In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

AUSTIN ROACH-YOHEY, *as representative of the Estate of* ANGELA ROACH,	*	No. 17-1744V Special Master Christian J. Moran
Petitioner,	*	
	*	Filed: October 17, 2025
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Sean Greenwood, The Greenwood Law Firm, PLLC, Houston, Texas, for petitioner;
Madelyn E. Weeks, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT TO COMPENSATION[1]

The petition alleges that an influenza ("flu") vaccine harmed Angela Roach. This allegation is supported by a doctor whom petitioner retained, Lawrence Steinman. Petitioner is proceeding on three causes of action: (1) Ms. Roach suffered Guillain-Barré syndrome ("GBS") as defined in the Vaccine Injury Table,

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

(2) the flu vaccine was the cause-in-fact of Ms. Roach's development of non-regulatory Guillain-Barré syndrome, and (3) the flu vaccine significantly aggravated an underlying disorder. The Secretary opposes compensation. The Secretary's opposition is based, in part, on the reports of a doctor he retained, Jeffrey Cohen. The parties advocated through briefs.

A review of the evidence and arguments shows that petitioner is not entitled to compensation. First, Ms. Roach does not meet the regulatory definition of Guillain-Barré syndrome. This finding defeats the on-Table claim. Second, the evidence does not preponderantly support a finding that Ms. Roach developed GBS at all. Third, the development of the significant aggravation claim was incomplete and misguided. A complete explanation follows.

I. Medical Conditions

As discussed in more detail below, three medical conditions are relevant to this case: alcoholic neuropathy, GBS, and the Miller-Fisher variant of GBS. A brief introduction is provided for context, although additional nuances are presented throughout the decision.

A. Alcoholic Neuropathy

Chronic consumption of alcohol can lead to "neurologic complications through both direct and indirect effects on the central and peripheral nervous systems." Noble & Weimer[2] at 624. One consequence in the central nervous system can be Wernicke syndrome, which "occurs due to thiamine deficiency [and] develops in an acute to subacute manner over the course of days to weeks, and is characterized by a cognitive disorder, gait ataxia, and ophthalmoparesis." Id. at 626.

Outside the central nervous system, the "association of peripheral nerve disease and ethanol use has been recognized for centuries." Noble & Weimer at 632.

> When identified, alcoholic neuropathy is indistinguishable from other distal sensorimotor axonal

[2] James M. Noble and Louis H. Weimer, Neurologic complications of alcoholism, 20 CONTINUUM 624 (2014). Filed as Exhibit A-6.

> processes. As with many other etiologies, symptoms typically begin with distal paresthesia in the feet and slowly progress proximally. In most cases, the onset is typically slow and insidious and may begin to affect the hands once leg symptoms ascend well above ankle level, thus yielding the classic symmetric stocking-glove sensory pattern.

Id. at 633.

Here, the parties agree that Ms. Roach suffered from alcoholic neuropathy. While not denying that Ms. Roach suffered from alcoholic neuropathy, petitioner and Dr. Steinman maintain that she also suffered from Guillain-Barré syndrome.

B. Guillain-Barré syndrome --- Acute Inflammatory Demyelinating Polyneuropathy

According to the Secretary, GBS "is an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes." 42 C.F.R. § 100.3(c)(15)(i). Here, Ms. Roach is alleged to have suffered from the subtype that is the most common in North America, acute inflammatory demyelinating polyneuropathy (often abbreviated "AIDP"). AIDP is characterized by "symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots." 42 C.F.R. § 100.3(c)(15)(ii). The regulatory diagnostic criteria is discussed in section V below.

A basis for the claim that the flu vaccine harmed Ms. Roach is that she suffered from the AIDP form of GBS. However, at least one doctor considered that she might suffer from another form.

C. Guillain-Barré Syndrome --- Miller Fisher Syndrome

According to the Secretary, Miller Fisher syndrome is another subtype of GBS. Miller Fisher syndrome is "characterized by ataxia, areflexia, and ophthalmoplegia." 42 C.F.R. § 100.3(c)(15)(iii). As of the filing of the Third Amended Petition on September 27, 2024, there is no claim that Ms. Roach suffered from Miller Fisher syndrome.

II. Events in Ms. Roach's Medical History

A. Before and Through Vaccination

Ms. Roach had a lengthy medical history. The earliest medical record filed is dated January 22, 2013. Exhibit 11 at 5. Ms. Roach saw her primary care provider, Andrew Swanson. She presented with depression, and described it as chronic and ongoing with some sleep disturbance. Id. Ms. Roach also presented with sores on her scalp and reported that the onset had been associated with stress. Id.

On July 30, 2014, Ms. Roach visited the emergency room at Northern Nevada Medical Center (NNM). Exhibit 14 at 94. At this time, she was 39 years old. Ms. Roach reported a two-month history of abdominal pain, nausea, and vomiting. She stated that she vomited nearly every day, occasionally with specks of blood, and had lost twenty pounds due to her inability to eat. Ms. Roach stated that she had "2 cocktails every night," and she "denie[d] excessive drinking or drinking to the point of intoxication." Id.

Labs revealed sludge in Ms. Roach's gallbladder and an enlarged liver. Exhibit 14 at 97, 106. The doctor who reviewed the results, Gina Dapra, opined that "some of her LFT [liver function test] elevation may be related to alcoholic hepatitis or other hepatitis, but we will get her for possible cholecystitis." Id. at 97.[3] Dr. Dapra expressed concern that Ms. Roach "may have a cholecystitis/biliary colic given the location of her tenderness, the increased pain with eating, [and her] vomiting." Id. She also noted that the AST to ALT ratio suggested alcohol abuse. Id. at 97-98. Dr. Dapra stated, "I suspect that some of the patient's hepatic enlargement . . . and LFT elevation may be related to alcohol, perhaps she drinks more than she is leading us to believe." Id. at 98.

Ms. Roach was discharged on July 31, 2014 with the following diagnoses:

> 1. Abdominal pain with no findings to suggest acute cholecystitis, unsure etiology.

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[3] The stem "cholecyst(o)" refers to the gallbladder. Dorland's Illus. Med. Dictionary 343 33rd ed. Thus, "cholecystitis" is inflammation in the gallbladder. Id. "Cholecystectomy," which is used later means the removal of the gallbladder. Id. at 343.

> 2. Anemia, macrocytic in nature. Elevations in alkaline phosphatase as well as AST and ALT with negative hepatitis panel. Likely nonalcoholic steatohepatitis.
>
> 3. Also history of alcohol use, likely dependence, likely alcohol liver disease as well.

Exhibit 14 at 111. It was noted that her pain "could be secondary to alcohol liver hepatitis" and she was advised to discontinue any drinking and consult with a surgeon, Dr. Swanson, about gallbladder removal. Id.

Ms. Roach returned to the NNM emergency department on August 5, 2014 with a complaint of severe upper abdominal pain and vomiting. Exhibit 14 at 82. It was noted that her LFTs had much improved since her last visit, and that she did not have active cholecystitis or cholelithiasis. Id. at 85. She was discharged the same day.

On August 13, 2014, Ms. Roach again presented to the NNM emergency department with abdominal pain. Exhibit 14 at 73. Ms. Roach stated that "she was supposed to follow up with a surgeon for possible removal" of her gallbladder. Id. Her LFTs were "similar to those in the past, and according to GI, more consistent with alcohol use." Id. at 76. She was discharged and stated that she would follow up with surgery and GI. Id.

Two days later, Ms. Roach consulted with Dr. Wynter Phoenix about her gallbladder. Exhibit 14 at 58. Dr. Phoenix assessed her as having biliary sludge and hepatosplenomegaly likely attributable to alcohol and acetaminophen use. Id. at 59. Dr. Phoenix explained to Ms. Roach that removing her gallbladder "may not alleviate all of her problems," but scheduled her for a cholecystectomy and prescribed a small number of narcotics until the surgery. Id.

Ms. Roach underwent the laparoscopic cholecystectomy on August 22, 2014 at NNM. Exhibit 14 at 68. "Her liver biopsy intraoperatively did not show any signs of cirrhosis or fibrosis; however, did show fatty enlarged liver, which was definitely seen intraoperatively." Id. She was discharged on August 25, 2014.

On September 3, 2014, Ms. Roach presented to the emergency department at Renown Regional Medical Center with complaints of numbness and pain in her hands and feet, starting about two weeks prior and predating her cholecystectomy, although the symptoms became worse after that point. Exhibit 13 at 4, 11. The

numbness was "progressively worse each day" and it had "become very painful to put any pressure on her hands and feet." Id. at 4. Ms. Roach reported that she had lost approximately 30 pounds over the past two months, and denied routine alcohol use. Id. She described her vision as a bit blurry, and noted that her hair seemed to be falling out more than usual. Id. at 11.

Upon exam, it was noted that Ms. Roach had "subjectively diminished" sensation around the left side of her lower face and on the lateral aspect of her upper left thigh. Exhibit 13 at 12. Her gait was normal, but she had a positive Romberg test with a loss of balance. She had 5/5 strength in her lower extremities and 4/5 in her upper extremities proximally and 4-/5 distally, which was described as "symmetric." Id. Given her high sed rate, there was concern for an acute inflammatory process. The doctor ordered an MRI of the cervical spine and brain, a CT scan of her chest, abdomen, and pelvis, and a hepatitis panel. Id.

Ms. Roach's September 4, 2014 brain MRI showed "symmetric hazy T1 hyperintensity in the basal ganglia. This has been described in hepato-cerebral encephalopathy, however, this usually seen in patients with end-stage cirrhotic liver disease." Exhibit 13 at 37. The MRI was otherwise unremarkable, "with no evidence of acute infarction, hemorrhage, or mass lesion." Id. The cervical spine MRI revealed "minimal degenerative retrolisthesis," Id. at 38-39. The CT scan was unremarkable, with findings consistent with Ms. Roach's recent cholecystectomy. Id. at 41.

Ms. Roach then saw Dauod N. Majid, a resident in the Renown neurology department, on September 5, 2014. Exhibit 13 at 14. Given the MRI results, Dr. Majid opined that her degenerative joint disease was not causing her symptoms, but that it was "possible that this could be a porphyria disorder." Id. at 16. He recommended an EMG and nerve conduction testing. Id.

Ms. Roach was discharged on September 5, 2014 with a primary diagnosis of severe bilateral peripheral neuropathy. Exhibit 13 at 9. She was prescribed gabapentin, ibuprofen, oxycodone, and Norco, and was instructed to follow up with neurology and neurosurgery. Id. at 18-19. Ms. Roach was noted to be "doing quite well" upon discharge. Id. at 9. She was given information to follow up with Dr. Bigley in neurology and Dr. Song in neurosurgery, and it was recommended that she follow up with an EMG and labs. Id. at 9-10.

Ms. Roach then saw gastroenterologist John Gray on September 9, 2014. Exhibit 9 at 7. It was noted that, at the time of her admission to the hospital for

severe abdominal pain, "she was taking frequent handfuls of Advil and Tylenol in addition to drinking 2 large alcoholic drinks daily." Id. She had not had alcohol since then. Id. Upon exam, her liver was enlarged and palpable. Id. at 8. Dr. Gray's impression was steatohepatitis, likely on the basis of alcohol, with ridging fibrosis, alcohol abuse, and chronic back pain with narcotic dependency. Id. at 9. He wrote that Ms. Roach had "chronic liver disease likely on the basis of alcohol and chronic excessive Tylenol intake." Id. Dr. Gray ordered blood work "to rule out other potential sources of liver disease." Id. He advised her to abstain from alcohol completely and to take no more than 6 Tylenols per day. Id.

Ms. Roach saw neurosurgeon Deven Khosla on September 16, 2014. Exhibit 14 at 114. She had been advised by Dr. Song that she required surgery on her cervical spine due to bone spurs, and sought a second opinion. She had 5/5 strength, 2+ reflexes, and her gait was antalgic due to the difficulty of putting pressure on her feet. Id. Dr. Khosla reported that Ms. Roach had "sudden onset of dysesthetic sensations in both hands and feet that appear to be a peripheral neuropathy issue," and opined that she did not require cervical spine surgery. Id. at 115.

On October 3, 2014, Ms. Roach saw a pain management physician, Dan Snow. Exhibit 14 at 12. She reported bilateral hand and foot numbness from August 2014, which became worse after her cholecystectomy. Id. She was referred to a neurologist, Kim Bigley, for further evaluation. Dr. Bigley saw Ms. Roach on October 15, 2014 and performed an EMG and nerve conduction study. Id. at 1. Dr. Bigley opined that Ms. Roach's study did "not have dramatic findings but the results are not what one would expect for a 39-year-old woman." Id. Dr. Kim's impression was that the results "may be consistent with a mild neuropathy," and suggested clinical correction. Id. at 3.

Ms. Roach saw Dr. Snow again on December 29, 2014. Exhibit 7 at 5. She presented with pain in her feet bilaterally going up into her knees, and pain in both hands. She stated that her hands would go from completely cold to "so hot that it feels like they're on fire." Id. Her left leg had more numbness than her right leg, and she felt more sensation laterally on her lower legs than medially. Id. She had normal strength and gait, but her "lower extremities had symmetric medial paresthesias from the knee down [and] inconsistent dermatonic paresthesias." Id. Dr. Snow assessed Ms. Roach as having peripheral neuropathy, paresthesia of the foot, and paresthesia of the hand. Id. at 6. Along with medications, he prescribed

an MRI of the lumbar spine to evaluate the possibility of a radiculopathy causing the pain. Id.

Ms. Roach next saw Dr. Snow on January 28, 2015 to follow up on her test results. Exhibit 7 at 7. She had pain in her feet bilaterally radiating up to her knees and tingling pain in both hands, and again described her hands as feeling icy to very hot. Ms. Roach also had "pain in her lumbar region with radiation into her hips that is aggravated by physical activity." Id. Dr. Snow noted that the MRI "showed degenerative disc disease with stenosis in the lumbar region." Id.; see also Exhibit 4 at 37. Dr. Snow again assessed Ms. Roach as having peripheral neuropathy, paresthesia of the foot, paresthesia of the hand, and peripheral neuropathy, as well as a hernia of the abdominal wall. Exhibit 7 at 7-8. He discussed the benefits of epidurals for her peripheral neuropathy, and Ms. Roach was to return for a massage and epidural. Id. at 8.

Ms. Roach returned for the epidural on February 11, 2015. Exhibit 7 at 9. She continued to see Dr. Snow over the next year for medication and pain management treatment for her degenerative disc disease. She received a termination letter "as a result of her positive amphetamine [urine drug screening]" in July 2016. Id. at 38.

Ms. Roach had another lumbar spine MRI on October 13, 2016, which again showed disc desiccation at L5-S1. Exhibit 6 at 19. Ms. Roach returned to Dr. Song on December 1, 2016, with complaints of severe low back pain radiating down her legs, neck pain radiating down both arms, and numbness and tingling in her legs. The pain was sharp and stabbing. Id. at 5. Dr. Song noted the recent MRI, and reordered an MRI of her cervical spine with plans to follow up in three months to decide whether to recommend surgical intervention or let Ms. Roach continue pain management. Id.

On December 5, 2016, Ms. Roach returned to Renown and was seen by Joshua Dubansky. Ms. Roach complained of nausea and vomiting and stated that she had "left sided numbness and worsening back pain." She and her husband reported that she had appeared jaundiced since about a week prior. Exhibit 3 at 39-40. Dr. Dubansky noted that Ms. Roach's "history and review of symptoms [was] confusing and not particularly coherent. She [did] not appear intoxicated or alerted, nonetheless, [Dr. Dubansky found] her history and review of systems to be unreliable." Id.

Lab results revealed that Ms. Roach had elevated LFTs, bilirubin, and white blood cells, and electrolyte changes consistent with GI losses. Exhibit 3 at 41-44. A CT of her abdomen showed that Ms. Roach had an enlarged fatty liver, and findings were consistent with acute appendicitis. Id. at 43-44. Dr. Dubansky was concerned for liver failure and sepsis if Ms. Roach was not treated, and recorded his final impression as acute appendicitis, transaminitis, jaundice, leukocytosis, and metabolic acidosis. Id. at 44.

The following day, December 6, 2016, Ms. Roach was seen by surgeon Robert Nachtsheim. Ms. Roach told Dr. Nachtsheim that she had experienced fevers and occasional abdominal pain over the last two weeks, and chills, nausea, and vomiting for the last three weeks. Her abdomen was nontender in the lower right quadrant, and she had an enlarged appendix and an enlarged liver. Exhibit 3 at 55-56. She tested positive for benzodiazepines and opiates on a urine screening. Id. at 57. Although Dr. Nachtsheim opined that it was unlikely that Ms. Roach was suffering from appendicitis and recommended that she not undergo an appendectomy, Ms. Roach went through with the procedure that same day. Id. at 58. She also received the flu vaccine. Id. at 329.

B. After Vaccination

Dr. Patrick Woodward saw Ms. Roach after her procedure. Exhibit 3 at 61. The day after her appendectomy, Dr. Woodward told Ms. Roach that her liver problems were likely caused by alcohol use. Id. at 65-66. Ms. Roach confirmed that she drank several vodka drinks each night and had been doing so "for quite some time," and perhaps "more over the last month." Id.

Ms. Roach remained in the hospital overnight. She was seen by a gastroenterologist, Dr. Erik de Jonghe, on December 8, 2016. Exhibit 3 at 49. Dr. de Jonghe said Ms. Roach appeared to be a "poor historian," highlighting that she believed she was in the hospital for pneumonia, numbness in her left leg, and kidney pain. He further noted that her liver enzymes had been elevated since at least 2014 and that she admitted to alcohol abuse, although she also stated that she "quit last week." Id. Dr. de Jonghe recorded that her condition was consistent with alcoholic hepatitis. He recommended complete alcohol cessation and a lab work-up. Id. at 54. Ms. Roach was discharged that same day. Her diagnoses were "resolved sepsis, unlikely appendicitis, acute alcoholic hepatitis, alcohol abuse, thrombocytopenia, acute on [sic] chronic anemia with acute blood loss, and hyperbilirubinemia, and she was "strongly advised to stop drinking alcohol in entirety." Id. at 45.

Ms. Roach returned to Renown on December 26, 2016. Exhibit 3 at 329. She reported numbness in her face, chest, and bilateral lower extremities that had started a couple days prior. Id. at 332. An emergency department provider, Dr. Andrew Abrass, examined Ms. Roach on December 27, and noted that she had "extensive jaundice," mild asterixis, decreased sensation and a "mild questionable facial droop" on the left side of her face, and decreased sensation in her left forearm, calf, and foot. Id. at 334. Her white blood cell count was "grossly elevated," and Dr. Abrass put Ms. Roach on an antibiotic to cover for a possible infection from her appendectomy. Id. at 346. He ordered CTs of her abdomen and lumbar spine to rule out an epidural abscess, and admitted Ms. Roach to the hospital. Id. at 346-47.

Ms. Roach was next seen by a D.O., Dr. Natalie Lewman. Exhibit 3 at 349. Ms. Roach reported that she noticed leg weakness two to three days prior, as if "her legs were going to collapse." Id. She estimated that she had fallen about 15 times over the last three days. Id. Ms. Roach also described "left-sided jaw, left neck and left shoulder numbness" that had started earlier that day and had been constant and had not improved with rest. Id. at 350. Ms. Roach reported that she had stopped drinking alcohol three weeks prior. Id.

Ms. Roach was seen by surgeon Dr. Paul Stumpf on December 27, 2016. Exhibit 3 at 353. Although Ms. Roach had a high white blood cell count and a diagnosis of sepsis, Dr. Stumpf stated that she had hepatic dysfunction and potentially hepatic failure. Id. at 354. He recommended GI medicine and repeating the hepatitis panel. Id. Dr. Stumpf saw no evidence of a surgical problem. Id.

Dr. Stumpf discussed Ms. Roach's condition with another doctor, David Julian. Exhibit 3 at 356. Dr. Stumpf again questioned whether Ms. Roach was actually septic. Id. Ms. Roach was positive for malaise/fatigue, abdominal pain, itching, and weakness, and she was "markedly jaundiced." Id. Dr. Julian suspected that her weakness was cirrhosis related. Id. at 358. On December 28, 2016, Dr. Julian confirmed that Ms. Roach was ready for discharge. Id. at 354. Her final diagnosis included acute alcoholic hepatitis, resolved leukocytosis, alcoholic cirrhosis, paresthesias, hyperkalemia, and Grade I diastolic dysfunction. Id. at 347. It was reported that she was feeling "much better" and that her paresthesias had largely resolved. Id. at 348. Ms. Roach was advised to discontinue alcohol use, which she promised she would. Id.

Ms. Roach returned to the Renown emergency department on January 1, 2017. Exhibit 3 at 512. She reported weakness and stated that she had been having difficulty walking. She had been "unsteady on her feet since her hospitalization and it seem[ed] to be worsening," and she was "almost wheelchair bound and require[d] full-time assistance from family members." Id. at 517. She denied drinking or drug use. Her lower extremities felt weaker than her upper extremities. She did not have slurred speech, but was "occasionally confused." Id.

Emergency department provider Dr. Brian Trimmer conducted an exam, and diagnosed her with back pain, spinal stenosis, neuropathy, and liver disease. Exhibit 3 at 517. He noted jaundice and muscle atrophy, and wrote that Ms. Roach had "Remarkable ataxia with hand flapping, poor finger to nose, poor heel to shin. Generalized weakness throughout. Paresthesias lower extremities primarily. Unable to ambulate. Lack of DTR at Achilles and patellas bilaterally." Id. at 519. Dr. Trimmer stated that Ms. Roach's exam was consistent with Wernicke's encephalopathy and ordered a detox bag with thiamine. Id. at 522. She also had significant hypokalemia[4], which was likely contributing to her weakness. Id. Dr. Trimmer's final impression was ataxia, generalized weakness, leukocytosis, electrolyte disturbances, alcoholic hepatitis, abnormal CT scan of the abdomen and pelvis, and ascites. Ms. Roach was admitted to the hospital, and Dr. Trimmer ordered "the highest level of care" with instructions to rule out bacteremia and spontaneous bacterial peritonitis. Id.

Dr. Susan Marron saw Ms. Roach upon admission and recorded her history and complaints of severe ataxia, numbness in her extremities, and left facial numbness. Exhibit 3 at 523. Dr. Marron observed that Ms. Roach was "obviously quite jaundiced" but noted no obvious motor deficits in her face. She had severe ataxia and some paresthesias in her bilateral upper extremities, and was able to move her lower extremities on the gurney. She could not hold herself up at all, and appeared to be ataxic with generalized bilateral weakness. Id. at 524-25. Dr. Marron did not note any encephalopathy, and Ms. Roach did not have slurred speech but answered questions "with difficulty." Id. at 525.

MRIs of Ms. Roach's brain and cervical spine, thoracic spine, and lumbar spine were taken on January 2, 2017. Exhibit 3 at 705. The brain MRI showed

[4] Hypokalemia is the "presence of an abnormally low concentration of potassium ions in the circulating blood." Hypokalemia, STEDMANS MEDICAL DICTIONARY 429130 (2014).

"stable symmetric signal abnormality in the basal ganglia which can be seen in the setting of hepatic encephalopathy." Id. The spinal MRIs showed stable degenerative changes. Id.

Dr. Omar Ashraf saw Ms. Roach on January 3, 2017. Exhibit 3 at 702. He recorded that Ms. Roach "was found to be septic on admission and started on empiric antibodies." Id. She had back pain, focal weakness, abdominal distention, edema, and pallor. Id. at 702-03. Dr. Ashraf had concern for GBS due to her ataxia and progressive neurological deficit. He consulted with neurology and ordered a lumbar puncture. Id. at 706.

Ms. Roach was seen by neurologist Dr. Jonathan Spivack on January 4, 2017. Exhibit 4 at 606. He recorded that she had "progressive quadriparesis beginning about 2 weeks prior to admission," which had been "preceded by a 1-2 week course of progressive coughing and a possible pneumonitis treated with antibiotics." Id. at 607. She did not describe "actual weakness, but fatigue and incoordination." Ms. Roach could usually walk with minimal assistance and occasionally a cane, but she eventually required the use of a walker and then lost the ability to stand as her ataxia progressed. Id. Dr. Spivack also noted her "chronic neuropathy, presumably related to alcohol," and a "constant burning paresthesias in the feet and hands, [and] some loss of sensation." Id. Upon exam, Dr. Spivack observed bilateral facial droop and bilateral ptosis, but Ms. Roach's smile was symmetric and there was no nystagmus. Id. at 608. She had strength almost intact throughout, although with some possible weakness distally in her hands. Ms. Roach had bilateral biceps and triceps reflexes but otherwise was areflexic. She had "consistent appendicular dystaxia in both upper and lower extremities out of proportion to the degree of weakness." Id.

Dr. Spivack's impression was "a progressive ataxia with hyporeflexia/areflexia and no evidence of ophthalmoplegia." Exhibit 3 at 609. He also noted bilateral ptosis and "questionable fatigable weakness with the shoulder girdles bilaterally" and diminished tone throughout. Id. Dr. Spivack wrote:

> Consideration would be for an acute inflammatory demyelinating polyneuropathy such as Guillain Barre, but also a Miller Fisher variant with the significant limb ataxia and a proportion to the degree of weakness, though there is absent ophthalmoplegia. Patient's weakness is minimal, the ataxia out of proportion. The areflexia again could be related to a progressive polyneuropathy, but

> again she has a history of chronic neuropathy that I assume is related to alcohol and this is serving to muddy the waters. Myasthenia gravis is the other possibility.

Id. Dr. Spivack ordered serum serologies for myasthenia reflex and for anti-GQ1b antibodies. Id.

Ms. Roach was also seen by a resident in the gastroenterology department, Dr. Htwe Yin, on January 4, 2017. Exhibit 3 at 610. Dr. Yin noted Ms. Roach's history of alcohol use and stated that she was confused upon admission but now appeared alert and oriented. Id. at 611. After reviewing her labs, Dr. Yin's presumptive diagnosis was "alcoholic hepatitis (with or without cirrhosis) with portal hypertension." Id. at 617. She also noted that Ms. Roach had possible hepatic encephalopathy upon admission, but it had since resolved. Id. Dr. Yin recommended prednisolone upon approval from neurology and alcohol cessation. Id. Dr. Yin's report was attested to by Dr. Thomas Caves, who wrote that Ms. Roach's clinical picture was consistent with alcohol induced hepatitis. Id. at 610.

Antibody treatment was discontinued on January 5, 2017, but restarted on January 6 when Ms. Roach tested positive for C. difficile.[5] Exhibit 3 at 672.

Dr. Spivack saw Ms. Roach again on January 6, 2017. Exhibit 3 at 684. Her symptoms were "essentially unchanged," and the protein, glucose, and cell count values from her lumbar puncture were all normal. Id. Ms. Roach had tingling and focal weakness, abnormal reflex, abnormal muscle tone, and abnormal coordination and gait. Id. at 685. Her quadriparesis was unchanged, and her upper extremity weakness was more profound distally than proximally, while her lower extremity weakness was more of a proximal issue than a distal issue. Id. Ms.

[5] Clostridium difficile is "a species [of bacteria] that is part of the normal colon flora in infants and some adults; it produces a toxin that can cause pseudomembranous enterocolitis in patients receiving antibiotic therapy." Dorland's at 368. Pseudomembranous enterocolitis is "an acute type [of inflammation involving both the small intestine and the colon] with formation of pseudomembranous plaques that overlie superficial ulcerations and pass out in the feces; it may result from ... aftereffects of antibiotic therapy." Id. at 618.

Roach was still areflexic except for her biceps, and she required maximum assistance to stand. She also had a negative Tensilon test.[6] Id. at 684, 687.

For his plan, Dr. Spivack wrote:

> Clinically, with a negative Tensilon test, and despite normal protein and white blood cell count in CSF, I still suspect that this is the Miller-Fisher variant of GBS. Absent ophthalmoplegia, she has the hypo-to areflexic throughout and the profound appendicular and gait ataxia. There is a percentage of patients with this condition that do have normal CSF protein value, the anti-GQ 1B antibody titers are positive in almost 85% of patients with this condition, these are still pending. She does require steroids sooner rather than later because of her liver disease, I think empiric treatment with IVIG is appropriate since this will cover all the bases including myasthenia gravis in crisis as well as GBS and its variants.

Exhibit 3 at 687. He prescribed steroids for her alcohol liver disease and neuropathy. Although steroids "are known to worsen myasthenic crises initially," Dr. Spivack stated that IVIG would "hopefully protect her from this if she in fact has myasthenia." Id.

Ms. Roach recovered her strength over the next few days, but continued to have difficulty with ataxia. Exhibit 3 at 650-68. Her ataxia was recorded as "likely from Guillain Barre Syndrome-Miller-Fisher variant vs alcohol." Id. at 655. Ms. Roach also continued to be seen by gastroenterology. On January 10, Dr. de Jonghe opined that she had end stage liver disease secondary to alcoholic hepatitis. Id. at 631. On January 11, Ms. Roach was discharged to a skilled nursing facility. Id. at 601. Her primary diagnoses were Guillain-Barre syndrome, clostridium difficile colitis, alcoholic cirrhosis and related hepatitis, acute delirium secondary to her other diagnoses, iron deficiency anemia, and peripheral neuropathy. Id.

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[6] A "Tensilon test" helps determine whether a person suffers from myasthenia gravis. Dorland's at 1871.

From January 23 to January 26, 2017, Ms. Roach was again hospitalized at Renown. Exhibit 3 at 1129, 1137. She stated she felt "totally fine" but had a fever of 100.9 and an elevated white blood cell count. Id. at 1132. The emergency department provider, Dr. Suzanne Larson, recorded an impression of a heart murmur and fever. Id. at 1136. Dr. Letitia Anderson examined Ms. Roach upon admission, and did "not hear a real heart murmur, but rather a hyperdynamic state," and ordered an echocardiogram. Id. at 1145. Ms. Roach was started on lactulose and rifaximin "to prevent encephalopathy." Id. at 1143. She was still somewhat ataxic but was able to walk short distances with a walker. Id. at 1221-22. Ms. Roach was discharged back to the skilled nursing facility in stable condition on January 26, with medications including lactulose, rifaximin, prednisone, gabapentin, oxycodone, and trazodone. Id. at 1137.

On January 30, 2017, Ms. Roach underwent an upper GI endoscopy with Dr. de Jonghe. Exhibit 2 at 31. His impressions were: normal esophagus, portal hypertensive gastropathy, and normal examined duodenum. Id. She was discharged on February 10, 2017. Id. at 11.

Ms. Roach saw Dr. Mohsen Tamasaby at the Reno Family Medical Center on February 23, 2017. Exhibit 4 at 1. She stated that she had been diagnosed with GBS two months prior after receiving the flu vaccine. She reported joint pain, weakness all over, and an inability to walk by herself. Id. Dr. Tamasaby assessed her as having GBS, insomnia, and low back pain. Id. at 2. He prescribed trazodone and Percocet, and had her follow up with her neurologist and with him in two weeks. Id. Ms. Roach continued to see Dr. Tamasaby for refills of her pain medication every few weeks until September 28, 2017. See Exhibit 4 at 1-28.

On April 3, 2017, Ms. Roach returned to Dr. de Jonghe to follow up about her alcoholic hepatitis and probable cirrhosis. Exhibit 4 at 30.[7] It was reported that she had been sober since her December 2016 hospitalization. Dr. de Jonghe stated that she did not look frankly jaundiced anymore, and noted that there was some uncertainty as to whether Ms. Roach had cirrhosis since her scans did not reveal a small or nodular liver. Id. Still, given other findings, he opined that she "probably has a degree of cirrhosis," but could "potentially regain significant function" since she was detoxing from alcohol. Id. He also noted that Ms. Roach's "hospitalization was complicated by extreme lower extremity weakness"

[7] This scanned record is difficult to read.

and that she was treated for GBS. Although she was not walking with crutches, her overall recovery could take years. Id.

Ms. Roach's next appointment was on April 26, 2017 for a physical therapy evaluation with Marc Magstadt, MPT. Exhibit 5 at 21. Her chief complaint was decreased motor control, standing balance, and overall functional mobility due to GBS. She reported that, shortly after her flu shot in December 2016, she "began having decreased motor control, balance, and coordination causing a fall every once in a while, to the point where she was hospitalized for approximately 2 months." Id. Ms. Roach reported that she had:

> Pain that is generalized, primary due to the peripheral neuropathy from the nerve issues with tingling and burning. Patient reports recently she had decreased gait tolerance, decreased standing balance, as well as decreased motor control and coordination in her bilateral lower extremities, resulting in decreased ambulation tolerance and ability to complete all functional mobility. Patient also reports numbness in her hands as well as decreased grip and coordination resulting in difficulty writing, pretty much being unable to write at this time, as well as dropping things often, resulting in decreased cooking ability and ability to complete IADLs.

Id. She had 4+/5 strength bilaterally on her upper and lower extremities; impaired sensation all over secondary to the numbness from her recent diagnosis; a grip strength test on the left to 12 pounds and the right to 20 pounds; and a moderate risk for falls with a 20/28 on the Tinetti Balance Assessment. Id. at 22. It was recommended that she attend physical therapy 2-3 times per week for 4-6 weeks to decrease pain and improve overall quality of life. Id. at 23.

Ms. Roach next saw Dr. Spivack on May 31, 2017. Exhibit 10 at 2. He described her as having a "slow and steady improvement." Dr. Spivack noted that Ms. Roach "never developed ophthalmoplegia to a notable degree, so the Miller Fisher variant of this disorder was difficult to establish." Her nerve pain had improved, although she was still taking pain medication. Overall, the gait ataxia had stabilized. She had numbness in her lower extremities in their entirety. Dr. Spivack wrote that Ms. Roach's hepatitis had stabilized and she was no longer on steroids. Id. In his assessment and plan, Dr. Spivack wrote:

> She is recovering slowly and steadily, it will take more time, but she also has a bit of a neuropathy related to the chronic alcohol use by history. In any case, I would expect steady improvement over the next several months, though I would expect a plateau after about one year. I did recommend that Neurontin be increased, the dose can be up to 1200 mg, 3 times a day. Caution needs to be maintained since the higher doses of the drug can often make people feel unsteady, and she already has a problem with this related to the [GBS] and maybe some effect of chronic alcohol overuse. Still she seems to be tolerating the drug at this time. I will defer these decisions to her primary care physician. There is no need for neurologic follow-up at this time.

Id. at 3.

Ms. Roach continued with physical therapy between April 26, 2017 and June 1, 2017. Exhibit 5 at 19. A progress note from June stated that her pain had consistently remained at about a 4 to 5 out of 10 throughout the sessions. It was described as "a generalized pain, kind of a numb and tingling type pain with an occasional shooting pain." Id. Her low back pain had improved since Ms. Roach had become more active. Overall, Ms. Roach felt that her motor control and strength and stability in her bilateral lower extremities was improving, but she continued to have trouble with prolonged walking, walking on uneven terrains, and difficulty with her grasp, carrying objects, and writing. She reported that she was "70% improved." Id. The physical therapist, Mr. Magstadt, stated that Ms. Roach was progressing well regarding her overall motor control of bilateral upper and lower extremities and had improved ambulation tolerance and gait pattern, but continued to demonstrate a compensatory gait pattern and strategies, particularly hyperextension of the left knee with decreased motor control. Id. at 20. He recommended that she continue with physical therapy.

Ms. Roach's next physical therapy evaluation was on July 6, 2017. Exhibit 5 at 17. She reported pain at a 6 to 7 out of 10, attributed to increased walking and walking on uneven terrain over the weekend. Mr. Magstadt noted that, prior to this appointment, Ms. Roach "did have multiple sessions where she had a 0 out of 10 pain rating." Id. At her next evaluation on August 9, 2017, Ms. Roach reported a 0 out of 10 pain level and stated that she noticed an improvement in overall

strength, endurance, and function. Id. at 15. The physical therapist assessing her, Jared Pugmire, DPT, noted that Ms. Roach had "shown great progress" so far with physical therapy, and recommended that she continue 2-3 times per week for 4-6 weeks. Id. at 16. It appears that Ms. Roach attended four more sessions through September 6, 2017. Id. at 7-8.

Ms. Roach's liver disease progressed, and she was hospitalized several times for complications of her liver disease. See generally Exhibit 50; see also Resp't's Br. at 32 (summarizing Ms. Roach's hospitalization course). Ms. Roach passed away on June 23, 2021, at age 46. Exhibit 50 at 147. Her cause of death was listed as "cardiopulmonary arrest due to or as a consequence of fulminant hepatic failure due to or as a consequence of alcoholic cirrhosis." Exhibit 48.

III. Procedural History

Attorneys at the Greenwood Law Firm submitted the petition on November 7, 2017. At this time, Ms. Roach was alive and was the petitioner. The November 7, 2017 petition alleged that the flu vaccine caused her to suffer from Guillain-Barré syndrome. Pet. at Preamble. Because the Vaccine Table associates the flu vaccine with GBS, the case was assigned to the special processing unit of the Office of Special Masters. Order, issued Nov. 7, 2017. Medical records were periodically filed.

The Secretary reviewed the material and recommended against compensation. Resp't's Rep., filed Dec. 21, 2018. The Secretary addressed the claim that Ms. Roach suffered GBS as defined for both AIDP and Miller Fisher syndrome. The Secretary maintained that she did not qualify. Id. at 9-11. In the Secretary's view, Ms. Roach was not entitled to compensation pursuant to a causation-in-fact claim. Id. at 11-12. Finally, the Secretary contended that Ms. Roach did not meet the Vaccine Act's severity requirement. Id. at 12.

The first report from Dr. Steinman was filed on May 15, 2019 as Exhibit 15. Dr. Steinman acknowledged that Ms. Roach suffered from chronic alcoholism. Id. at 4. This chronic alcoholism contributed to Dr. Steinman's view that the case was "complex" and "sift[ing] the impact of the influenza vaccine" on the chronic alcoholism was "challenging." Id. at 1.

Dr. Steinman's report begins with a summary of his qualifications. Exhibit 15 at 1-4. His summary of pertinent medical facts contains quotes from the Secretary's report. Id. at 4-7. In the section discussing the relevant diseases, Dr.

Steinman asserted that Ms. Roach "had alcoholic neuropathy and GBS." Id. at 7. Citing the Vandenbulcke & Janssens[8] article, Dr. Steinman stated that a person can suffer from alcoholic neuropathy and GBS. Id. at 8. Notably absent in this section is an explanation as to why Ms. Roach should be diagnosed with GBS. In the remainder of his report, Dr. Steinman presented an opinion as to why the flu vaccine was the cause-in-fact of Ms. Roach's GBS. Id. at 8-18. He also asserted that the flu vaccine "significantly aggravated the alcoholic neuropathy by triggering GBS." Id. at 19.

The Secretary responded to Dr. Steinman's report by obtaining opinions from two people. The first is Dr. Cohen. Exhibit A. The second is Robert Fujinami. Exhibit C. Dr. Fujinami generally addressed the assertions that the flu vaccine can cause GBS. But, given that this case is being resolved on the issue of diagnosis, neither Dr. Fujinami's opinion nor portions of Dr. Steinman's opinions relating to causation are particularly relevant. Thus, although those reports have been reviewed, this decision does not summarize them.

In contrast to causation, diagnosis is very important to this decision and the Secretary's arguments regarding causation are mostly based upon opinions presented by Dr. Cohen. Dr. Cohen's report begins with his qualifications. Exhibit A at 1. In approximately one single-spaced page, Dr. Cohen summarized Ms. Roach's medical records. Id. at 2. He then explained why, in his opinion, Ms. Roach did not suffer from Miller Fisher syndrome. Id. at 3-4. Dr. Cohen maintained that the Vandenbulcke & Janssens article "confirms that alcoholic neuropathy can appear identical to acute Guillain-Barre [] syndrome." Id. at 4.

Given the dispute over whether Ms. Roach suffered from Guillain-Barré syndrome, adjudication through the special processing unit seemed infeasible. The case was assigned to a special master. Order, issued Oct. 18, 2019. The new special master directed petitioner to obtain a report from Dr. Steinman addressing Dr. Cohen's opinion that Ms. Roach did not suffer from Miller Fisher syndrome. Order, issued Oct. 23, 2019.

Dr. Steinman's second report addressed opinions from both Dr. Cohen and Dr. Fujinami. (Again, however, the details of the debate between Dr. Steinman

[8] M. Vandenbulcke and J. Janssens, Acute axonal polyneuropathy in chronic alcoholism and malnutrition, 99 ACTA. NEUROL. BELG. 198 (1999). Filed as Exhibit 22.

and Dr. Fujinami do not affect the resolution of the case.) Dr. Steinman wrote: "Both Dr. Spivack and Petitioner indicated that the differential is large and explained why they both arrived at Miller Fisher Syndrome as a tenable and correct diagnosis." Exhibit 36 at 1 (emphasis removed).[9] Quoting his first report, Dr. Steinman states that "Careful reading of Dr. Spivack's notes indicate that he considered a spectrum of diagnoses ranging from inflammatory neuropathy including the 'Miller Fisher' variant, myasthenia, ADEM and even motor neuron disease." Id. at 2. Dr. Steinman quoted one of Dr. Spivack's reports in which Dr. Spivack wrote: "Consideration would be for an acute inflammatory demyelinating polyneuropathy such as Guillain Barre, but also a Miller Fisher variant." Id. at 2, quoting Exhibit 10 at 11.

The Secretary responded with a second report from Dr. Fujinami on May 26, 2020. Exhibit E. At this time, the Secretary did not submit a second report from Dr. Cohen. Dr. Steinman addressed Dr. Fujinami's opinions in a report filed on August 27, 2020. Exhibit 41, filed Aug. 27, 2020. This report did not add any information regarding diagnosis.

The Secretary requested that petitioner submit updated medical records. Resp't's Status Rep., filed Oct. 27, 2020. Ms. Roach stated that she did not have any updated medical records as she had not received any medical care due, in part, to the Covid-19 pandemic. Pet'r's Status Rep., filed Nov. 30, 2020. The Secretary planned to file more reports from Doctors Cohen and Fujinami. Resp't's Status Rep., filed Feb. 2, 2021.[10]

The next round of reports does not meaningfully advance the analysis. Dr. Cohen wrote essentially one page, asserting that Ms. Roach's post-vaccination symptoms "could be explained by her alcoholic neuropathy." Exhibit F. Dr.

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[9] Dr. Steinman's statement that "Petitioner" asserted Miller Fisher syndrome is curious in at least two respects. First, it is not readily apparent that Ms. Roach alleged that she suffered from Miller Fisher syndrome. When Dr. Steinman wrote his second report, the operative petition alleged that the flu vaccine caused Guillain-Barré syndrome. Pet., filed Nov. 7, 2017, at Preamble. Second, and more importantly, it is not readily apparent why the assertion of the petitioner, who appears not to have any medical training, should influence the opinion of a trained neurologist.

[10] The Secretary's plan to obtain another report from Dr. Cohen was unusual in the sense that Dr. Steinman's most recent report (Exhibit 41) did not address diagnosis.

Steinman maintained his opinion. Exhibit 45. Dr. Steinman's comments on diagnosis largely repeated information from Dr. Spivack and again quoted from the Vandenbulcke & Janssens article.

The Secretary stated that petitioner's attorney learned on July 22, 2021 that Ms. Roach had died. Resp't's Status Rep., filed Sep. 13, 2021.[11] In due course, Austin Roach-Yohey, who is Ms. Roach's son, became the administrator of her estate and was substituted as the petitioner. Order, issued Oct. 8, 2021.

Mr. Roach-Yohey was directed to obtain updated medical records. He submitted them via compact disc on February 2, 2022.

For the Secretary, Dr. Cohen reviewed the more recent medical records, which continued to show that Ms. Roach was consuming too much alcohol. For example, Dr. Cohen cited hospitalizations in 2019 and June 2020. Exhibit H at 2, citing Exhibit 50 at 1226 and 905.[12] Overall, Dr. Cohen maintained that "None of her diagnostic studies were consistent with GBS." Exhibit H at 2. He concluded that "Dr. Steinman has said nothing new or given any new proof that Ms. Roach had GBS." Id. at 3. This report (plus the report from Dr. Fujinami) appeared to complete the disclosure of opinions from the expert. The case was scheduled for a hearing to take place in April 2024. Order, issued Aug. 1, 2022. However, the Secretary stated that Dr. Cohen was not available for unspecified reasons. Resp't's Status Rep., filed Jan. 30, 2024. The hearing was canceled. Non-PDF order, issued Jan. 30, 2024. The case was reassigned to the undersigned. Order, issued Feb. 15, 2024.

The undersigned attempted to understand the claims and the defenses to whatever claims were being asserted. Order, issued Feb. 23, 2024. This order also advised that the parties may want to seek additional information from Dr. Spivack. The order directed Mr. Roach-Yohey to file an amended petition, potentially pleading alternative causes of action.

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[11] It is not readily apparent why nearly two months passed during which both attorneys were aware that Ms. Roach had died yet neither informed the special master.

[12] These hospitalizations contradict the statement in petitioner's November 30, 2020 status report that Ms. Roach did not have any additional medical care.

Although Mr. Roach-Yohey duly filed an amended petition on March 18, 2024, the amended petition is not a model of clarity. It asserted that the flu vaccine "is both the cause-in-fact for Petitioner's [actually Ms. Roach's] GBS and the cause-in-fact of significant aggravation of Petitioner's [actually Ms. Roach's] pre-existing symptoms and conditions." First Am. Pet., filed Mar. 18, 2024, at Preamble. Mr. Roach-Yohey also requested an opportunity to seek more information from Dr. Spivack. Mr. Roach-Yohey recounted that Dr. Steinman was interested in knowing whether Dr. Spivack thought Ms. Roach's progression of symptoms was more consistent with GBS or more consistent with alcoholic neuropathy. Pet'r's Status Rep., filed March 20, 2024.

Both the First Amended Petition and Mr. Roach-Yohey's request to seek more information from Dr. Spivack were discussed in the April 23, 2024 status conference. Mr. Roach-Yohey's counsel was again informed that if Ms. Roach suffered from GBS as defined in the regulations, then Mr. Roach-Yohey was not required to establish that the flu vaccine was the "cause-in-fact" of the regulatory GBS. When asked about what type of GBS afflicted Ms. Roach, counsel responded that it was Miller Fisher, and stated that he would add that specificity to another amended petition. As to Dr. Spivack, petitioner's counsel was welcome to seek additional information from him. See Order, issued Apr. 23, 2024.

Mr. Roach-Yohey amended the petition a second time. This petition alleged that the flu vaccine "triggered Miller Fisher Syndrome, a variant of Guillain Barré Syndrome ("GBS"). Alternatively, the vaccine is the cause-in-fact for Angela Roach's Miller Fisher variant of GBS which significantly aggravated Angela Roach's alcoholic neuropathy." Second Am. Pet., filed May 1, 2024, at Preamble. This second amended petition stated that Mr. Roach-Yohey is claiming that Ms. Roach suffered an injury contained in the Vaccine Injury Table. Id. at ¶ 1.

As to Dr. Spivack, efforts to obtain information from him did not proceed smoothly for a variety of reasons, none of which affect the outcome of this case. Eventually, Dr. Spivack answered a series of questions posed to him in writing via a letter, filed as Exhibit 51 on August 23, 2024. He stated that in his opinion: "The clinical course including the rate of progression for Ms. Roach's disease is more consistent with Guillain-Barré syndrome, not an alcohol-related polyneuropathy." Id. at ¶ 4.e. He added: "Based on the data available at the time of her disease presentation, it is most likely that she did suffer from an atypical presentation of the Miller-Fisher variant of Guillain-Barré syndrome." Id. at ¶ 4.f.

After Dr. Spivack's letter was filed, a status conference was held. The parties suggested that a ruling on the record might be appropriate. Accordingly, they were instructed to file briefs. The briefing order emphasized that the claims that Mr. Roach-Yohey was asserting remained unclear. Order, issued Aug. 30, 2024, at 4-13 (discussing three potential causes of action).

Mr. Roach-Yohey obtained relatively short reports from Dr. Steinman. Dr. Steinman stated that his previous reports "have been clear and unwavering . . . that the diagnosis is GBS, also known as acute inflammatory demyelinating polyneuropathy." Exhibit 57. Dr. Steinman then cited a series of his reports that use the term "GBS."[13]

In Dr. Steinman's final report, he identified the criteria he uses to diagnose Guillain-Barré syndrome, including acute inflammatory demyelinating polyneuropathy and Miller Fisher syndrome. Exhibit 61. Dr. Steinman put forward an article from the European Academy of Neurology / Peripheral Nerve Society.[14] (The details of these criteria are set forth in section VI.A below). Dr. Steinman also quoted (again) his previous reports, which used the term "GBS." Lastly, Dr. Steinman commented upon the possibility of a significant aggravation case. He separated the two conditions:

> The influenza vaccine triggered a new disease GBS, that appeared on top of Mrs. Roach's alcohol neuropathy. The two diseases are independent. Alcohol neuropathy is metabolic, and the other disease-GBS- is autoimmune. This is a significant aggravation case, because both

[13] A potential source of ambiguity is that the term "GBS" can be used as an umbrella term for both acute inflammatory demyelinating polyneuropathy and the Miller Fisher variant. Although "GBS" is often used interchangeably with "acute inflammatory demyelinating polyneuropathy," the possibility that Ms. Roach suffered from the Miller Fisher variant might have warranted a higher degree of precision. In addition, Dr. Steinman's second report stated "Dr. Spivack . . . indicated that the differential is large and explained why [he] arrived at Miller Fisher Syndrome as a tenable and correct diagnosis." Exhibit 36 at 1 (emphasis removed). Plus, it appears that Mr. Roach-Yohey's attorney might also have been confused as the Second Amended Petition asserted claims based upon Ms. Roach suffering from Miller Fisher variant.

[14] Pieter A. van Doorn et al., European Academy of Neurology/Peripheral Nerve Society Guideline on diagnosis and treatment of Guillain-Barré syndrome, 30 EUR. J. NEUROL. 3646 (2023). Filed as Exhibit 62.

> alcohol neuropathy and GBS are peripheral neuropathies, and the peripheral neuropathy was worsened by vaccine induced GBS.

Id. at 5.

These reports from Dr. Steinman prompted Mr. Roach-Yohey to revise the petition again. The third amended petition, which is the operative petition, asserts three causes of action. These are: (1) Ms. Roach developed acute inflammatory demyelinating polyneuropathy as defined in the Vaccine Table (Third Am. Pet., filed Sep. 27, 2024, at Preamble and ¶ 1); (2) the flu vaccine was the cause in fact of Ms. Roach's acute inflammatory demyelinating polyneuropathy (Third Am. Pet. at Preamble and ¶ 27); and (3) the flu vaccine significantly aggravated Ms. Roach's alcoholic neuropathy (Third Am. Pet. at Preamble and ¶ 27).

With the clarification from the Third Amended Petition, the parties could argue their cases through briefs. Mr. Roach-Yohey presented his arguments in a 35-page entitlement brief, filed October 10, 2024. The Secretary responded on December 13, 2024 with essentially two relevant submissions. (Again, the material from Dr. Fujinami is being set aside). The Secretary presented another report from Dr. Cohen. Dr. Cohen challenged Dr. Steinman's use of the article from the European Academy of Neurology and the Peripheral Nerve Society. Exhibit J at 1-2. In his view, Ms. Roach did not suffer from acute inflammatory demyelinating polyneuropathy. The Secretary's other main submission was an 85-page brief.

As discussed in the analysis below, the Secretary made multiple strong points challenging the arguments Mr. Roach-Yohey presented in his brief. Thus, a reply brief would have been appropriate. However, Mr. Roach-Yohey did not file a reply.

Because the time for submitting a reply elapsed months ago, the case is ready for adjudication. As both parties have had a fair opportunity to present their evidence and their arguments, an adjudication based upon the papers is appropriate. See Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

IV. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

V. Analysis: First Cause of Action – On-Table AIDP

Mr. Roach-Yohey's first cause of action is that Ms. Roach suffered acute inflammatory demyelinating polyneuropathy as defined in the regulations. Third Am. Pet. at Preamble and ¶ 1; see also Pet'r's Br., filed Oct. 10, 2024, at 3-7. A petitioner bears the burden of demonstrating that the vaccinee meets the definition of disease as defined in the regulations. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 574 (2015).

The Qualifications and Aids to Interpretation define acute inflammatory demyelinating polyneuropathy with both inclusive and exclusive factors. The inclusive factors include:

> (A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;
>
> (B) A monophasic illness pattern;
>
> (C) An interval between onset and nadir of weakness between 12 hours and 28 days;

> (D) Subsequent clinical plateau (the clinical plateau leads either to stabilization at the nadir of symptoms, or subsequent improvement without significant release; however, death may occur without a clinical plateau).

42 C.F.R. § 100.3(c)(15)(ii).

The Secretary also requires "The absence of an identified more likely alternative diagnosis." 42 C.F.R. § 100.3(c)(15)(ii)(E). The regulations specify a long list of "[e]xclusionary criteria for the diagnosis of all subtypes of GBS" and this list includes "hypokalemia" and "hyperkalemia." 42 C.F.R. § 100.3(c)(15)(vi).

In this case, the Secretary presented at least three arguments explaining why Ms. Roach did not fulfill these criteria. First, the Secretary argued that Ms. Roach's course was not monophasic. See Resp't's Br. at 34-35. Second, the Secretary argued that alcoholic neuropathy is a more likely alternative diagnosis. Id. at 35-47. Third, the Secretary argued that Ms. Roach suffered from hypokalemia. Id. at 47-48.

For purposes of resolving the on-Table claim, the third argument about hypokalemia is dispositive. The arguments about monophasic and alcoholic neuropathy are reviewed in the context of the off-Table claim below.

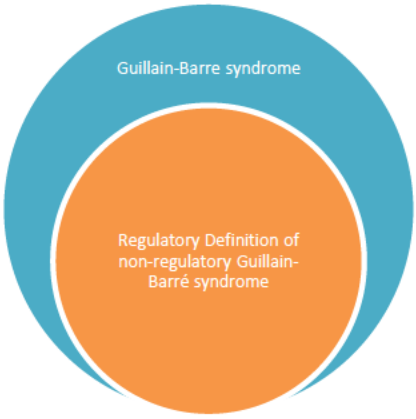
The Secretary identified a series of medical records showing that Ms. Roach suffered from hypokalemia. Resp't's Br. at 41-42. The Secretary also pointed out that Dr. Cohen also raised Ms. Roach's hypokalemia. Id. at 41. By way of contrast, Dr. Steinman did not comment upon hypokalemia. See Exhibits 15 and 36.

Thus, an abundance of evidence supports the finding that Ms. Roach had low potassium. Because hypokalemia excludes an on-Table diagnosis of any form of Guillain-Barré syndrome (including acute inflammatory demyelinating polyneuropathy), Ms. Roach does not meet the standards in the regulation. Therefore, she does not prevail upon her on-Table claim. See Bauer v. Sec'y of Health & Hum. Servs., No. 18-1451, 2024 WL 4534147, at *30 (Fed. Cl. Spec. Mstr. Sep. 23, 2024) (finding that a vaccinee who suffered from hyperkalemia, which is also listed in the exclusionary criteria, did not qualify for Guillain-Barré syndrome as defined in the regulations).

VI. Analysis: Second Cause of Action – Off Table AIDP

The second cause of action is that the flu vaccine was the cause-in-fact of Ms. Roach suffering from acute inflammatory demyelinating polyneuropathy. Third Am. Pet. at Preamble and ¶ 27; see also Pet'r's Br. at 7-23. To prevail on this claim, Mr. Roach-Yohey must establish with preponderant evidence that Ms. Roach suffered acute inflammatory demyelinating polyneuropathy as a preliminary matter. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). When a petitioner fails to establish the claimed diagnosis, special masters are not required to assess whether the vaccine caused the disease by evaluating the Althen prongs. See Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011) ("[i]n the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached").

In determining whether Ms. Roach suffered from AIDP outside of the Table, a beginning point is that the Secretary's definition in the regulation does not necessarily preclude a finding of AIDP outside the regulation. The August 30, 2024 order for briefs explained this concept with reference to a Venn diagram in which the "regulatory GBS" is a circle wholly contained within a larger circle called "non-regulatory GBS."



The parties did not challenge this understanding. Thus, the finding that Ms. Roach did not meet the regulatory definition of AIDP leaves open the possibility that she suffered AIDP as defined elsewhere.

The evidence regarding Ms. Roach's diagnosis comes from two different sources. The first is the set of opinions from doctors the parties retained in the litigation (Dr. Steinman and Dr. Cohen). The second source is the set of opinions

from medical professionals who treated Ms. Roach. Although these groups are separated for purposes of analysis, the opinions from all doctors are ultimately based upon Ms. Roach's signs and symptoms.

A. Opinions from Doctors Retained in the Litigation

The definition for AIDP that Dr. Steinman proposes is, as already mentioned, from the European Academy of Neurology and the Peripheral Nerve Society. This article is relatively long (approximately 20 pages) and cites more than 250 references. The purposes of the article were "to develop an evidence-based international guideline on the diagnosis and treatment of Guillain-Barré syndrome (GBS) . . . and to formulate evidence-based recommendations and consensus-based good practice points (GPPs) for clinical practice." Exhibit 62 (van Doorn) at 537. For diagnosis, these authors compiled a list of items for consideration. They included: "Features required" (3 items); "Features that support diagnosis" (7 items); "Laboratory findings that support diagnosis" (3 items); and "Findings which make GBS less likely" (15 items). Id. at 539.

Of this group, Dr. Steinman commented upon only the three "Features required." Exhibit 61 at 3-5. These required features are:

- Progressive weakness of arms and legs
- Tendon reflexes absent or decreased in affected limbs
- Progressive worsening for no more than 4 weeks

Exhibit 62 (van Doorn) at 539 (footnotes omitted). On pages of 3-5 of his September 26, 2024 report (Exhibit 61), Dr. Steinman emphasized certain attributes for Ms. Roach, such as "numbness and tingling [in] her legs" (Exhibit 6 at 5); "progressive quadriparesis" and "bilateral ptosis" (Exhibit 3 at 608); "progressive quadriparesis beginning about two weeks prior to admission" (Exhibit 3 at 607); "strength [was] actually almost intact throughout, though there may be some weakness distally in the hands. She was diffusely hypo- to aflexic" (Id.).

As Dr. Cohen maintains, Dr. Steinman's opinion is incomplete in two significant respects. First, "Ms. Roach does not meet the third prerequisite due to the prolonged course of her illness. She suffered from progressive worsening for much longer than 4 weeks." Exhibit J at 2; accord Resp't's Br. at 50-52. Second, in Dr. Cohen's view, neurologists with expertise in peripheral neuropathies do not stop with the first three factors. Instead, other factors listed in Table 1 should be

considered. In Dr. Cohen's assessment, Ms. Roach did not have many of the features that support diagnosis and conversely, Ms. Roach did have some of the findings that make a GBS diagnosis less likely. Exhibit J at 2-4.[15]

Dr. Cohen's review of the 25 other factors affecting a diagnosis of GBS is sensible and persuasive for two reasons. First, Dr. Cohen has a great deal of experience in treating patients with peripheral nerve disorders. Exhibit A (report) at 1; Exhibit K (curriculum vitae). In contrast, Dr. Steinman's more specific field of expertise is diseases of the central nervous system. See Exhibit 53 at 2 (noting prizes won for his work on multiple sclerosis). As a board-certified neurologist, Dr. Steinman is certainly qualified to opine on a neurologic diagnosis like Guillain-Barré syndrome. But, on the narrower question about a disease of the peripheral nervous system, Dr. Cohen has superior qualifications. A special master may consider the differences in qualifications in weighing the relative value of competing opinions. See Depena v. Sec'y of Health & Hum. Servs., No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 Fed. App'x 938 (Fed. Cir. 2018); Copenhaver v. Sec'y of Health & Hum. Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016). Although the Secretary argued this point (Resp't's Br. at 66), Mr. Roach-Yohey did not refute it in a reply.

Second, the consideration of other factors listed in Table 1 of the van Doorn article aligns with the overall tone of the article. At a basic level, the authors from the European Academy of Neurology / Peripheral Nerve Society took the trouble to develop a consensus list of features to consider. If there is a reason not to consider these features, neither Dr. Steinman nor Mr. Roach-Yohey has provided one. To take one example, the Taskforce investigated: "In patients with clinically suspected GBS, does examination of the CSF compared with no CSF examination influence the diagnostic test accuracy, treatment response and patient outcome?" Exhibit 62 (van Doorn) at 539 (PICO 2). Laboratory findings that support diagnosis include a finding of increased protein in the CSF, although "normal

[15] Dr. Cohen's report would have been improved if he cited evidence supporting his opinions. For example, he wrote "Ms. Roach had asymmetrical weakness," but did not support this statement by pointing to an exhibit number and page.

protein does not rule out diagnosis." Id. at 540. Ms. Roach's CSF protein was normal. Exhibit 3 at 684, 797.

Another example from Dr. Cohen is that van Doorn states another feature that supports the diagnosis of Guillain-Barré syndrome is cranial nerve involvement. Exhibit 62 (van Doorn) at 539. When Dr. Spivak examined Ms. Roach on January 6, 2017, he found no deficits in her cranial nerve. Exhibit 3 at 685.

Neither Ms. Roach's protein nor the lack of cranial nerve problems are not diagnostic by themselves. However, when multiple findings tend to point away from Guillain-Barré syndrome, the collection of findings carry more substantial weight. Thus, Dr. Cohen's opinion that Ms. Roach did not suffer from AIDP is more persuasive than Dr. Steinman's contrary opinion because Dr. Cohen's opinion is more consistent with the medical literature (van Doorn) and more consistent with Ms. Roach's medical records.

Ms. Roach's pre-existing and undisputed alcoholic neuropathy also tends to weaken the likelihood that Ms. Roach also suffered from AIDP. To start, it is important to acknowledge that the Secretary recognizes that as a matter of logic, a person with an alcoholic neuropathy can also develop AIDP. Resp't's Br. at 49. The possibility of co-existing diseases underlies the Vandenbulcke & Janssens article. See Exhibit 22. But, saying as a theoretical matter that a person could suffer from two diseases is not the same as saying as a practical matter that Ms. Roach suffered from both alcoholic neuropathy and AIDP.

The weight of the evidence favors a finding that Ms. Roach suffered from only alcoholic neuropathy. The Secretary comprehensively and persuasively argued that Ms. Roach's course before and after the flu vaccine was better explained by her alcoholic neuropathy. Resp't's Br. at 35-42. Mr. Roach-Yohey did not rebut any of these arguments through a reply brief.

At best, Mr. Roach-Yohey attempted to anticipate arguments regarding alcoholic neuropathy in his initial brief. Without citing medical records in this context, Mr. Roach-Yohey argues that "Ms. Roach's presentation included new onset facial numbness, left arm weakness, and bilateral lower extremity numbness, which were not part of her clinical presentation prior to the vaccination." Pet'r's Br. at 8. But, as the Secretary points out, "Many of Ms. Roach's post-vaccination complaints mirror her earlier complaints, further supporting Dr. Cohen's opinion that her alcoholic neuropathy is a more likely explanation for her condition than

GBS. Resp't's Br. at 36. For example, for facial numbness, although Ms. Roach had decreased sensation on the left side of her face after the vaccination (Exhibit 3 at 334 – December 27, 2026), she also had decreased sensation before the vaccination (Exhibit 14 at 21 --- September 3, 2014).

Overall, Dr. Cohen's opinion that Ms. Roach suffered from only alcoholic neuropathy and its sequela is more persuasive than Dr. Steinman's opinion that Ms. Roach suffered from alcoholic neuropathy and AIDP. However, Mr. Roach-Yohey's argument rests on more than Dr. Steinman's opinion. Mr. Roach-Yohey also cites an opinion from a treating doctor, Dr. Spivack.

B. Opinions from Doctors who Treated Ms. Roach

The opinions of treating doctors can be quite probative. Cappizano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. See McCulloch v. Sec'y of Health & Hum. Servs., No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). However, the views of a treating doctor are not absolute, Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 745 n.67 (2009), even on the question of diagnosis, R.V. v. Sec'y of Health & Hum. Servs., 127 Fed. Cl. 136, 141 (2016), appeal dismissed, No. 16-2400 (Fed. Cir. Oct. 26. 2016).

During Ms. Roach's hospitalization that began on January 1, 2017, she saw Dr. Spivack. Ms. Roach informed him that she developed weakness after her potential infection the previous month. Exhibit 3 at 606. But, in Dr. Spivack's opinion, Ms. Roach did not have "actual weakness, but fatigue and incoordination." Id. Dr. Spivack's examination detected bilateral facial droop and bilateral ptosis. Id. at 608. Her tone was decreased throughout but her strength was almost normal throughout.

Dr. Spivack considered that Ms. Roach had a "chronic neuropathy, presumably related to alcohol." Exhibit 3 at 606. He also considered that she could have either the AIDP type of Guillain-Barré syndrome or the Miller Fisher variant. Id. at 609. He ordered tests of Ms. Roach's cerebrospinal fluid and tests for an antibody closely associated with the Miller Fisher variant, GQ1B.

When Dr. Spivack saw Ms. Roach on January 6, 2017, the results on her cerebrospinal fluid had come back. They showed normal protein, glucose, and cell

counts. Exhibit 3 at 797. The anti-GQ1B antibody titers were pending. After a review of the available information and another examination, Dr. Spivack "still suspect[ed] that this is the Miller-Fisher variant of GBS." Id. at 687. Dr. Spivack prescribed IVIG empirically because, in part, IVIG would "cover all the bases . . . [including] GBS and its variants." Id.[16]

Dr. Spivack did not see Ms. Roach for the remainder of this hospitalization. See Resp't's Br. at 25. The next visit was as an outpatient on May 31, 2017. Exhibit 10 at 2. Dr. Spivack memorialized that Ms. Roach did not develop any "notable degree" of "ophthalmoplegia." Thus, establishing the "Miller Fisher variant" "was difficult." Dr. Spivack stated that additional follow up was not needed and Ms. Roach did not return to see him.

In the course of this litigation, Mr. Roach-Yohey sought more information from Dr. Spivack. Dr. Spivack answered written questions. He wrote that: "Based on the data available at the time of her disease presentation, it is most likely that she did suffer from an atypical presentation of the Miller-Fisher variant of Guillain-Barré syndrome." Exhibit 51 ¶ 4.f. Relying upon this letter, Mr. Roach-Yohey argues that "Dr. Spivack ultimately concludes that Ms. Roach's condition is consistent with GBS rather than just an exacerbation of her alcoholic neuropathy." Pet'r's Br. at 8.

This argument misconstrues the evidence. Dr. Spivack's diagnosis is the Miller-Fisher variant. But, as reviewed in the procedural history, Mr. Roach-Yohey is not claiming that Ms. Roach suffered the Miller-Fisher variant. The claim is that Ms. Roach suffered from AIDP. Thus, Dr. Spivack's August 22, 2024 letter does not preponderantly support an argument that Ms. Roach suffered from AIDP.

C. Summary regarding AIDP

The evidence does not preponderate in favor of finding that Ms. Roach suffered from the acute inflammatory demyelinating polyneuropathy form of Guillain-Barré syndrome. As stated earlier, Dr. Cohen's opinion weighs more

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[16] The Secretary emphasizes that "empiric" means "founded on practical experience, rather than on reasoning alone, but not established scientifically." Resp't's Br. at 44, quoting Stedman's Medical Dictionary at 632.

heavily than Dr. Steinman's opinion. Dr. Spivack's work points away from the AIDP form as an appropriate diagnosis.

Given the finding that Mr. Roach-Yohey did not meet his burden of showing that Ms. Roach suffered from AIDP, exploring causation via the Althen test is not necessary. The finding regarding (the lack of) diagnosis suffices to resolve the Second Cause of Action.

VII. Analysis: Third Cause of Action – Significant Aggravation

The third and final cause of action is that the flu vaccination "significantly aggravated [Ms. Roach's] alcoholic neuropathy. Third Am. Pet. ¶ 27; accord Pet'r's Br. at 23-32. This cause of action was developed in Dr. Steinman's September 26, 2024 report. He stated: "The influenza vaccine triggered a new disease GBS, that appeared on top of Mrs. Roach's alcohol neuropathy. The two diseases are independent. Alcohol neuropathy is metabolic, and the other disease-GBS- is autoimmune." Exhibit 61 at 5. He explained why, in his view, there could be a claim for significant aggravation: "because both alcohol neuropathy and GBS are peripheral neuropathies, and the peripheral neuropathy was worsened by vaccine induced GBS." Id. Mr. Roach-Yohey follows in his footsteps. Pet'r's Br. at 26-27. Mr. Roach-Yohey argues: "[t]he flu vaccine does not directly worsen alcoholic neuropathy but triggers a new autoimmune response (GBS) that further compromises the peripheral nervous system, thereby significantly aggravating the existing neuropathy." Pet'r's Br. at 28.

The Secretary seizes this language. According to the Secretary, Mr. Roach-Yohey's acknowledgment that "the flu vaccine does not significantly aggravate alcoholic neuropathy" is "fatal to his significant aggravation claim." Resp't's Br. at 73-74. A response to the Secretary's argument might have been expected, but no reply was filed.

A leading case that differentiates initial onset cases from significant aggravation cases is Paluck. In consideration of granting a first motion for review, the Court stated: "If [the vaccinee] Karl's neurological, not mitochondrial, symptoms, however defined, were manifested pre-vaccination, then Karl's case involves a significant-aggravation claim." Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. 457, 467 (2012). This statement implies that if the vaccinee's neurologic problems were not manifest before the vaccination, then the claim is an initial onset claim. As part of a ruling on a second motion for review, the Court declined to overturn a determination that the child's neurologic problems started

before vaccination. Paluck v. Sec'y of Health & Hum. Servs., 113 Fed. Cl. 210, 228 (2013), aff'd on non-relevant grounds, 786 F.3d 1373 (Fed. Cir. 2015). Thus, Paluck teaches that in characterizing a claim as an initial onset claim or as a significant aggravation claim, a critical question is determining whether the vaccinee suffered the condition before the vaccination. See Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1362 (Fed. Cir. 2000) (ruling that the special master did not err in reasoning that because the child-vaccinee's seizure disorder started after the second dose of the diphtheria-tetanus-pertussis vaccine, the petitioners could proceed only on a theory that the third dose significantly aggravated the seizure disorder); Childs v. Sec'y of Health & Hum. Servs., 33 Fed. Cl. 556, 559 (1995) (ruling that when the vaccinee did not have a history of a problem before the vaccination, petitioners could not proceed on a theory of significant aggravation).

Here, the Secretary's argument is persuasive and consistent with the cases cited above. Mr. Roach-Yohey did not present any persuasive evidence that the flu vaccine worsened the disease from which Ms. Roach suffered before vaccination, the metabolic alcoholic neuropathy. Indeed, Dr. Steinman actually emphasizes that alcoholic neuropathy and AIDP are "independent" diseases. Exhibit 61 at 5. This distinction is, to borrow a word from the Secretary, "fatal" to this cause of action.

VIII. Additional Comments

Through decisions, special masters decide whether compensation should be awarded. 42 U.S.C. § 300aa–12(d)(3). Appellate authorities expect that the decision set forth sufficient reasoning to explain the outcome. Stratton v. Sec'y of Health & Hum. Servs., 138 F.4th 1368, 1371-73 (Fed. Cir. 2025). However, special masters are not required to address every element of a claim, and they are not required to detail in the decision each piece of evidence.

This decision complies with those requirements by focusing on the decisive issues in the case. In doing so, two issues have not been addressed. One of those depends upon Ms. Roach's health--- whether any condition caused by the flu vaccine lasted for more than six months. See Resp't's Rep. at 12 (raising the severity issue); Pet'r's Br. at 32; Resp't's Br. at 74.

The other unaddressed issue, arguably, has potentially more importance for the Vaccine Program as whole---whether petitioners can persuasively present a reliable theory as to whether the flu vaccine can cause Guillain-Barré syndrome. This is the topic on which Dr. Steinman and Dr. Fujinami presented conflicting

opinions and contrary evidence. For the parties' summaries of their arguments, see Pet'r's Br. at 9-20 and Resp't's Br. at 58-71. Although this issue merits careful consideration in some future case, an analysis here is not required because Mr. Roach-Yohey failed to present persuasive evidence that Ms. Roach suffered from Guillain-Barré syndrome.

IX. Conclusion

Ms. Roach had multiple difficulties in her life and her death is another reason to extend sympathy to Mr. Roach-Yohey. However, her medical conditions did not include the AIDP form of Guillain-Barré syndrome. Thus, Mr. Roach-Yohey cannot prevail upon any claim that the flu vaccine caused her to suffer this medical condition.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master