# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**
**No. 11-707V**
**(Not to be published)**
**Filed: November 12, 2014**

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| BONYE WOLF BARONE, as Conservator of Person and Estate of JOAN NOVARRO, | * | |
| Petitioner, | * | Special Master Corcoran |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | Entitlement Ruling; Ruling on the Record; Influenza ("Flu") Vaccine; Guillain-Barré Syndrome ("GBS"); Molecular Mimicry; Ileus |
| Respondent. | * | |

*Peter Meyers*, National Law Center, Washington, D.C., for Petitioner.

*Lisa Watts*, U.S. Dep't of Justice, Washington, D.C., for Respondent.

## RULING ON ENTITLEMENT[1]

Joan Novarro filed a petition on October 25, 2011 seeking compensation under the National Vaccine Injury Compensation Program (the "Program")[2] based on injuries she alleges she incurred after her receipt of the influenza ("flu") vaccine on October 31, 2008. Petition at 1 (ECF No. 1). The Secretary of Health and Human Services ("Respondent") has requested that I rule on Ms. Novarro's claim based solely on the record as it currently exists. Respondent's

[1] Because this ruling contains a reasoned explanation for my action in this case, I will post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole ruling will be available to the public. *Id.*

[2] The Program comprises 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 - 34 (2006)) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

Supplemental Rule 4(c) Report and Request for a Ruling on the Record (ECF No. 45) at 8.

In support of her claim, Petitioner has proffered medical records, a medical expert report causally linking her diagnosed Guillain-Barré syndrome ("GBS") to the flu vaccination she received, and medical literature supporting that opinion. For the reasons stated below, I find such evidence is sufficient to meet Petitioner's burden to establish an entitlement to compensation.

## I. Procedural Background

After initiating this action, Ms. Novarro spent the period of time from the fall of 2011 into 2012 obtaining and filing medical records pertinent to her claim in this case. On August 8, 2012, Respondent filed her Rule 4(c) Report, asserting that Petitioner was not entitled to an award of compensation because she could not satisfy her burden of establishing causation-in-fact based upon the test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). ECF No. 27. Petitioner subsequently filed additional medical records, including evidence of her influenza vaccination (an omission Respondent had pointed out in her Rule 4(c) Report). Ex. 49 (ECF No. 32).

The parties spent the bulk of 2013 preparing to file expert reports. After several delays, Ms. Novarro filed her expert report on December 11, 2013. Ex. 50. Respondent's expert report was to be filed on or before February 10, 2014, but Respondent instead opted to file a supplemental Rule 4(c) Report in which she also asked for a ruling based on the existing record. *See* January 30, 2014, Supplemental Rule 4(c) Report and Request for Ruling on the Record (ECF No. 45). This past spring, after a status conference held in the case on April 15, 2014, Petitioner requested and was granted the opportunity to respond in writing to Respondent's request for a ruling on the record, and to that end Petitioner filed a supplemental expert report on May 16, 2014. Ex. 53 (ECF No. 52). On September 24, 2014, Ms. Novarro filed some additional medical literature referenced by her expert. Ex. 62-63 (ECF No. 55). This matter is now ripe for resolution.[3]

## II. The Record

The record in this case consists of Ms. Novarro's medical records plus two reports from the same expert and the associated medical literature cited therein.[4] I have reviewed the entire

[3] In addition, on February 18, 2014 (ECF No. 46), Petitioner moved to amend the caption to make Bonye Wolf Barone, Conservator of Person and Estate of Joan Novarro, the petitioner, and I granted that motion on April 17, 2014. ECF No. 49.

[4] Ms. Novarro's petition is not supported by an affidavit, as the Vaccine Act requires. § 300aa-11(c)(1). Petitioner did, however, include in her medical records filings a report made to the Vaccine Adverse Event Reporting System ("VAERS") that contains some facts setting forth the specific elements of her alleged illness. *See* Ex. 10. In addition, the medical records themselves contain proof of vaccination, and also corroborate the facts pertaining to Petitioner's alleged illness and its course in considerable detail. I therefore find that the failure to include an affidavit

record as required by the Vaccine Act (§ 300aa-13(a)(1)). In this ruling I address the sufficiency of Petitioner's evidence in support of an award of compensation.

A. *Petitioner's Medical Records*

On October 31, 2008, Ms. Novarro received the flu vaccine. Ex. 49 (ECF No. 32).[5] Ms. Novarro appears (based solely on the contemporaneous medical records) to have experienced no initial adverse reaction to the flu vaccine. Approximately two months later, on January 3, 2009, she went to the Yale-New Haven Hospital Emergency Roomcomplaining of "uncontrollable back pain and body aches," malaise, nausea, and vomiting. Ex. 1 at 2-4; Ex. 2 at 4-14. Ms. Novarro was thereafter admitted to Yale-New Haven Hospital for a suspected viral syndrome. Ex. 2 at 5. As the medical history indicates, Ms. Novarro's treating physicians initially understood (based on her reported prior history) that she had experienced a brief viral gastroenteritis with abdominal discomfort and diarrhea approximately two weeks prior to her admission. *Id.*

On January 5, 2009, Dr. Joseph Schindler (a neurologist) evaluated Ms. Novarro, who now complained that she was having difficulty maintaining her balance. Ex. 2 at 5, 333-34. At this doctor's visit, she specifically informed Dr. Schindler that she had experienced digestive distress and other physical symptoms two weeks prior to New Year's Eve. *Id.* at 333-34. She also again indicated that two days before coming to the hospital she had developed nausea and experienced vomiting associated with diaphoresis, as well as difficulty keeping food down. *Id.* Dr. Schindler noted during her exam that she had gait instability, ataxia, dysmetria, and a suspected cerebellar process. *Id*.

Only a few days later, by January 7, 2009, Ms. Novarro was finding it difficult to hold objects in her right hand and was also experiencing left-side facial paresthesia. Ex. 2 at 350-52. Her differential diagnosis included viral syndrome with peripheral nerve manifestations, questionable GBS[6], vasculitis, porphyria, sarcoid, or a paraneoplastic disorder. *Id*. at 352. Later that day, Ms. Novarro experienced episodes of altered mental status and significantly elevated blood pressure. *Id*. at 356. Her doctor speculated that she might be suffering from hypertensive

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was a *de minimis* omission not prejudicial to the Petitioner. *See also* Vaccine Rule 2(B) (describing circumstances in which affidavits are required to supplement existing medical record).

[5] At the time of her vaccination, Ms. Novarro had a history of coronary artery disease, hyperlipidemia, hypertension, hypothyroidism, seasonal allergies, and depression. Ex. 1 at 3; Ex. 2 at 4. Ms. Novarro had previously undergone cardiac catheterization on October 2, 2006 in response to an abnormal computed tomography angiography ("CTA") and chest pain. Ex. 15 at 1. She specifically reported having an ongoing chest pain syndrome for approximately four years. *Id*. at 6. However, there is no evidence that her prior health problems had anything to do with the injury claimed.

[6] GBS is a rapidly progressive ascending motor neuron paralysis. *Dorland's Illustrated Medical Dictionary* 1832 (32d ed. 2012) [hereinafter "Dorland's"]. It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the upper limbs, and face. *Id.*

encephalopathy, although Ms. Novarro's computed tomography ("CT') scan was normal and her brain magnetic resonance imaging ("MRI") scan had not changed. *Id*. at 627-29.

Thereafter, on January 8, 2009, Ms. Novarro was transferred to the neuro-intensive care unit ("ICU") for hypertension. Ex. 2 at 361-69. Her examination in the ICU showed normal eye movements, left facial weakness, normal strength bilaterally in the upper and lower extremities, and absent lower extremity deep tendon reflexes ("DTRs"). *Id*. An abdominal X-ray performed on Ms. Novarro that day was read by Dr. Morton Burrell, a diagnostic gastrointestinal radiologist. *Id.* at 633. The X-ray showed multiple distended loops of the small and large intestines. *Id.* Dr. Burrell also specifically noted air in the colon down to the rectosigmoid junction. *Id*. As the contemporaneous medical records indicate, Dr. Burrell believed these findings collectively were consistent with ileus.[7] *Id.* Laboratory results for tests conducted during this time were negative for a variety of disease specific antibodies, as well as acute Epstein-Barr virus infection and *Campylobacter jejuni*. *Id*. at 6, 629-41. Ms. Novarro also tested negative for the hepatitis and varicella viruses. *Id*.

The treating physician now expressed his suspicion that Ms. Novarro had the Miller-Fisher variant of GBS[8], and started her on IVIG[9] for five days. Ex. 2 at 6, 633. Another neurologist, Dr. Richard Nowak, stated after examining Ms. Novarro that he believed she had autonomic instability and high blood pressure due to GBS. *Id.* at 373. After completing her fifth day of IVIG, Ms. Novarro was minimally responsive to painful stimulation, her eye was deviated to the right, and her left arm showed decreased movement consistent with an acute stroke. *Id.* at 7-8, 415. A January 13, 2009 MRI showed "[a]cute stroke in the region of the bilateral posterior temporal and parietal lobes, right greater than left, as well as, in the right insula and bilateral temporal lobes." *Id*. at 651.

On January 21, 2009, Ms. Novarro's electromyography and nerve conduction studies showed evidence of an axonal sensorimotor neuropathy. Ex. 2 at 312. During her neurologic examination, Ms. Novarro was awake and able to follow simple commands, had normal horizontal eye movement, no facial weakness, trace DTRs, and was able to move her toes. *Id*. at 485-87.

By January 29, 2009, Ms. Novarro required a tracheostomy because she could not be weaned off her ventilator. Ex. 2 at 559, 738. The following day, a gastrostomy tube was inserted

[7] An ileus is an obstruction of the intestines due to a nonmechanical cause, such as paralysis or failure of peristalsis. *Dorland's* at 914.

[8] Miller Fisher variant represents approximately five percent of GBS cases. Peter J. Dyck & P.K. Thomas, 2 Peripheral Neuropathy 2210 (4th ed. 2005). The majority of individuals with Miller Fisher Syndrome have a unique antibody present that characterizes the disorder (antiganglioside antibodies). *Id.*

[9] IVIG is defined as intravenous immunoglobulin. *Medical Abbreviations* 179 (15th ed. 2011).

into Ms. Novarro's abdomen due to her inability to swallow without aspiration. *Id.* Dr. Schindler subsequently noted that Ms. Novarro's mental status and lower extremity strength had improved, but that she had residual blindness. *Id.* at 566.

In early February 2009, Ms. Novarro was discharged to inpatient rehabilitation at Gaylord Hospital. Ex. 2 at 4. Her discharge summary noted her history of viral gastroenteritis with abdominal discomfort and diarrhea two weeks prior to her January 3rd admission, and her onset of ataxia and dysmetria on January 5th. *Id*. at 5. Petitioner was dependent on others for all daily living activities throughout her stay at Gaylord due to quadriplegia. Ex. 3 at 793-804. She was evaluated by an optometrist for cortical blindness and prescribed prismatic lenses to expand her visual fields. *Id*. at 805.

On March 12, 2009, Petitioner was transferred to the Saybrook Convalescent Home, with diagnoses of GBS (Miller-Fisher variant) among other things. Ex. 3 at 793-804; Ex. 7 at 14-16. Petitioner remained at Saybrook until July 14, 2009, and had several subsequent hospitalizations due to complications, including altered mental status, seizures, and intractable pain. *See generally* Ex. 7. In October 2009, Petitioner was moved to a skilled nursing facility. Ex. 6, 8-9, 13, 18-33. There she required assistance for all activities, a wheelchair for ambulation, and a Hoyer lift for transfers from bed to wheelchair. Ex. 6, 8-9, 13, 18-33. She remained there for most of 2010; more recently she resides at her home, where (as an October 5, 2011 physiatry note documents) she requires 24-hour care for quadriparesis and multiple medical conditions. Ex. 14 at 20.

B. *Petitioner's Expert Report: Dr. Carlo Tornatore*

On December 11, 2013, Petitioner filed an expert report by Carlo Tornatore, M.D., as well as his curriculum vitae. Ex. 50-51. Petitioner later filed a supplemental expert report prepared by Dr. Tornatore on May 16, 2014 with accompanying medical literature. Ex. 53-60.

1. Qualifications - Dr. Tornatore is a board-certified neurologist. Ex. 51 at 1. He graduated from Cornell University with Bachelor of Arts in Neurobiology, and then attended Georgetown University Medical Center where he received a Master of Science in Physiology. *Id.* at 2. He subsequently graduated from medical school at Georgetown University School of Medicine, completed a residency in the Department of Neurology at Georgetown University Hospital, and completed a fellowship in molecular virology at the National Institutes of Health in Bethesda, Maryland. *Id.* He has published articles addressing cell biology and pathology of demyelinating disorders. *Id.* at 7-14. Currently, he serves as Vice Chairman in the Department of Neurology at MedStar Georgetown University Hospital and as a Professor of Neurology at Georgetown University Medical Center. *Id.* at 3.

2. Opinion - Dr. Tornatore opines that coincident with gastrointestinal

symptoms, Ms. Novarro experienced diffuse myalgias and gait inability which as of January 8, 2009 were properly diagnosed as symptoms of GBS. Ex. 50 at 7. He concludes that the flu vaccination that Ms. Novarro received in October of 2008 was the cause of her development of GBS. *Id.* at 8.

Dr. Tornatore's reports propose a theory for how the flu vaccine could generally cause GBS. To that end, he observes that other vaccines (such as the swine flu and tetanus vaccines) have been reported to trigger autoimmune responses which can result in inflammatory demyelinating polyneuropathies. Ex. 50 at 7.[10] To explain the process for how this would occur, he invokes the theory of molecular mimicry, citing several articles that discuss it as a mechanism occurring in the context of autoimmune neuropathies occurring as the result of *Campylobacter jejuni* infections. *Id.*

Molecular mimicry occurs when viral or bacterial antigens share homology with host antigens. Ex. 50 at 7. Dr. Tornatore explains that if the proteins that comprise a given vaccine share any homology with host antigens, then the immune response will be directed at both the injected antigens and host antigens, leading to an immune response. *Id.* In rare cases, the activation of the immune system is misdirected and both the humoral and cellular arms of the immune system attack the nervous system. *Id.* Specifically in GBS, the target of the immune response is the myelin of the peripheral nervous system, which results in injury by numbness and weakness of the extremities, truncal muscles, and muscles of the face and neck. *Id.*

In his report, Dr. Tornatore's next opines that, based upon his review of the medical records, Ms. Novarro's GBS was in fact caused by her vaccination. He concludes that her first symptoms (diarrhea and vomiting) were gastrointestinal occurring in December 2008 – two weeks prior to her initial hospital visit on New Year's Eve. Ex. 5 at 6, 8. These symptoms continued when she was hospitalized in January 2009, by which time the ileus was observed. *Id.* Dr. Tornatore references an article that describes ileus as a well-recognized sequela of GBS; in his opinion, it was the disease's presenting symptom in this case. *Id.* at 8. Ex. 62 at 1; Ex. 63 at 3.

The specific sequence of events surrounding Ms. Novarro's illness proposed by Dr. Tornatore is thus as follows: (1) an influenza vaccination administered on October 31, 2008; (2) development of GBS-related ileus mid-December 2008, or approximately six weeks later; (3) development of GBS-related diffuse myalgias and gait inability by the end of December-early January 2009; (4) development of GBS-related weakness and areflexia early January 2009; (5) treatment of GBS with IVIG initiated January 8, 2009; (6) development of IVIG-related cerebral infarcts with resulting cortical blindness and spastic quadriparesis (muscular weakness affecting all four limbs) on January 13, 2013; and (7) surgical placement of an intrathecal baclofen pump

[10] Although I do not address specifically in this decision all articles cited by Dr. Tornatore in his expert report, I have reviewed each of them in preparation of this ruling.

to better control her spasticity which was due to cerebral infarcts. Ex. 50 at 6-7.

Finally, in addressing whether the time between Ms. Novarro's vaccination and onset of the symptoms was medically acceptable, Dr. Tornatore refers to an article reporting that the period of increased risk for developing GBS after receipt of the flu vaccine was concentrated within a five week period, although it could last up to approximately nine to ten weeks. Ex. 59 (Lawrence B. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977*, 110 Am. J. Epidemiology 105, 112 (1979) [*hereinafter* "Schonberger Article"]). In Ms. Novarro's case, Dr. Tornatore opines, her GBS symptoms occurred within six to seven weeks of vaccination, a temporal period he views as medically plausible for the initiation of an immune response following vaccination. Ex. 50 at 8.

## III. Respondent's Contentions

Respondent's two Rule 4(c) Reports are substantively similar, although the supplemental report refines the nature of Respondent's argument.[11] In both, Respondent contends that because Ms. Novarro does not allege a "Table Injury" (meaning a vaccine-specific injury as listed on the Vaccine Injury Table (42 C.F.R. § 100.3 (2011)), she was obligated to establish, by a preponderance of the evidence, that her flu vaccination was the cause-in-fact for her GBS. Respondent's Rule 4(c) Report (ECF No. 27) at 9 [*hereinafter* Report]. Respondent asserts that the Petitioner did not carry this burden for a number of reasons.

Respondent employs the *Althen* causation prongs as a yardstick for demonstrating Petitioner's purported failure to carry her burden. First, Respondent disputes Ms. Novarro's satisfaction of the first prong of the *Althen* test: that the vaccine in question "can" cause GBS. Respondent's Supplemental Report (ECF No. 45) at 6 [*hereinafter* Supp. Report]. She argues that Dr. Tornatore's theory for how the flu vaccine might cause GBS is too heavily reliant on studies involving the relationship between the swine flu vaccine and GBS. *Id.* Although Respondent acknowledges that Dr. Tornatore at least proffers a plausible theory (molecular mimicry), she points to the 2011 Report of the Institute of Medicine ("IOM") concluding that, based on epidemiologic studies and mechanistic evidence, there was insufficient evidence to accept or reject a causal relationship between flu vaccine and GBS. *Id.* at 7.

Second, Respondent questions whether the existing medical records, as augmented by Dr. Tornatore's opinion, establish the second *Althen* prong – that Ms. Novarro's receipt of the flu vaccine "did" cause her GBS. In support of this argument, Respondent points to the evidence in the record that, prior to her hospitalization in January of 2009, Ms. Novarro and her family

[11] Respondent's August 2012 Report had asserted that Ms. Novarro had failed to substantiate her receipt of the flu vaccine (Report at 9), but Ms. Novarro cured this omission thereafter by filing medical records that proved that she had received the vaccination. Ex. 49 (ECF No. 32) at 1.

reported to treating physicians that she was suffering from some sort of gastrointestinal distress which could well be an alternative cause for Ms. Novarro's GBS (although Respondent at the same time concedes that she is not formally attempting to establish an alternative cause for the GBS). Supp. Report at 7-8. Respondent also contends that the paralytic ileus Dr. Tornatore identifies as the presenting symptom of Ms. Novarro's GBS was not discovered until after her hospitalization – allowing for the possibility that the ileus was *itself* the product of an antecedent infection rather than a presenting symptom for Ms. Novarro's ultimate illness. *Id.* at 7.

Finally, Respondent disputes Petitioner's satisfaction of the third *Althen* prong, arguing (parallel to Respondent's questioning of Dr. Tornatore's overall causation theory) that Dr. Tornatore relies too heavily on determinations from swine flu studies to opine that it is medically acceptable to conclude that onset for Ms. Novarro's illness could have occurred within six to seven weeks of the administration of the flu vaccine. Ex. 50 at 8.

## IV. Applicable Legal Standards.

To receive compensation under the Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question, or (2) that his illnesses were actually caused by a vaccine (a category of claim often referred to as a "non-Table Injury"). *See* §§ 300aa-13(a)(1)(A), 11(c)(1); § 300aa-14(a); § 300aa-11(c)(1)(C)(ii)(I); 42 C.F.R. § 100.3; *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[12]

The Vaccine Act requires a petitioner to establish his entitlement to a Program award by a preponderance of the evidence. § 300aa-13(a)(1). Under this evidentiary standard, a petitioner must demonstrate that the injury claimed was "more likely than not" caused by the alleged vaccine. *Moberly*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). Once a petitioner is deemed to have satisfied this burden, he is entitled to compensation unless Respondent can rebut the showing by preponderant proof that the vaccinee's injury is "due to factors *unrelated* to the administration of the vaccine." § 300aa-13(a)(1)(B) (emphasis added).

In satisfying his burden, a petitioner is required to prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355

[12] In this decision, I reference published decisions of other special masters, which constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). I also cite Federal Circuit decisions, which are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

(Fed. Cir. 2006). Before finding in favor of the party with the burden to prove a fact's existence, the special master must "believe that the existence of a fact is more probable than its nonexistence." *Moberly*, 592 F.3d at 1322 n.2 (internal citations omitted). The special master must assess "the record as a whole" and may not find that a petitioner has established an entitlement to compensation "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a)(1).

Ms. Novarro has not alleged a Table Injury in this case (and in fact there are no Table injuries specified for the flu vaccine, although the vaccine itself can be the basis for a Program claim). I must therefore consider the requirements needed to prove a non-Table Injury. A petitioner alleging such a claim must satisfy (by a preponderance of the evidence) the three prongs set forth by the Federal Circuit in the *Althen* decision: (1) a medical theory causally connecting the vaccination to the injury (*i.e.*, that the vaccine "can cause" the injury); (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury (*i.e.*, that in this case the vaccine "did cause" the injury); and (3) a proximate temporal relationship between the vaccination and the injury. *Althen*, 418 F.3d at 1279. A petitioner who successfully does so is entitled to compensation, unless the Respondent can then demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *Id.*

In attempting to substantiate a Program claim, petitioners may rely on different kinds of evidence and may satisfy their burden with circumstantial proof. *Althen*, 418 F.3d at 1280. This includes the opinions of treating physicians. *Moberly*, 592 F.3d at 1325 (holding that "treating physician evidence . . . [can] support[] the claim of causation"); *see also Carter v. Sec'y of Health & Human Servs.*, No. 05-1500V, 2007 WL 415185, at *21 n. 25 (Fed. Cl. Spec. Mstr. Jan. 19, 2007). Contemporaneous medical records are also especially useful in establishing Petitioner's claim. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Special masters decide questions of credibility, plausibility, probability, and reliability, and ultimately determine on which side the balance of evidence is tipped. *Pafford*, 451 F.3d at 1359.

Petitioners may be awarded Program compensation based on "medical records *or* . . . medical opinion." § 300aa-13(a)(1) (emphasis added); *see also Althen*, 418 F.3d at 1279-80. Although expert testimony may be helpful and may be considered, there are no "hard and fast *per se* scientific or medical rules" for finding causation under the Vaccine Act, and thus no requirement that a petitioner offer expert testimony to prevail. *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Indeed, a special master may determine that a petitioner has carried his or her burden of proof sufficient to receive a Program award even where the claim is not supported with conclusive medical literature, epidemiological studies, and/or theories enjoying general acceptance in the scientific or medical communities. *See Andreu*

*v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009).

Where (as here) an expert opinion is offered, a special master should consider its overall reliability in helping a petitioner establish causation. In *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues.[13] The Federal Circuit has ruled that it is appropriate for special masters to utilize *Daubert*'s factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases (even though the *Daubert* standards are not applied in this context to determine whether an opinion should be excluded from evidence entirely, as they would be in federal district courts). *Terran ex rel. Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999).

After *Terran*, Court of Federal Claims decisions as well as the decisions of other special masters have cited the *Daubert* criteria as useful in assessing the reliability of an expert opinion. *See, e.g., Synder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 742-45 (2009); *Cedillo v. Sec'y of Health & Human Servs.*, 89 Fed. Cl. 158, 182 (2009) ("[f]ederal Circuit precedent clearly permits the Special Master to apply Daubert when evaluating the reliability of the parties' evidence"), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *see also Hirmiz v. Sec'y of Health and Human Servs*., No. 06-371V, 2014 WL 4638375, at *3 (Fed. Cl. Spec. Mstr. Aug. 26, 2014); *Godfrey v. Sec'y of Health and Human Servs.*, No. 10-565V, 2014 WL 3058353, at *4 (Fed. Cl. Spec. Mstr. June 11, 2014).

## V. Analysis

There is no dispute in this case that Ms. Novarro was properly diagnosed with GBS, nor is there any question that she received the flu vaccine. Resolution of this matter therefore comes down to whether Petitioner can establish that she has carried her burden of demonstrating causation-in-fact. Based on the existing medical records, expert reports, and relevant medical literature,[14] I find that Petitioner has done so.

### A. *Petitioner Satisfies Prong One of the Althen Test*

Dr. Tornatore's expert report proposes a reasonable medical theory explaining how the flu vaccine could cause GBS, and it is sufficiently reliable and persuasive to satisfy the first part of the *Althen* test. First, Dr. Tornatore observes a relationship between vaccination and GBS. He

[13] The *Daubert* factors for analyzing the reliability of testimony are: (1) whether the theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community. *Id*. at 592-95.

[14] I have considered the entire record in arriving at my decision (§ 300aa–13(a)(1)), but will only discuss evidence specifically relevant to resolution of this matter. *See Paterek v. Sec'y of Health & Human Servs.*, 527 Fed. App'x 875, 884 (Fed. Cir. 2013). This includes medical literature submitted by both sides.

specifically references an epidemiologic study showing an increased risk of developing GBS in the period following a 1976-77mass swine flu immunization program. Ex. 50 at 8; Ex. 59 (Schonberger Article). Dr. Tornatore posits that the influenza vaccine can similarly cause GBS through the biological mechanism of molecular mimicry. Ex. 50 at 7.

Respondent does not contend that Dr. Tornatore's credentials render this portion of his opinion generally unreliable, and I find that he is qualified to opine on the topic at hand. Nor has Respondent argued that the specific connections he posits between vaccination and illness are not actually supported by the literature he relies upon. Rather, she asserts that Petitioner relies too heavily on swine flu studies, which involved a different vaccine entirely. Although this raises a reasonable point, I do not find that this markedly reduces the value of these studies as a basis for Dr. Tornatore's overall opinion. In fact, other special masters have cited the Schonberger Article in support of determinations that flu vaccine can cause GBS. *See, e.g., Stewart v. Sec'y of Health & Human Servs.*, No. 06-777, 2011 WL 3241585, at *16 (Fed. Cl. Spec. Mstr. July 8, 2011).

Second, Dr. Tornatore's report offers a medical theory – molecular mimicry – as the biological mechanism by which the flu vaccine would induce GBS, and substantiates the theory with citation to reliable medical literature. Ex. 56-57. Respondent acknowledges that molecular mimicry is a plausible theory (*see, e.g.*, Supp. Report at 7) – and in fact it has been accepted in other Program cases as a reliable medical explanation for how various autoimmune conditions could develop after the receipt of different kinds of vaccinations. *See, e.g., Althen v. Sec'y of Health & Human Servs.*, 58 Fed. Cl. 270, 278-79, *aff'd*, 418 F.3d 1274 (Fed. Cir. 2005) (tetanus toxoid vaccine); *Keenan v. Sec'y of Health & Human Servs.*, No. 99-561V, 2007 WL 1231592, at *11 (Fed. Cl. Spec. Mstr. Apr. 5, 2007) (hepatitis B vaccine); *Scott v. Sec'y of Health & Human Servs.*, No. 03-2211V, 2006 WL 2559776, at *18 (Fed. Cl. Spec. Mstr. Aug. 21, 2006) (measles, mumps, and rubella vaccine). Petitioners have also successfully invoked molecular mimicry as a theory in support of entitlement awards in cases involving similar neuropathic injuries alleged to have been caused by the flu vaccine. *See, e.g., Petronelli v. Sec'y of Health & Human Servs.*, No. 12-285V, 2013 WL 6054752, at *6 (Fed. Cl. Spec. Mstr. Oct. 25, 2013) (citing other Program cases in which entitlement awards were obtained in cases alleging an association between GBS and the flu vaccine).

Ms. Novarro has thus presented a reliable medical theory for how the flu vaccine could cause GBS (through her expert reports and the medical literature cited therein) sufficient to satisfy the first *Althen* prong. The fact that the evidence mustered in support of the argument may not quite go far enough to close the door on the question from a scientific standpoint, as Respondent suggests,[15] does not weigh against a finding that this prong has been satisfied. For as

[15] Thus, while admitting that the molecular mimicry theory has had scientific acceptance, Respondent refuses to "concede" that Dr. Tornatore's theory for the mechanism is scientifically reliable – pointing to findings of the

the Federal Circuit observed in *Knudsen*, "to require identification and proof of specific biological mechanisms would be 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 Program is "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 others." *Id.* at 549.

Relevant to my determination is the fact that Respondent has made no effort to rebut Dr. Tornatore by providing an expert report of her own, preferring instead simply to raise questions about the adequacy of proof offered by Petitioner overall. In some cases this approach to defending against a Program claim might be sufficient. But here, I find that because Petitioner has offered adequate preponderant proof in support of her claim, including an adequate expert report, Respondent needed to do more than simply stand on her thinly-substantiated objections. *Lankford v. Sec'y of Health & Human Servs.*, 37 Fed. Cl. 723, 726 (1996); *see also Gerhardt v. Sec'y of Health & Human Servs.*, No. 09-180V, 2014 WL 4712690 (Fed. Cl. Spec. Mstr. Aug. 29, 2014) (granting motion for ruling on the record in favor of Petitioner where Respondent offered no competing expert opinion to rebut Petitioner's case).

B. *Ms. Novarro's Flu Vaccine "More Likely than Not" Caused her GBS (Althen Prong Two)*

In this case, there is no dispute that Ms. Novarro received the flu vaccine, or that she was properly diagnosed with GBS. Supp. Report at 2-4, 6-7. The only question is whether Petitioner has established sufficient evidence to find it "more likely than not" that her GBS was caused by the flu vaccine. I find that (keeping in mind the goals of the Program) there is enough evidentiary support to resolve this prong of the *Althen* test in favor of Petitioner. *Rooks v. Sec'y of Health & Human Servs.*, 35 Fed. Cl. 1, 7 (1996) (noting the Program's goal of awarding damages to "vaccine-injured persons quickly, easily, and with certainty and generosity") (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344). This is especially so in a case like this one – where Respondent opts not to attempt to defend by offering her own expert to counter the statements of Petitioner's expert. *See, e.g., Petronelli*, 2013 WL 6054752, at *6 (Respondent was unable to "tip the balance" of evidence in its favor in case where she attempted to counter expert report solely with medical literature citations).

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Institute of Medicine ("IOM") that there is no epidemiologic link between GBS and the flu vaccine as undermining any theory that would purport to link the two. Supp. Report at 7 (*citing* Ex. A (ECF No. 27) at 334). But given the nature of Petitioner's burden in this case (which is merely to offer preponderant evidence in support of a medical theory and not resolve a scientific question) I do not find this argument persuasive, despite the weight accorded to the reports and findings of the IOM. *Falksen v. Sec'y of Health & Human Servs.*, No. 01–317V, 2004 WL 785056, at *13 (Fed. Cl. Spec. Mstr. Mar. 30, 2004) ("the Court gives great deference to the findings of the Institute of Medicine on the issue of cause and effect between vaccines and discrete injuries"). Indeed, as Respondent acknowledges, the IOM found only that "[t]he evidence is *inadequate* to accept or reject a causal relationship between influenza vaccine and GBS," (Ex. A at 334) – a more inconclusive determination (at least on present IOM findings) than Respondent suggests.

The Federal Circuit has identified several factors that may be probative in determining whether a petitioner has met her burden of establishing that a given vaccine "did" cause her injuries – including, among other things, the opinions of the petitioner's treating physicians and expert testimony. *See Capizzano*, 440 F.3d at 1322. In this case, the treating record says little about a potential relationship between Ms. Novarro's vaccination and her subsequent GBS. Ms. Novarro's treating physicians were aware that she had received the flu vaccine two months before her January hospitalization, but I find no evidence in the record that any of them ever identified the vaccine as a possible causal factor. Treating physicians' views as to the relationship between a petitioner's vaccination and his subsequent injuries are of course usually most probative of the second *Althen* prong, because those doctors are uniquely positioned to determine whether "a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1280.

A petitioner can, however, still satisfy this prong of the *Althen* test even when such contemporaneous records opining the existence of a link between vaccine and injury are lacking. In attempting to establish that a vaccination did cause a petitioner's injury, a petitioner is "permitted to use evidence eliminating other potential causes to help carry the burden on causation." *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007). Indeed, "the exclusion of alternative etiologies is usually quite probative with respect to prong two of the *Althen* analysis – i.e., whether the vaccine caused the injury in a particular case." *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 144 (Fed. Cl. 2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012).

Here, Ms. Novarro marshals Dr. Tornatore's opinion (and in particular his review of her medical history) to establish a causal sequence that logically implicates the flu vaccination as a trigger for her GBS. Dr. Tornatore attempts to do so by proposing a timeframe in which he purports her illness progressed. Ex. 50 at 6-7. Based upon his review of the treatment records, Dr. Tornatore opines that Ms. Novarro's gastrointestinal symptoms (reported both upon her admission to the hospital and then subsequently) were most likely the result of the ileus first observed in early January of 2009 after an abdominal X-ray. *Id.*; *see also* Ex. 53 at 1. Dr. Tornatore further believes (taking into account reports from the medical history that Ms. Novarro had some sort of gastrointestinal distress or symptoms about two weeks before she first went to the hospital) that Ms. Novarro's ileus likely began around the same time he pinpoints the onset of her GBS – prior to her hospitalization – and may have been the presenting symptom. Ex. 53 at 1. He further explains that an ileus can wax and wane in the early stages of GBS since it is fairly dependent on a patient's diet. *Id.* Because ileus is consistent with an autonomic involvement, its discovery in the course of Ms. Novarro's treatment suggested to Dr. Tornatore that GBS was most likely the ultimate cause of her symptoms. *Id.*

Respondent acknowledges the existence of the ileus, and does not deny it likely had some

relationship to Ms. Novarro's GBS. Supp. Report at 7. However, Respondent points out that the record suggests Petitioner suffered from a gastrointestinal disease prior to her hospital admission at the end of 2008. *Id.* Respondent also speculates that Petitioner's paralytic ileus (observed only after her hospitalization) is more plausibly understood to be the *product* of an antecedent infection rather than a substantial presenting symptom for GBS, as Dr. Tornatore believes. *Id.* Respondent relies purely on legal argument (rather than offering an expert's contrary review of the medical records or other evidence – since Respondent offers no expert at all) for these assertions. Dr. Tornatore's supplemental expert report in response maintains that there is no corroborative proof supporting the existence of an antecedent infection – something the Respondent herself tacitly admits in her supplemental Rule 4(c) Report. S*ee* Supp. Report at 7-8 ("[R]espondent recognizes that providing preponderant evidence of an alternative cause for petitioner's GBS in this case given her extensive work-up . . . would be exceedingly difficult").

Considering all the evidence, I find that Petitioner has met her preponderant burden as to the second *Althen* prong.

A significant element of Dr. Tornatore's opinion as to the "did cause" aspect of Petitioner's case is his proposal that Ms. Novarro's ileus was either a presenting symptom or significant clinical diagnostic manifestation of her GBS. In reaching this determination, he references two pieces of medical literature. One is a case study in which it appears that ileus was the presenting symptom of GBS for a single individual who was specifically hospitalized with a paralytic ileus. Tim Nowe, et al., *Paralytic Ileus as a Presenting Symptom of Guillain-Barré Syndrome*, 255 J. Neurology 756-77 (2008) (Ex. 63). But this filing is merely a letter to the editor of a medical journal rather than a reproducible experiment or study. More significantly, anecdotal patient case studies have inherently less probative value than reproducible controlled studies. John B. Wong, et al., "Reference Guide on Medical Testimony," in *Reference Manual on Scientific Evidence* 687, 723-24 (3d ed. 2011) (stating that in the hierarchy of medical evidence, "unsystematic clinical observations or case reports" are at the bottom). Indeed, this piece of literature itself acknowledges its limited scope, when it states that ileus "is rarely reported as an early symptom" of GBS. *Id.* at 1-2.[16]

The other piece of ileus-specific literature, however, is somewhat more reliable and persuasive. *See, e.g.*, Ted M. Burns, M.D., et al., *Adynamic Ileus in Severe Guillain-Barré Syndrome*, 24 Muscle & Nerve 963-65 (July 2001) (Ex. 62) [*hereinafter* "Burns"]. This study reviewed the experiences of patients suffering from severe GBS who had been admitted to Mayo Clinic-affiliated hospitals. *Id.* Out of 114 patients whose histories were reviewed, seventeen patients (or fifteen percent) experienced some form of ileus, with a slight majority of them (nine

[16] Individuals afflicted with GBS usually present 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. *Dorland's* at 1832.

patients) experiencing ileus either during the time that the patient's GBS was most acute (within ten days of its onset) or during its plateau phase, right before patients began to improve. Burns at 1-2. The remaining eight patients were determined to have developed ileus as a result of some other cause unrelated to their GBS. *Id.* Although some of the patients were found to have developed an ileus as a result of being immobilized in the hospital while their GBS was treated, the study opined that the remaining patients experienced the ileus as a result of immune-mediated inflammation – the same process that would result in the other more commonly-understood presenting symptoms of GBS. *Id.* Thus, Burns supports the conclusion that ileus is a symptom reasonably associated with GBS.

I find that the Burns article lends reliable support to Dr. Tornatore's opinion that Ms. Novarro's ileus was likely a significant GBS-related symptom that produced some of her pre-hospitalization gastrointestinal symptoms. It appeared in a peer-reviewed publication and reflects a retrospective study identifying particular kinds of patients from a "larger project on severe GBS." Burns at 1. It is offered not to prove the greater issue in dispute (*i.e.*, the connection between the flu vaccine and GBS), but a smaller point (the connection between ileus and GBS) establishing support for Dr. Tornatore's medical opinion that ileus and GBS are related. Respondent for her part has not attempted to rebut either the conclusions of the Burns article or the larger point that there is likely a relationship between ileus and GBS.

Dr. Tornatore's opinion that Ms. Novarro's ileus was a clue to the nature of her condition ties in with his view, based on his review of the test results in Ms. Novarro's medical records, that in this case an antecedent infection was not likely present (and therefore could not be responsible for Petitioner's GBS). Although the medical records reveal early speculation on the part of Ms. Novarro's initial treating physicians that she may have experienced a viral gastroenteritis before her January 3rd emergency room visit (and certainly the statements of Ms. Novarro and her family members encouraged that view), the treatment record does not corroborate this view. By the time Petitioner did present to the hospital, she had no clinical symptoms of a lingering infection, and the extensive battery of tests performed on Ms. Novarro did not reveal evidence of a prior infectious process. *See, e.g.*, Ex. 1 at 2-4; Ex. 2 at 4-14. This is the basis for Dr. Tornatore's discounting the possibility of an antecedent infection as the cause of Petitioner's illness. Ex. 53 at 1.

Dr. Tornatore has offered a reasonable reading of the evidence in this case that eliminates other potential explanations for Ms. Novarro's illness, and is therefore sufficient to help Petitioner carry her burden. The medical record can further plausibly be understood to suggest that Ms. Novarro's ileus developed contemporaneously with her later-diagnosed GBS – and may have been the cause of her initial gastrointestinal symptoms. The interpretation of those records that Dr. Tornatore provides is logical and cogent.

Respondent has not effectively rebutted this interpretation of the medical history. She offers no expert opinion to provide an alternative reading of the evidence, nor does she question Dr. Tornatore's qualifications to interpret the existing medical record based on his personal expertise with neurologic matters. And although she does speculate that an antecedent infection may have been to blame for Ms. Novarro's symptoms, she is quick to point out that she does not believe she could prove the point even if she so desired. In such a case, the fact that Petitioner's case is not especially strong will not bar recovery – Petitioner has offered just enough preponderant evidence to outweigh Respondent's lack of contrary evidence.

C. *Petitioner has Carried her Burden to Establish a Medically Acceptable Temporal Relationship Between the Flu Vaccine and GBS (Althen Prong Three)*

To satisfy the third prong of the *Althen* test, a petitioner must demonstrate the existence of a "scientific temporal relationship" between vaccination and onset of illness. *Pafford v. Sec'y of Health & Human Servs.*, 64 Fed. Cl. 19, 29-30 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). Establishing such a proximate temporal relationship requires preponderant proof that the onset of a petitioner's symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact. *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). In determining what is a medically acceptable timeframe, the temporal relationship must coincide with the theory of how the relevant vaccine can cause an injury (prong one's requirement). *de Bazan*, 539 F.3d at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (Fed. Cl. 2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *motion for review denied* (Fed. Cl. Dec. 3, 2013), *appeal docketed* (Fed. Cir. 2014).

Dr. Tornatore opines that the onset of Ms. Novarro's GBS occurred within six to seven weeks after her October 31, 2008 vaccination, which is in his opinion a medically appropriate timeframe. Ex. 50 at 8. As he explains, Ms. Novarro appears to have experienced her initial gastrointestinal symptoms (diarrhea and vomiting) in mid-December 2008 (about six weeks after vaccination), which continued when she was hospitalized in January 2009. *Id.* Dr. Tornatore relates Petitioner's pre-hospitalization symptoms to the ileus revealed by her January 8, 2009 X-ray. Ex. 2 at 633. To support the proposed timing of onset, he cites literature supporting the concept that a six week timeframe is within the acceptable onset period for GBS following a vaccination. Ex. 50, Ex. 54 at 1, Ex. 59 at 5. The Schonberger Article in particular reports (with respect to the swine flu vaccine) that the period of increased risk for development of GBS was within the five week period after vaccination, although it could last for up to ten weeks. Ex. 59 at 5.

Other special masters have never gone beyond a two-month (meaning eight week) interval in holding that a vaccination caused a demyelinating illness. *See, e.g., Aguayo v. Sec'y of*

*Health & Human Servs.*, No. 12-563V, 2013 WL 441013, at *3 (Fed. Cl. Spec. Mstr. Jan. 15, 2013); *Corder v. Sec'y of Health & Human Servs.*, No. 08-228V, 2011 WL 2469736, at *27-*29 (Fed. Cl. Spec. Mstr. May 31, 2011) (proposed four month onset period from vaccination to GBS too long; two months is longest reasonable timeframe). Respondent for her part offers no evidence from the record or elsewhere that would argue against such a conclusion. I therefore find that Ms. Novarro has offered sufficient evidence for the proposition that six weeks from the vaccination for onset of Ms. Novarro's GBS is medically acceptable.

## CONCLUSION

Having considered the evidence in the record in its totality, I am persuaded that Ms. Novarro has offered sufficient evidence to meet her burden of proof. Respondent's reasoned objections lack the evidentiary ballast of a responsive expert report, and otherwise do not rebut Petitioner's showing. The record establishes that it is "more likely than not" that Ms. Novarro's flu vaccination injured her. I shall next issue a separate damages order.

**IT IS SO ORDERED.**

s/Brian H. Corcoran
Brian H. Corcoran
Special Master