiological support for Petitioner's position. R's Post-Hearing Brief at 12. Again, contrary to Respondent's argument, it is well-recognized that Petitioner is not required to present epidemiological evidence to satisfy her burden. *Andreu*, 569 F.3d at 1378.

The evidence presented here is sufficient to satisfy Petitioner's burden as to *Althen's* prong one. Petitioner presented through her expert a medical theory for how the vaccine could have caused Mrs. Stitt's GBS. The medical literature provides evidence of the reliability of Petitioner's medical theory that there is a causal connection between the flu vaccine and GBS. Indeed, the CDC's warning on the Vaccine Information Statement for the flu vaccine also supports this. Petitioner has shown by a preponderance of evidence a medical theory evidencing a causal connection between the flu vaccine and GBS.

B. Petitioner Has Provided Sufficient Evidence Which Demonstrates a Logical Sequence of Cause and Effect Showing the Vaccine Was a Substantial Factor Leading to Mrs. Stitt's GBS, Satisfying *Althen's* Prong Two.

Petitioner's expert, Dr. Morgan, opined that, to a reasonable degree of medical probability, the flu vaccine was the cause of Mrs. Stitt's GBS and subsequent death. P's Ex. 12; Tr.at 51, 71. He reached his conclusion by reviewing the various medical records evidencing Mrs. Stitt's symptoms and medical test results to conclude that it is more likely than not that the influenza vaccine was a substantial factor in causing her GBS. Tr. at 35-74.

As explained by Dr. Morgan, to determine the cause of Mrs. Stitt's GBS, he and, to a degree, the treating physicians used a clinical diagnostic approach, which included a differential diagnosis method. Differential diagnosis is an established scientific technique used to identify the cause of a medical problem by eliminating the potential causes until the most probable cause is identified. *Westburry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999). Differential diagnosis "generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is most likely." *Id*. While not labeling it as such, the Federal Circuit has recognized that a petitioner may present "evidence eliminating other potential causes to help carry the burden on causation and may find it necessary to do so when the other evidence on causation is insufficient to make out a *prima facie* case." *Walther*, 485 F.3d at 1151. But, a simplistic elimination of other causes does not necessarily mean that a remaining factor actually caused the condition. *Moberly*, 592 F.3d at

1323 (quoting *Althen*, 418 F.3d at 1278). On the other hand, it has been recognized that a sufficiently rigorous differential diagnosis can support a finding of causation under the Vaccine Act. *See Hocraffer v. Sec'y of Health & Human Servs.*, 63 Fed. Cl. 765, 777, 779 (2005) (finding that Petitioner was entitled to compensation based on the differential diagnosis testimony presented by her expert witnesses); *Ruggero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) (stating that the district judge has broad discretion in determining whether in a given case a differential diagnosis is enough by itself to support a causation opinion); *see generally Doe 93 v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 553, 570 (2011). The foregoing suggests that where a differential diagnosis is part of the record, as part of the consideration of the record as a whole, the special master should consider this process and any resulting diagnosis and accord it weight in the same way other evidence is considered.

Here, the doctors treating Mrs. Stitt applied this method in looking for a cause for her GBS. P's Ex. 6 at 36-38. The treating physicians looked at various potential causes, including the flu vaccine. *Id.* The doctors asked questions to establish clinical symptoms and performed diagnostic tests in an effort to determine the particular cause of Mrs. Stitt's GBS. *Id.*

Regarding potential bacterial and viral agents, they tested for a number of alternative causes of GBS, including West Nile virus, various bacterial infections, Lyme disease, *C. jejuni*, as well as Hepatitis B and C, acknowledging that these conditions "can cause" GBS. P's Ex 6 at 37-38, 176-79. All these tests were negative. *Id.*

The doctors also explored the possibility of a causal link by considering the stomach upset Mrs. Stitt had reported experiencing after returning from her New York trip. They did this by asking her questions upon her admission related to the symptoms of gastroenteritis, *i.e.*, whether she had had nausea, vomiting, or diarrhea. P's Ex. 6 at 36-38. They also took a stool sample and tested for, *inter alia*, *C. jejuni*, which was negative. P's Ex. 6 at 178.

As is well established in the record, Mrs. Stitt did not have these symptoms at the time she first came to the hospital and had only very minor symptoms beforehand. *Id.* The absence of these symptoms coupled with the negative test results are evidence that those various bacterial and viral infections were not the cause of Mrs. Stitt's GBS. P's Ex. 6 at 36-38.

The doctors also considered the flu vaccine as a potential cause. P's Ex. 6 at 38. The doctors acknowledged that, in a practice setting, the flu vaccine/GBS connection is one regularly explored, that a flu shot can cause GBS. P's Ex. 6 at 36-38. The treating neurologist's impression upon consultation states specifically that Petitioner developed ascending paralysis four weeks after receiving a flu shot. P's Ex. 6 at 37. Upon learning of Mrs. Stitt's recent vaccination, the treating neurologist made note to inquire with the CDC and FDA to learn whether there were reports of concerns regarding the vaccine's potential risks. *Id.*

The doctors did appear to eliminate or minimize certain potential causes based on results of objective tests and lack of clinical symptoms. P's Ex. 6 at 36-38. But, they were unable to eliminate all of them. One which they did not eliminate was the flu vaccine. The neurologist's notes specifically discuss other potential causes, such as West Nile virus. P's Ex. 6 at 36-38. In some instances, after looking at symptoms, circumstances and test results, he eliminates or

discounts them. *Id.* He did not necessarily do that with regard to the flu vaccine.

That the doctors still considered the flu vaccine a potential cause is evidenced by the discussion they had with Petitioner. When discussing the cause of Mrs. Stitt's GBS, the treating physicians advised Petitioner that it was either the flu vaccine or some other, unidentified infection. Tr. at 76. They did not say it was either the flu vaccine or West Nile or *C. jejuni.* Rather they limited it to the flu vaccine or some "other" infection. This is certainly some evidence, albeit circumstantial, that the vaccine caused the injury. *Capizzano,* 440 F.3d at 1326 (treating physician's opinions should be considered).

Dr. Morgan also used the clinical and diagnostic information to determine the likely cause of Mrs. Stitt's GBS. Tr. at 43. Dr. Morgan explained that because GBS is an acute inflammatory demyelinating polyneuropathy, related to an inflammatory immune process, the possible causes would break down as either post-infectious, post-viral or post-vaccinal. Tr. at 48, 108.

According to Dr. Morgan, in looking at the clinical time line, a crucial piece of information was the fact that Mrs. Stitt had seen her primary care physician on October 30, 2008, a little over four weeks after the vaccination. Tr. at 51-52, referencing P's Ex. 18; *see also* P's Ex. 4 at 19. At that time, Mrs. Stitt mentions tingling in her hands and numbness. But there is no mention of any fever, nausea, vomiting or diarrhea. Mrs. Stitt does not have a gastrointestinal issue or a fever and does not mention her recent stomach upset. Tr. at 53.

Consistent with this, when first arriving at the hospital on November 3, 2008, although Mrs. Stitt again mentions tingling, she does not mention fever, nausea or diarrhea. P's Ex. 6 at 6, To Dr. Morgan, the absence of symptoms of illness or even stomach upset is significant because if there were a bacterial or viral condition, there would be some manifestation of those conditions. Tr. at 51-52.

The negative results of diagnostic tests taken at the time of her hospital admission are also evidence Mrs. Stitt was not and had not been suffering from a bacterial or viral infection. The results of the tests conducted for a variety of bacterial and viral infections, such as Lyme disease, were all negative. P's Ex. 6 at 178. Mrs. Stitt's stool culture test for *C. jejuni* was also negative. *Id.* Additionally, Mrs. Stitt had no symptoms other than tingling and no fever at the time of her admission and did not have a fever or an elevated white blood count. P's Ex. 6 at 27, 31-32, 36-38. Based on these test results, Dr. Morgan, like the treating physicians, concluded that Mrs. Stitt's GBS was not due to a bacterial or viral infection. Tr. at 53. At the same time, the tingling suggests some autoimmune process, which would operate without a fever or signs of a gastroenteritis. The vaccine certainly stimulates the immune system. These facts provide circumstantial evidence that a substantial factor that caused Mrs. Stitt's GBS was the vaccine and not a bacterial or viral infection or other process.

Respondent contends that Petitioner has failed to satisfy the second prong, arguing that "Dr. Morgan points to no specific evidence, such as biological markers, tests, or clinical symptoms, which implicate the flu vaccination as the likely cause of petitioner's injury." R's Post-Hearing Brief at 14. Respondent seems to suggest that there must be some specific, direct proof that the particular vaccine

at issue, here the influenza vaccine, caused a specific autoimmune response that led to Mrs. Stitt's GBS. Respondent's suggested approach is inconsistent with governing principles. It "prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Capizzano*, 440 F.3d at 1324 (quoting *Althen*, 418 F.3d at 1280). Indeed, were the standard such that a petitioner could only prevail if there were direct evidence, especially as to *Althen's* prong two, it would be unlikely that a petitioner would ever be found entitled to compensation.

Reliance on circumstantial evidence to find that Petitioner has satisfied her burden is consistent with the purpose of the Vaccine Act. Indeed, "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280; s*ee Knudsen*, 35 F.3d at 549 (explaining that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program"). As explained above, the circumstantial evidence points to the vaccine as being a substantial factor in causing Mrs. Stitt's GBS.

Respondent cites *Moberly*, 592 F.3d at 1323, and argues that Dr. Morgan has done nothing more than show a proximate temporal relationship and eliminate other potential causes and that is insufficient to prove vaccine causation. Certainly, evidence that satisfies prongs one and three, can overlap and be used to satisfy Prong 2. *Capizzano*, 440 F.3d at 1326. Here, as discussed in VI.A, *supra*, there is strong evidence to satisfy prong one. Similarly, with regard to temporal relationship, there is not much question that it is satisfied. *See infra* VI.C. That evidence also overlaps and supports the evidence in the record relating to prong two.

Rather than simply summarily eliminate other potential causes, the record shows that both Dr. Morgan and the treating physicians applied a recognized diagnostic approach as a means to establish the cause of Mrs. Stitt's GBS. They methodically performed diagnostic tests and reviewed clinical symptoms to determine the cause of Mrs. Stitt's GBS. This is a logical manner to use to identify the cause of Mrs. Stitt's GBS. *See Capizzano*, 440 F.3d at 1327 (A logical sequence of cause and effect means that a claimant's theory of cause and effect must be logical).

Respondent also argues that Petitioner has failed to show that a potential alternative cause, *C. jejuni*, was not a factor in causing Mrs. Stitt's GBS.[18] To support this argument, Respondent's

[18] Although Respondent presented *C. jejuni* as an alternative cause, Respondent presented this evidence only to show that Petitioner had not satisfied her burden and not to show that there was a sole, unrelated cause of Mrs. Stitt's GBS. 42 U.S.C. § 300aa-11. Indeed, 42 U.S.C. § 300aa-11 provides that entitlement is not appropriate where Respondent shows that another unrelated factor was the sole reason for Mrs. Stitt's GBS. Here, Respondent's expert, Dr. Raabe, acknowledged that he could not unequivocally say that *C. jejuni* was the cause of Mrs. Stitt's GBS. Tr. at 253. Rather, he testified that he could not say whether *C. jejuni* or something else was responsible for Mrs. Stitt's GBS, including the vaccine. Tr. at 253. Also, the results of the one test for *C. jejuni* were negative. P's Ex. 6 at 178. This evidence is insufficient for Respondent to show by preponderant evidence that a factor unrelated to the vaccine was the sole cause of Mrs. Stitt's GBS. *de Bazan*, 539 F.3d at 1353-54.

expert, Dr. Raabe, relied on literature that showed that *C. jejuni* is strongly associated with GBS. Tr. at 170. Dr. Raabe points to the upset stomach Mrs. Stitt experienced after her return from New York and concluded that this was likely *C. jejuni*, which is responsible for GBS in about 30% of cases. Tr. at 170-71; R's Ex. A. The actual evidence does not support the existence of a *C. jejuni* infection. Mrs. Stitt did not have the classic symptoms of *C. jejuni*: diarrhea, vomiting and nausea. Tr. at 97-98; 99-100. As Dr. Morgan explained, if Mrs. Stitt had gastroenteritis that was caused by *C. jejuni*, that would certainly not have been something Mrs. Stitt would have forgotten or referred to as a mere stomach ache. Tr. at 114-19. And the fact is that the results of the objective diagnostic evidence from her stool sample test for *C. jejuni* were negative. P's Ex. 6 at 178.

To counter this evidence, Dr. Raabe presents literature that indicates that *C. jejuni* could still be the cause of Mrs. Stitt's GBS even if she did not have symptoms. R's Ex. F. Dr. Raabe has never treated a patient with *C. jejuni*, and he based his opinion entirely on his research of medical literature. P's Ex. E, and F. Given the lack of any classic symptoms and a negative test result, Respondent's argument that *C. jejuni* could be the cause of Mrs. Stitt's GBS is weak.

This case presents a close call, especially with regard to *Althen's* prong two. In reviewing the record, to reach a decision, the undersigned must also weigh the persuasiveness of the testimony. To do this, one of the factors to be considered is the relative expertise of the witnesses. *Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1380 (Fed. Cir. 2012) (holding that the special master was not arbitrary or capricious in finding that one of the parties' expert's testimony was more persuasive in light of different backgrounds and specialties and because the literature supports that expert's theory); *see also Moberly*, 592 F.3d at 1325 (special master must be able to assess the reliability of the expert testimony).

Both parties' experts were very well qualified and certainly demonstrated expertise in their fields. But, in weighing their testimony, the undersigned gives greater weight to Dr. Morgan's testimony. Dr. Morgan is a clinician who has treated patients with GBS, including those that suffered from GBS that appeared to have been caused by vaccines. Tr. at 37. His most recent contact with a patient suffering from GBS was approximately two years ago. Tr. at 106-07. In his testimony, he logically explained how Mrs. Stitt's symptoms did not suggest a bacterial or viral illness in that she did not exhibit the classic symptoms. Tr. at 53. He also explained how the test results precluded bacterial and viral causes. Tr. at 53.

Dr. Raabe, who is also a qualified neurologist, did not appear to base his testimony on any clinical experience. He testified that he was semi-retired, and that his prior area of specialty had been electromyography. Tr. at 162-63. He has never testified in the Vaccine Program before. *Id.* He became involved in this case when a doctor approached him. Tr. at 163. He agreed to serve as an expert as he is interested in neurological diseases and this related to GBS. Tr. at 163. Agreeing to act as an expert forced him to read the literature and to perform research regarding the case. Tr. at 163-64. There was no indication that he had treated patients with GBS. He did not have experience with diagnosing or treating patients with *C. jejuni*. Tr. at 174. He did not articulate reliance on clinical work but instead relied nearly entirely on his review of medical literature as a basis for his opinions. Tr. at 163.

At times, Dr. Raabe's opinions appeared to be unsupported by the record or literature. For instance, with regard to his opinion that Mrs. Stitt's GBS was more likely due to her having *C. jejuni*, in his original report Dr. Raabe stated he was relying in part on the fact that Mrs. Stitt was never

evaluated for *C. jejuni*. R's Ex. A. But, contrary to this assertion, the medical records clearly indicate that a test was done for *C. jejuni*, the results of which were negative. Tr. at 224-25, referencing P's Ex. 6 at 178. And, although he postulated that it was likely that Mrs. Stitt's GBS was caused by *C. jejuni*, he admitted that he did not know the symptoms of *C. jejuni* and had never treated anyone for it. Tr. at 174. Even during his testimony, Dr. Raabe did not rule out the flu vaccine as a potential cause. When asked about his conclusion regarding cause, he acknowledged that he could not conclude whether the cause was *C. jejuni* or the flu vaccine or something else. Tr. at 253.

In addition, in his initial report, Dr. Raabe opined that an appropriate post-vaccinal temporal relationship was approximately 10-14 days and that he believed that 5-1/2 weeks made it less likely to have caused Mrs. Stitt's GBS. Tr. at 168; R's Ex. A. But, during his testimony, Dr. Raabe acknowledged that based on studies, the accepted standard time frame was six weeks. Tr. at 237.

In sum, Dr. Morgan had more experience with treating patients with GBS including those where the cause was post-vaccinal. He also appeared to have more familiarity with the literature regarding vaccines and GBS. Dr. Morgan's testimony is given more weight.

As to whether there is sufficient evidence to establish a logical sequence of cause and effect between Mrs. Stitt's GBS and her death, the parties have stipulated that one of the causes of Mrs. Stitt's death was GBS. Stip. ¶¶ 16 & 17. The parties' respective experts acknowledged this although they had slightly different views as to the connection. Petitioner's view was that the flu vaccine was a substantial factor in causing Mrs. Stitt's GBS and that that brought about her death. Tr. at 66-67. Respondent's view was that Mrs. Stitt's GBS led to her hospitalization and weakened condition and that the treatment she received, including intubation, caused her to contract pneumonia which, in turn, led to her death. Tr. at 231. Under either view, Mrs. Stitt's GBS was a substantial factor in bringing about her death.

Based on the record as a whole and giving appropriate weight to the evidence, undersigned finds that Petitioner has provided sufficient evidence and has satisfied *Althen* prong two. She has proven that it is more likely than not that the vaccine was a substantial factor in causing Mrs. Stitt's GBS, which in turn was a substantial factor in bringing about her death.

C. Petitioner Has Shown That Mrs. Stitt's GBS Occurred Within a Medically Acceptable Time Frame, Thereby, Satisfying *Althen's* Prong Three.

With regard to *Althen's* prong three, there is little, if any, dispute that this prong is satisfied. Dr. Morgan said that six weeks was generally accepted as a medically appropriate time period for the onset of GBS after infection. P's Ex. 14; Tr. at 124. Given Mrs. Stitt's hospitalization occurred on November 3, 2008, 5-1/2 weeks after her vaccination on September 25, 2008, the temporal relationship prong is satisfied. The literature submitted in the record indicates that six weeks is the standard, accepted time frame. R's Ex. E-1at 8. n.26; R's Ex. E-3 at 4 (p. 646); R's Ex. E-4 at 1; R's Ex. C-3 at 3. Although Dr. Raabe initially said that the 5-1/2 week lapse between vaccination and Mrs. Stitt's hospitalization made it unlikely to be the cause, *see* R's Ex. A, at the hearing, he acknowledged that the studies all use up to six weeks as the accepted time period. Tr. at 221-23, 236. Petitioner has produced sufficient evidence to show that Mrs. Stitt's hospitalization, within 5-1/2 weeks of the vaccination, occurred within a

medically acceptable time frame, thereby satisfying *Althen's* prong three.

VII. CONCLUSION

For the reasons stated above, the evidence presented demonstrates that the flu vaccine Mrs. Stitt received was a substantial factor in causing Mrs. Stitt's GBS. And, her GBS was a substantial factor in causing her death. Petitioner has established entitlement to compensation under the Vaccine Act. This matter shall now proceed to consideration of damages.

IT IS SO ORDERED.

/s/ Daria J. Zane
Daria J. Zane
Special Master