In the United States Court of Federal Claims

No. 08-601V
Filed: January 25, 2013

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LAKEYSHA ISAAC,	*	
	*	**Motion for Review of Special**
Petitioner,	*	**Master's Decision; National**
v.	*	**Vaccine Injury Act,**
	*	**42 U.S.C. § 300aa-1 et seq.;**
SECRETARY OF THE DEPARTMENT	*	**Standard of Review; Tetanus-**
OF HEALTH AND HUMAN SERVICES,	*	**Diphtheria Vaccine; Guillain-**
	*	**Barré Syndrome; Molecular**
Respondent.	*	**Mimicry.**
	*	
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Renée J. Gentry, Shoemaker & Associates, Vienna, Virginia for Petitioner. With her was **Clifford Shoemaker**, Shoemaker & Associates, Vienna, Virginia.

Lisa A. Watts, Trial Attorney Branch, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for Respondent. With her were: **Lynn E. Ricciardella,** Trial Attorney, **Rupa Bhattacharyya**, Director, Torts Branch, and **Stuart F. Delery**, Principal Deputy Assistant Attorney General, Civil Division.

O P I N I O N

HORN, J.

FINDINGS OF FACT

On August 26, 2008, Petitioner, LaKeysha Isaac, filed a timely petition for compensation with the National Vaccine Injury Compensation Program, pursuant to the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660, Title III, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-1 et seq. (2006)) (Vaccine Act). Following Special Master Lord's July 30, 2012 decision, Petitioner filed a timely Motion for Review pursuant to Vaccine Rule 23 of the Rules of the United States Court of Federal Claims (RCFC) Appendix B (2012) (Vaccine Rules).[1]

[1] The Motion for Review, however, was not in compliance with the RCFC, as the Motion did not include a table of contents or a table of authorities. The court ordered Petitioner to re-file the Motion for Review, which Petitioner accomplished on August 31, 2012 by filing a corrected Motion for Review.

Petitioner received the tetanus-diphtheria[2] vaccine and the hepatitis A vaccine[3] on September 15, 2005. The parties have stipulated that, prior to receiving the hepatitis A vaccine and the tetanus vaccine, Petitioner was a relatively healthy adult. At some point shortly after receiving these vaccinations, Petitioner stated she "felt pain in my arms and back, and weakness in my right leg that caused me to limp." Petitioner also claims that "[a]pproximately two weeks following the immunizations, I noticed tingling in my fingers and toes when I went to bed." On September 28, 2005, Petitioner went to the emergency room at the Mississippi Baptist Medical Center in Jackson, Mississippi. The admission form at the medical center noted that Petitioner suffered from nausea, vomiting, chest pressure, and numbness in her extremities. Petitioner was released from the hospital without a diagnosis on September 30, 2005. On October 1, 2005, Petitioner went to the emergency room at St. Dominic Hospital in Jackson, Mississippi after she continued having trouble standing.

The hospital admission form at St. Dominic Hospital noted that Petitioner's chief complaint was numbness of her feet and weakness of her legs. On October 3, 2005, Petitioner underwent an electromyography, and a nerve conduction study, which according to The Merck Manual of Diagnosis and Therapy, "identify the affected nerves and muscles." The Merck Manual of Diagnosis and Therapy 1758 (Mark H. Beers et al. eds., 18th ed. 2006). The tests indicated "findings 'most consistent with acute inflammatory demyelinating polyneuropathy.'"[4] One of Petitioner's treating neurologists, at St. Dominic Hospital, Dr. Alan Moore, indicated that her "AIDP [acute inflammatory

[2] The Special Master's decision, the parties' filings, and the experts generally refer to the vaccination received by Petitioner simply as "tetanus" and not "tetanus-diphtheria." In order to be consistent, this opinion will likewise refer to the vaccine as tetanus.

[3] In her July 30, 2012 decision, Special Master Lord dismissed Petitioner's hepatitis A claim, finding that Petitioner "effectively abandoned the allegation of causation by the Hep A [hepatitis A] vaccine" because, during the course of the hearing, Petitioner's expert, Dr. Carlo Tornatore, "did not opine that the Hep A [hepatitis A] vaccination caused Petitioner's GBS [Guillain-Barré Syndrome]." Petitioner does not allege that Special Master Lord improperly dismissed Petitioner's hepatitis A claim, nor does Petitioner now claim entitlement to compensation under the Vaccine Act pursuant to the hepatitis A claim. Therefore, this opinion addresses only Petitioner's tetanus vaccine claim.

[4] According to Dorland's Illustrated Medical Dictionary, inflammation is "characterized in the acute form by the classical signs of pain (dolor), heat (calor), redness (rubor), swelling (tumor), and a loss of function (function laesa)." Dorland's Illustrated Medical Dictionary 936 (32nd ed. 2012). The Merck Manual of Diagnosis and Therapy notes that "some myelin disorders (eg Guillain-Barré syndrome, chronic inflammatory disseminated polyneuropathy…) tend to affect primarily the peripheral nerves…." The Merck Manual of Diagnosis and Therapy 1887. Moreover, it also defines polyneuropathy as "a diffuse peripheral nerve disorder not confined to the distribution of a single nerve or a single limb." Id. at 1904.

demyelinating polyneuropathy] is likely related to gastrointestinal illness." The next day, however, Dr. Moore noted that the nerve study was "consistent with early GBS." Petitioner was discharged from Saint Dominic Hospital on October 13, 2005. The discharge summary, which listed Dr. John Foss as her attending physician, in consultation with Dr. Adele A. Thiel, a neurologist, identified her "Discharge Diagnosis," as "1. Guillain-Barré syndrome.[5] 2. Bell's palsy, bilateral weakness and paresthesias secondary to Guillain-Barre Syndrome. 3. Hypertension." Petitioner transferred to the Methodist Rehabilitation Center on October 13, 2005, also in Jackson, Mississippi, where she was treated by physiatrist, Dr. Michael Winkelmann, who was a physical rehabilitation specialist.

In the admission note at the Methodist Rehabilitation Center, Dr. Winkelmann stated: "Ms. LaKeysha Greer[6] [sic] is a pleasant 30-year-old black woman who has a history of progressive weakness. The patient was admitted at St. Dominic Hospital with the same symptoms. She was finally diagnosed with Guillain-Barré Syndrome. It was felt that immunization series had been the trigger for the development of Guillain-Barré." The admission note continued under the heading "review of systems:"

> She denies headache, fever, chills, cough, or sputum production. No abdominal pain, constipation, or diarrhea. No hesitancy or frequency. She does have the weakness with slow onset leading to her admission and the above-mentioned diagnosis. The culprit at this point in time, is felt to be the immunization, but this is an endemic area for West Nile, I would not rule out the same as an etiology of this condition.

The admission note concluded, under the heading "impression:" "At this point, my impression is that of a pleasant 30-year-old with what appeared to be Guillain-Barré. I would like to still rule out possible West Nile infection." The West Nile test came back negative. On October 21, 2005, Petitioner underwent another electromyography and nerve conduction study. As part of taking the patient's history, electromyographer Dr. Art Leis stated that Petitioner "[h]ad vaccination for TD [tetanus] and hepatitis [A] about 2 weeks before onset altered sensation."

Petitioner was discharged home on October 27, 2005, and began outpatient and physical therapy on November 2, 2005. In a January 5, 2009 affidavit filed in the above

[5] According to Dorland's Illustrated Medical Dictionary, Guillain-Barré Syndrome is a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection." Dorland's Illustrated Medical Dictionary 1832. Enteric is defined as "1. Intestinal. 2. Within the small intestine." Dorland's Illustrated Medical Dictionary 624.

[6] Despite the different last name on the admission notes, both parties cite to, and quote from, the admission notes in the filings, and Petitioner included the admission note as Petitioner's Exhibit 6 in Petitioner's petition for compensation. Moreover, both experts discussed the admission note at the July 27, 2010 hearing, and Special Master Lord discussed the admission note at length in her July 30, 2012 decision.

captioned case, Petitioner indicated that "[i]n January 2006, I was to be considered for a partner position at the law firm where I worked. Instead, I was forced to choose to return to work or apply for disability. I eventually returned to work, but I felt like a worthless employee." Petitioner also stated that "[e]ventually, I did recover from GBS. However, I still experience certain symptoms."

As indicated above, on August 26, 2008, Petitioner filed a timely petition seeking compensation under the National Vaccine Injury Compensation Program, alleging that she suffers from Guillain-Barré Syndrome as a result of the tetanus vaccine and the hepatitis A vaccine. The case was initially assigned to Special Master Abell and, on August 26, 2009, subsequently reassigned to Special Master Lord. On February 11, 2009, Respondent filed a response, pursuant to Vaccine Rule 4(c), opposing compensation to Petitioner. In the response, Respondent asserted that Petitioner was ineligible for compensation because Petitioner had "yet to offer a reputable medical or scientific theory causally connecting the Td and/or hep A vaccines to her GBS."

On June 15, 2009, in response to an Order issued by Special Master Abell, Petitioner filed the Medical Expert Report of Dr. Carlo Tornatore, who, as noted in Special Master Lord's July 30, 2012 decision, "is a neurologist at Georgetown University Hospital in Washington, D.C., and director of the Multiple Sclerosis Center there." In the expert report, Dr. Tornatore concluded that there was a "logical sequence of cause of effect to explain the onset of an inflammatory demyelinating polyneuropathy (Guillain-Barre) following tetanus vaccination." Included with Petitioner's expert report were four articles on which Dr. Tornatore relied to support his conclusion. He cited to R. Lahesmaa et al., Molecular Mimickry between HLA B27 and *Yersinia*, *Salmonella*, *Shigella* and *Klebsiella* within the Same Region of HLA α_1-helix, Clin. Exp. Immunol. [Clinical & Experimental Immunology], 1991, vol. 86, at 399-404, to explain molecular mimicry, a process in which autoimmune responses occur if antigens in a vaccine share homology with host agents. Dr. Tornatore further cited to Tomoko Komagamine and Nobuhiro Yuki, Ganglioside Mimicry as a Cause of Guillain-Barré Syndrome, CNS & Neurological Disorder – Drug Targets, 2006, vol. 5, at 391-400, which, according to Dr. Tornatore discussed molecular mimicry in the context of Guillain-Barré Syndrome and *Campylobacter jejuni*.[7] Dr. Tornatore also cited to an article by Lawrence B. Schonberger et al., Guillain-Barre Syndrome following Vaccination in the National Influenza Immunization Program, United States, 1976-1977, Am. J. Epidemiology, 1979, vol. 110(2), at 105-23, which discussed how swine flu and tetanus vaccines trigger autoimmune responses, such as molecular mimicry, which may lead to Guillain-Barré Syndrome and to an article by J.D. Pollard & G. Selby, Relapsing Neuropathy Due to Tetanus Toxoid, J. Neurological Sci., 1978, vol. 37, at 113-25. Dr. Tornatore stated in his expert report that "vaccines have been recognized to trigger autoimmune responses, albeit rarely, that lead to autoimmune responses directed against antigens

[7] *Campylobacter jejuni* is a bacterial infection that causes axonal degeneration. According to Dorland's Illustrated Medical Dictionary, axons are "[t]he process of a neuron by which impulses travel away from the cell body," and degeneration is defined as "deterioration; change from a higher to a lower form; especially [a] change of tissue to a less functionally active form." Dorland's Illustrated Medical Dictionary 186, 479.

on peripheral nerves, resulting in inflammatory demyelinating polyneuropathies. Swine flu and tetanus are two such vaccines." Dr. Tornatore explained that "[i]ndeed, the Institute of Medicine has recognized that tetanus vaccination can be a cause of Guillain-Barre based on the article by Pollard and Selby." Dr. Tornatore concluded, "[i]t is my opinion, to a reasonable degree of medical certainty, that the vaccinations of September 15, 2005, specifically the tetanus vaccination, resulted in the development of Ms. Isaac's inflammatory neuropathy."

On August 6, 2009, Respondent filed the Medical Expert Report of Dr. Thomas Leist, an expert in adult neurology and "an assistant professor of neurology at Thomas Jefferson University in Philadelphia and chief of the division of neuroimmunology," who concluded that Petitioner's Guillain-Barré Syndrome was caused neither by the tetanus nor the hepatitis A vaccinations, but rather by a gastrointestinal illness.[8] Dr. Leist agreed with the diagnosis of Guillain-Barré Syndrome. Dr. Leist stated, however, that:

> It is my opinion that more likely than not the gastrointestinal illness was the proximate, causal event leading to Guillain Barre Syndrome. The elevated glucose during admission to Baptist Hospital can serve as evidence of impaired glucose tolerance as can be observed during infections particularly in persons with a diabetic condition. It is my opinion that Ms. Isaac did not suffer from any adverse effects of hepatitis A or Td other than possibly transient erythema at the injection sites whether such complications are listed in the Vaccine Injury Table or not contained therein. I hold this opinion to a reasonable degree of medical certainty.

Dr. Leist submitted six articles with his expert report to support his conclusions: S. Kuwabara et al., Does Campylobacter jejuni infection elicit "demyelinating" Guillain-Barré, Neurology, 2004, vol. 63(1), at 529-33; Steven Black et al., A post-licensure evaluation of the safety of inactivated hepatitis A vaccine (VAQTA, Merck) in children and adults, Vaccine, 2003, vol. 22, at 766-72; Mary Beth Koslap-Petraco et al., Hepatitis A: Disease Burden and Current Childhood Vaccination Strategies in the United States, J. Pediatr. Health Care, 2008, vol. 22(1), at 3-11; M. Koga et al., Antecedent symptoms in Guillain-Barré syndrome: an important indicator for clinical and serological subgroups, Acta Neurol Scand [Scandinavica], 2001, vol. 103, at 278-87; Tetsuo Nakayama &

[8] In his expert report, Dr. Leist stated that "Dr. Moore diagnosed Ms. Isaac with early acute inflammatory demyelinating polyneuropathy (AIDP form of GBS) likely caused by a gastrointestinal illness." Dr. Moore's statement actually indicated that: "AIDP is likely related to gastrointestinal illness." (emphasis added). Special Master Lord correctly identified Dr. Moore's statement as "likely related to gastrointestinal illness," in her decision, except when, citing Dr. Leist's expert report, she stated: "He [Dr. Leist] noted that Dr. Moore, the neurology consultant who evaluated Petitioner at St. Dominic-Jackson, commented that she had a form of GBS likely caused by a gastrointestinal illness." In her Motion for Review, Petitioner also refers to Dr. Moore's note as stating "AIDP is likely caused by gastrointestinal illness," with a reference to Petitioner's own exhibit, which is a copy of Dr. Moore's original statement, and which, as noted above, stated "AIDP is likely related to gastrointestinal illness."

Kazumasa Onoda, Vaccine adverse events reported in post-marketing study of the Kitasato Institute from 1994 to 2004, Vaccine, 2007, vol. 25, at 570-76; and Tuttle et. al., The Risk of Guillain-Barré Syndrome after Tetanus-Toxoid-Containing Vaccines in Adults and Children in the United States, Am. J. Pub. Health, 1997, vol. 87(12), at 2045-48. The Tuttle et. al. article explained that, while the forty-two-year-old man discussed in the Pollard and Selby article had suffered from Guillain-Barré Syndrome, he experienced those episodes following acute, viral illness. Following two subsequent "large, active surveillance studies," the Tuttle et al. article concluded that, "on the basis of available data, no association of public health significance exists between tetanus-toxoid-containing vaccine and Guillain-Barré syndrome."

Addressing molecular mimicry, Dr. Leist recognized that molecular mimicry can cause Guillain-Barré Syndrome in the presence of certain pathogens, notably, the bacterium *C. jejuni*. Dr. Leist noted, however, there are no scientific studies linking tetanus vaccine with the theory of molecular mimicry, and noted that the association between tetanus vaccination and Guillain-Barré Syndrome was only based on the Pollard and Selby article. He also stated that the article submitted by Dr. Tornatore, Komagamine and Nobuhiro Yuki, Ganglioside Mimicry as a Cause of Guillain-Barré Syndrome, describing *C. jejuni* as a cause of Guillain-Barré Syndrome by molecular mimicry, does not demonstrate that molecular mimicry explains how the tetanus vaccination can cause Guillain-Barré Syndrome.

On August 26, 2009, the above captioned case was reassigned to Special Master Lord, who held a causation hearing on July 27, 2010. The two experts who had submitted expert reports testified during the July 27, 2010 hearing: neurologist Dr. Carlo Tornatore for Petitioner and neurologist Dr. Thomas Leist for Respondent. In his report, Petitioner's expert, Dr. Tornatore, had raised the issue of molecular mimicry, describing it as the process in which "vaccines have been recognized to trigger autoimmune responses, albeit rarely," which may result in inflammatory demyelinating polyneuropathies, such as Guillain-Barré Syndrome. Dr. Tornatore addressed the issue of molecular mimicry during his testimony and referenced the Schonberger article, Guillain-Barre Syndrome following Vaccination in the National Influenza Immunization Program, United States, 1976-1977, which addresses Guillain-Barré Syndrome and the flu vaccine. Dr. Tornatore also relied on the Pollard and Selby article during his testimony to explain that "a vaccine is basically just a protein . . . the expectation is that the body will fight if off, and rarely it gets it wrong and not only does it clear that protein but then the white blood cells will attack native proteins and cause in very rare cases things like Guillain-Barré." He specifically described molecular mimicry in relation to Guillain-Barré Syndrome as occurring when:

> [T]he white blood cells which are dutifully trying to get rid of whatever this antigen is will then start to try to remove the myelin, and so as they remove the myelin then patients end up with neurologic symptoms, and those are predominantly numbness, tingling, weakness, pain. . . . And then that's in essence what Guillain-Barré is, and this affects the nerves of the peripheral nervous system.

Dr. Tornatore also referenced the Pollard and Selby article to explain the theory of challenge/rechallenge as a method to prove that a tetanus vaccine caused Guillain-Barré Syndrome, as opposed to another factor. The summary to the Pollard and Selby article begins: "A unique case history is presented, of a 42-year-old patient who has suffered three episodes of demyelinating neuropathy, each of which followed an injection of tetanus toxoid." Dr. Tornatore explained that "the Pollard and Selby article, although they [the authors] did not speak to molecular mimicry, spoke more to the idea that there is some specificity." The specificity that Dr. Tornatore referred to is the identification of individual components of a vaccine. Dr. Tornatore tried to clarify that the Pollard and Selby article showed specificity because "somebody who was rechallenged with the same protein developed the same problem on three different occasions, and so that that [sic] antigenic stimulus was recognized as the inciting factor for causing the Guillain-Barré." Under cross-examination at the July 27, 2010 hearing, Respondent asked Dr. Tornatore, "in order to apply the theory of molecular mimicry to this case, don't you have to be able to identify which antigens in the tetanus/diphtheria vaccine share homology with the host antigens?" Dr. Tornatore stated Petitioner did not, and testified:

> Because you have the Pollard and Selby article where you had the positive rechallenge. And so all you need to know is that it's the vaccine itself. The individual components it would be nice to know what those are specifically. However, that is for this case, that specificity is not required. The only specificity is that there was a challenge positive rechallenge case, the Pollard and Selby case, that the Institute of Medicine said, you don't need to know the absolute molecular component but it's teaching us that if something happens one time and you challenge a person a second time with that same entity, that entity is the case.

Although the Pollard and Selby article describes a single case history from the 1970s, Dr. Tornatore concluded that "specificity was seen as evidence that, yes it's a rare event, but rare if you can reproduce it is indeed true." Dr. Tornatore testified that "in Ms. Isaac's case the entity was the tetanus toxoid, and she ended up with Guillain-Barré, which is exactly what Pollard and Selby described in that patient. So we're not saying she got tetanus and had something else, her toe fell off, this is the same entity." Dr. Tornatore also explained that the lack of epidemiologic studies following the thirty-two years since publication of the Pollard and Selby article was insignificant because the association between the tetanus vaccine and Guillain-Barré Syndrome had already been reported, and "the Institute of Medicine had spoken to this."[9] In response to a

[9] The 1994 Institute of Medicine Report referenced by Dr. Tornatore, titled Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality 88-89 (Kathleen Stratton et al. eds., 1994), stated in part that "there is biologic plausibility for a causal relation between vaccines and demyelinating disorders. The literature describing a possible association between GBS and tetanus toxoid, DT, or Td consists of case reports. The most convincing case in the literature is that reported by Pollard and Selby (1978), who described a 42-year-old man who developed GBS on three separate

question inquiring as to whether the "Pollard and Selby case report [was] over 32 years old," Dr. Tornatore stated: "Science is science. That's a very interesting case. If it happened and you have a patient that demonstrates a very peculiar process you don't discard it just because, oh that happened some time ago. What difference does that make?"

Dr. Tornatore further testified that Guillain-Barré Syndrome can present itself in either a demyelinating form or an axonal form.[10] He claimed that distinguishing between these two forms is important because there is a "demyelinating form, which is very typical after one's had a viral infection or after vaccination, but the axonal form is more typical of what you see with campylobacter jejuni." Dr. Tornatore testified that since Petitioner's axons were intact, her form of Guillain-Barré Syndrome was a demyelinating form, not caused by *C. jejuni*. He also testified that a viral infection did not cause Petitioner's Guillain-Barré Syndrome, because Petitioner did not have a fever, elevated white blood cells, neutrophils, or liver enzymes, but had atypical antibodies, borderline elevation of rheumatoid factors, and elevated ANA [antinuclear antibodies] immunofluorescence, which "are not things you see following a routine infection." Moreover, Dr. Tornatore explained that Petitioner's high glucose levels, a factor that sometimes indicates infection, was actually due to Petitioner's pre-diabetic state.

Dr. Leist, testifying as an expert for Respondent, agreed that Petitioner did suffer from Guillain-Barré Syndrome and had received a tetanus vaccination, but pointed out that she also "presented with GI [gastrointestinal] symptoms within a time frame consistent for an association with Guillain-Barré Syndrome." In his expert report and in his testimony, Dr. Leist further indicated that the gastrointestinal symptoms, including nausea and vomiting, were reported in plaintiff's hospital records. Moreover, Dr. Leist testified on direct examination that, "two thirds of patients that come down with GBS indicate occurrence of an infection in the period of time prior to onset of the symptoms associated with Guillain-Barré Syndrome. And so obviously the occurrence of symptoms that are possibly indicative of an infection prior to her onset of Guillain-Barré Syndrome is important as this then could represent the proximate cause of her GBS." Dr. Leist further testified that Petitioner's elevated white blood cells and pre-diabetic condition did not rule out an infection. Moreover, Dr. Leist testified that since antibody testing was not done, an infection was never effectively evaluated as a possible cause for Petitioner's Guillain-Barré Syndrome.

In his testimony, Dr. Leist also questioned the significance of the individual studied in the Pollard and Selby article, on which Dr. Tornatore had relied in his

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occasions (over a 13-year period) following receipt of tetanus toxoid." As discussed below, Special Master Lord introduced an excerpt of the 1994 Institute of Medicine Report into the record in the above captioned case.

[10] According to Dorland's Illustrated Medical Dictionary, axons are the "process of a neuron by which impulses travel away from the cell body," and demyelination is the "destruction, removal, or loss of the myelin sheath of a nerve or nerves." Dorland's Illustrated Medical Dictionary 186, 486.

testimony. He explained that subsequent information following the Pollard and Selby article indicated that the symptoms of the individual referenced in the article were "independent of tetanus." Therefore, Dr. Leist stated that because the 1994 Institute of Medicine Report had significantly relied on the Pollard and Selby article to conclude the tetanus vaccine could lead to Guillain-Barré Syndrome, he believed "if the Institute of Medicine will come around to look at this data again at some point in time, because I think these recommendations are living and breathing things, they will have to be reevaluated, then the opinion of the IOM [Institute of Medicine] probably will change."

Dr. Tornatore rejected Respondent's theory that a gastrointestinal illness caused Petitioner's Guillain-Barré Syndrome because, as Dr. Tornatore explained, she did not have elevated white blood cells, and was constipated. Furthermore, according to Dr. Tornatore's testimony, the symptoms that did coincide with gastrointestinal illness, such as nausea and vomiting, improved with anti-reflux medication, which indicated to him that Petitioner did not suffer from gastrointestinal illness. During his hearing testimony, Dr. Tornatore did not give much weight to the note in the record by treating physician Dr. Moore, which stated: "AIDP [acute inflammatory demyelinating polyneuropathy] is likely related to gastrointestinal illness." Dr. Tornatore testified that Dr. Moore based his conclusion on Petitioner's symptoms of nausea and vomiting, which are not enough to establish a gastrointestinal illness. Although Dr. Tornatore conceded that antibody tests would have more accurately shown that an infection did not bring on her illness, Dr. Tornatore stated that Petitioner "had no symptoms coincident" with any of the antibody tests available. Therefore, according to Dr. Tornatore, Petitioner's doctors would not have ordered tests just "to see if the antibodies [were] there or not." Dr. Tornatore concluded, "we've kind of, we have ruled out all these other potential issues just based on her clinical story and the literature that's here. So based on that, you know, we can say, well that really leaves us with only one other possible culprit, and then that would be the tetanus vaccination."

Subsequent to the causation hearing held in Petitioner's case, Special Master Lord filed an Order on September 23, 2011, including as Court Exhibit 1, a pre-publication[11] excerpt from a 2011 Report issued by the Institute of Medicine, Adverse Effects of Vaccines: Evidence and Causality 477-80 (Kathleen Stratton et al. eds., pre-publication ed. 2011). This excerpt from the 2011 pre-publication Institute of Medicine Report was not available to the parties at the time of the July 27, 2010 causation hearing. The Special Master, therefore, gave the parties thirty days to "file responses, if any, expressing the parties' views on Court Exhibit 1." The excerpt of the 2011 pre-publication Institute of Medicine Report states, in part:

[11] The final version of the Institute of Medicine Report was published in 2012. Special Master Lord in her Ruling on Entitlement, issued on July 30, 2012, however, only referred to the 2011 pre-publication Institute of Medicine Report, Adverse Effects of Vaccines: Evidence and Causality. There are no material differences in the relevant sections introduced into the record by Special Master Lord between the pre-publication and final versions, only typographic and minor clarifying changes which do not affect the issues raised in this case. Therefore, the court also refers to the pre-publication version in this opinion.

> The epidemiologic evidence is insufficient or absent to asses an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccines and GBS.
>
> Mechanistic Evidence
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> The committee identified 10 publications reporting the development of GBS after the administration of vaccines containing diphtheria toxoid, tetanus toxoid, and acellular pertussis- antigens alone or in combination. The publications did not provide evidence beyond temporality, some too long or too short based on the possible mechanism involved…. Long latencies between vaccine administration and development of symptoms make it impossible to rule out other possible causes.
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> …
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> The symptoms described in the publications referenced above are consistent with those leading to a diagnosis of GBS. Autoantibodies, complement activation, immune complexes, T cell and molecular mimicry may contribute to the symptoms of GBS; however, publications did not provide evidence linking these mechanisms to diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine.

Under the heading "Causality Conclusion," the pre-publication excerpt from the 2011 Report issued by the Institute of Medicine stated: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccines and GBS." (internal citations omitted).

The pre-publication excerpt of the 2011 Institute of Medicine Report also included an examination of Chronic Inflammatory Disseminated Polyneuropathy and the association between Chronic Inflammatory Disseminated Polyneuropathy and diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccines. That examination discussed the Pollard and Selby article and indicated:

> Pollard and Selby (1978) appear to present evidence of vaccine rechallenge leading to symptoms of peripheral neuropathy in a patient, subsequently diagnosed with a spontaneously relapsing remitting neuropathy, who developed symptoms in association with acute viral infections; however, the authors did not rule out other possible causes and did not provide evidence beyond a temporal relationship with vaccine administration. The spontaneous development of peripheral neuropathy makes it difficult to conclude that the tetanus toxoid vaccines were the causative agent.

In response to Court Exhibit 1, Petitioner filed Petitioner's Exhibit 26, the preface to the 2011 pre-publication Institute of Medicine Report which indicated that, "the

committee particularly counsels readers not to interpret a conclusion of inadequate data to accept or reject causation as evidence either that causation is either present or absent." Petitioner alleged that the 2011 pre-publication Institute of Medicine Report provided weak circumstantial evidence because it neither accepted nor rejected whether a tetanus vaccine could cause molecular mimicry and Guillain-Barré Syndrome. Furthermore, Petitioner emphasized that she was "not required to satisfy any element of the *Althen* test [Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (described below)] with scientific certainty." (footnote omitted). Rather, Petitioner claims that she has met her legal burden because the record as a whole "demonstrates, more likely than not, that her Td vaccine caused her GBS. The IOM report is of little probative value in this record." Petitioner asserted that she has satisfied the legal standard because her record demonstrates: (1) "proposed biologically plausible theory;" (2) "a logical sequence of cause and effect" and; (3) "an appropriate temporal relationship," between the tetanus vaccination and the Guillain-Barré Syndrome. Moreover, Petitioner argued that her medical record, as a whole, proved, by a preponderance of the evidence, that no other alternative cause exists for her Guillain-Barré Syndrome.

Respondent replied in its own filing with the Special Master that the 2011 pre-publication Institute of Medicine Report observations were consistent with the Respondent's view that "the concept of whether or not Td vaccine actually induces GBS via molecular mimicry has not been established." Therefore, the Respondent argued that Petitioner has not proven by a preponderance of the evidence that the tetanus vaccine, in fact, caused her Guillain-Barré Syndrome, for which reason Respondent requested a dismissal of Petitioner's claim on the merits.

On May 24, 2012, Special Master Lord filed an Order, including as Court Exhibit 2, another excerpt from the 2011 pre-publication Institute of Medicine Report, Adverse Effects of Vaccines: Evidence and Causality 61-63. The Order again gave the parties thirty days to "file responses, if any, expressing the parties' views on Court Exhibit 2." The 2011 pre-publication Institute of Medicine Report excerpt, in relevant part, stated:

> Molecular mimicry as a mechanism that can cause pathologic damage and disease has been demonstrated in several animal models, most notably experimental allergic encephalomyelitis (EAE) in mice and rabbits.
>
> . . .
>
> Proving that a particular human autoimmune disease is due to molecular mimicry is problematic…. A realistic and consistent temporal relationship between exposure to exogenous antigen and development of disease must be documented. This can be difficult in the case of a natural exposure to pathogen where infection may have been subclinical, making it impossible to define an exact temporal relationship.

The excerpt of the 2011 pre-publication Institute of Medicine Report continued: "While molecular mimicry is a well-established mechanism in selected animal models,

its relevance to human autoimmune disease remains in most cases to be convincingly proven." Addressing adverse events the pre-publication excerpt 2011 of the Institute of Medicine Report thought to be due to molecular mimicry, the 2011 Institute of Medicine Report pre-publication excerpt stated:

> Some of the vaccine AEs [adverse events] under consideration by our committee share symptoms with human autoimmune diseases for which molecular mimicry has been hypothesized (i.e., arthritis, systemic lupus, erythematosus, insulin-dependant diabetes mellitus, central and peripheral nervous system demyelinating diseases). However, we found little clinical evidence (e.g., challenge/rechallenge), diagnostic evidence (e.g., presence of antigen or relevant immune complexes in affected tissue), or experimental evidence (e.g., in vitro evidence of cross-reactive T-cells derived from a site of tissue injury) that could be consistent with the hypothesis of molecular mimicry in rare and selected case reports.
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> …
>
> Based on the literature reviewed, molecular mimicry was not confirmed to be a mechanism leading to the development of the adverse events post-vaccination.

In response to Court Exhibit 2, Petitioner filed Exhibit 27, another pre-publication excerpt of the 2011 Institute of Medicine Report. Adverse Effects of Vaccines: Evidence and Causality 70-71, 77-78. The relevant portion of that 2011 pre-publication excerpt filed by Petitioner stated:

> There are multiple uses of animal models in vaccine studies. It is possible to study each tissue of the body for microbial invasion and microbe-induced or immune-mediated damage.
>
> …
>
> With animal models it is possible to study whether particular genetic deficiencies or preexisting conditions attenuate, augment, or alter the immune response to infectious agents or microbial antigen, or whether the microbial or antigenic challenge exacerbates the preexisting condition or reveals otherwise unappreciated consequences of the genetic deficiency.
>
> It is possible to look for molecular mimicry between vaccine antigen and self-antigen, although mimicry at the antibody level is more likely to translate to the human situation than molecular mimicry at the T cell level due to the diversity of histrocompatibility molecules. Should molecular mimicry be found in an animal model, it still needs confirmation in humans.

Petitioner argued that while the excerpt of the 2011 pre-publication Institute of Medicine Report requires "direct evidence to prove the existence of molecular mimicry," and is, therefore, unable to accept animal models, the Vaccine Program "allow[s] use [sic] indirect, circumstantial evidence." Petitioner alleges that in order for the Institute of Medicine to accept the existence of molecular mimicry within humans, it would require

"practices that do not and probably never will, occur in clinical practice." Petitioner asserted that directly proving causation between molecular mimicry and vaccines with challenge/rechallenge is "highly unlikely, as it would require a medical practitioner to knowingly re-expose a patient to a potentially harmful circumstance." Therefore, Petitioner concluded that it would go against the standard set forth in the Vaccine Program to force Petitioner to prove causation within a scientific certainty. Petitioner again argued she had shown causation by a preponderance of the evidence by providing a medical theory, logical sequence, and a proximate temporal relationship between the tetanus vaccination and her Guillain-Barré Syndrome.

In its response to Special Master Lord's May 24, 2012 Order, Respondent argued that even with the lower threshold under the Vaccine Program standard, Petitioner had failed to satisfy her burden of proof because she did not provide the court with "'a reputable medical or scientific explanation that pertains specifically to [her] case.'" (quoting Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir.), reh'g en banc denied (Fed. Cir. 2010)). Respondent argued that Petitioner had not met this standard because: (1) Dr. Tornatore failed to establish which essential elements of the tetanus vaccine contributed to molecular mimicry; (2) Court Exhibits 1 and 2 show that molecular mimicry has not been established as a mechanism by which the tetanus vaccine causes Guillain-Barré Syndrome and; (3) Court Exhibits 1 and 2 undermine Dr. Tornatore's reliance on the Pollard and Selby article. Respondent again argued in favor of dismissal of the Petitioner's claim on the merits.

On July 27, 2012, Special Master Lord filed an Order, including as Court Exhibit 3, an excerpt of the 1994 Institute of Medicine Report. Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality 88-89. Special Master Lord entered the excerpt of the 1994 Institute of Medicine Report in order to complete the record because "both parties' experts discussed this portion of the 1994 Institute of Medicine ('IOM') publication, but it was not previously in the record."[12] The parties, and the experts in their reports and testimony, had discussed the 1994 version of the Institute of Medicine Report because, at the time, the 2011 pre-publication Institute of Medicine Report had not yet been issued, and because the 1994 Institute of Medicine Report had indicated a potential, causal connection between vaccines and Guillain-Barré Syndrome. Under the heading "Causality Argument," the excerpt from the 1994 Institute of Medicine Report stated:

> There is a biologic plausibility for a causal relation between vaccines and demyelinating disorders. The literature describing a possible association between GBS and tetanus toxoid, DT, or Td consists of case reports. The most convincing case in the literature is that reported by Pollard and Selby (1978), who described a 42-year-old man who developed GBS on three separate occasions (over a 13-year period) following receipt of tetanus toxoid. The relation between tetanus toxoid and GBS is convincing at least for that one individual, even though this man has subsequently

[12] Unlike the two previous exhibits, the parties did not respond to the Special Master's filing. As Special Master Lord noted, "I am entering the excerpt to complete the record."

> experienced multiple recurrences of demyelinating polyneouropathy, most following acute viral illnesses.

The relevant portion of the excerpt from the 1994 Institute of Medicine Report also stated that "[f]ew cases of GBS [Guillain-Barré Syndrome] following receipt of DT [tetanus] have been reported." After examining two other cases, which the 1994 Institute of Medicine Report indicated did not include enough specific information to consider "the relation between tetanus toxoid, DT, or Td and the occurrence of GBS." The 1994 Institute of Medicine Report continued:

> However, because the case by Pollard and Selby (1978) demonstrates that tetanus toxoid *did* cause GBS, in the committee's judgment tetanus toxoid *can* cause GBS.
>
> Conclusion
>
> The evidence favors a causal relation between tetanus toxoid and GBS. If the evidence favors a causal relation between tetanus toxoid and GBS, then in the committee's judgment the evidence favors a causal relation between vaccines containing tetanus toxoid (DT and Td) and GBS. Because the conclusions are not based on controlled studies, no estimate of incidence or relative risk is available. It would seem to be low.

(emphasis in original).

On July 30, 2012, Special Master Lord issued her decision on Petitioner's case. As noted above, Special Master Lord dismissed Petitioner's hepatitis A claim, finding that Petitioner had "effectively abandoned the allegation of causation by the Hep A vaccine" because, during the course of the hearing, Dr. Tornatore "did not opine that the Hep A vaccination caused Petitioner's GBS." Special Master Lord, therefore, focused on Petitioner's tetanus vaccination claim. Special Master Lord stated that, in order to qualify for compensation, Petitioner had to prove causation of the tetanus vaccine and her Guillain-Barré Syndrome, "by a sound and reliable 'medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be "legally probable, not medically or scientifically certain."'" (quoting Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir.) (quoting Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)), reh'g en banc denied (Fed. Cir. 2010)).

In arriving at her decision, Special Master Lord applied the three-prong causation analysis set forth in Althen v. Secretary of Health & Human Services, 418 F.3d at 1278, which is discussed more fully below, stating:

> Petitioner's burden is to show that the vaccination brought about her injury by providing: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the

> vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury."

(quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278).

Regarding to the first prong of the Althen test, "a medical theory causally connecting the vaccination and the injury," Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278, Special Master Lord concluded that "none of the medical records support molecular mimicry or any other theory of possible vaccine causation. Petitioner's case therefore rests on the reliability of her expert's conclusion." Special Master Lord found Dr. Tornatore's testimony unreliable in Petitioner's case, and, therefore, found that Petitioner was not able to establish Petitioner's medical theory. The Special Master articulated three reasons: (1) Dr. Tornatore's "undue reliance on ambiguous evidence, and erroneous statements concerning the article by Pollard and Selby," (2) that Dr. Tornatore was "unable to explain the basis for the theory of molecular mimicry as it might pertain to Td vaccination and GBS," and (3) Dr. Tornatore's "misplaced reliance on an isolated, ambiguous statement by a physiatrist," Dr. Winkelmann.

Special Master Lord concluded that Dr. Tornatore had relied too heavily on the Pollard and Selby article as evidence of vaccine causation through challenge/rechallenge because the 2011 pre-publication Institute of Medicine Report "no longer characterized the individual reported on [in the earlier 1994 Institute of Medicine Report] as suffering from GBS, but from a recurring/relapsing disorder called CIDP [Chronic Inflammatory Demyelinating Polyneuropathy]." She also noted that during the course of the proceedings, Special Master Lord introduced Court Exhibits 1 and 2 into evidence, and offered both parties an opportunity to respond: "Dr. Tornatore did not update his testimony when offered the opportunity to do so. By order dated September 23, 2011, the pertinent portion of the 2011 IOM [Institute of Medicine] report was entered into the record, without objection, and the parties were invited to comment on the new information. Dr. Tornatore offered no supplementation of his report or his testimony, notwithstanding that the new IOM report indicated that his reliance on Pollard and Selby to bolster his theory of causation in this case was misplaced." (internal citation omitted).

Special Master Lord stated that she had relied on the 2011 pre-publication Institute of Medicine Report's evaluation of the Pollard and Selby case only to find in Petitioner's case that Dr. Tornatore's report and testimony were "unreliable." Special Master Lord further specified that she had not relied on the Report's "non-conclusion" of Guillain-Barré Syndrome causation to reach her final conclusion. In a footnote, Special Master Lord stated:

> This may be an appropriate point to note that Petitioner and her expert laid great emphasis on the conclusion from the 1994 IOM report of a causal link between Td and GBS. Now that the IOM has withdrawn its previous endorsement of a causal link, Petitioner urges that the IOM's information

> should not be considered significant. I understand and appreciate the distinction between the proof that is required to establish entitlement to compensation in the Vaccine Program and the greater proof that may be required to satisfy the scientific community of vaccine injury causation, and I do not place undue reliance on the IOM's causality conclusion (which is a non-conclusion, in any event). But I do rely on the IOM's evaluation of the scientific significance of the Pollard and Selby report. That evaluation was undertaken and communicated to the public by a committee of scientific experts assigned by law to evaluate scientific evidence. See Terran [ex rel. Terran v. Sec'y of Health & Human Servs.], 195 F.3d [1302,] 1313, 1315 [(Fed. Cir. 1999), cert. denied, 531 U.S. 812 (2000)] (noting that Congress "directed the Secretary to request that the Institute of Medicine of the National Academy of Sciences conduct studies exploring the link between childhood vaccines with certain illnesses"). The IOM's latest evaluation of the significance of the Pollard and Selby report contradicts Dr. Tornatore's testimony at hearing. The argument that special masters should not rely on the opinion of the IOM concerning the significance of particular scientific evidence is unpersuasive.

(internal citations omitted).

In her decision, Special Master Lord stated "I am aware that in some earlier cases, GBS has been attributed to tetanus vaccination. See, e.g., Althen."[13] Special Master Lord reasoned, however, "[f]or all the reasons stated above, the decisions in other cases are not binding in this one. In addition, as science advances, decisions in the Program must respond accordingly." She also correctly noted that, "[i]t follows that each case must be considered on the record in that case." (citing Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 548).

Special Master Lord also found Dr. Tornatore's testimony unreliable because, relying on the process of molecular mimicry, he failed to link the tetanus vaccine and the Guillain-Barré Syndrome. Special Master Lord concluded that "[n]one of the medical literature submitted by Petitioner and her expert discusses molecular mimicry as a possible theory of causation linking Td vaccination and GBS." (footnote omitted). Special Master Lord found that when Dr. Tornatore was asked to link the tetanus

[13] The United States Court of Federal Claims decision in Althen v. Secretary of Health & Human Services, 58 Fed. Cl. 270 (2003), aff'd, 418 F.3d 1274 (Fed. Cir. 2005), mentioned in passing a potential link between the tetanus vaccination and Guillain-Barré Syndrome. The Court of Federal Claims decision noted that "Dr. Safran also criticized Dr. Smith's reliance on the relationship between tetanus toxoid and Guillain-Barre Syndrome, discussed in the 1994 IOM REPORT, to support a theory that a similar causal relationship could exist between the tetanus toxoid vaccine and CNS [central nervous system] disorders." Id. at 277 (footnote omitted). This reference was not discussed in the reviewing opinion issued by the United States Court of Appeals for the Federal Circuit on appeal, and the comment was based on the 1994 Institute of Medicine Report.

vaccination to Guillain-Barré Syndrome using the molecular mimicry theory, he, instead, switched to relying on the case history in 1978 Pollard and Selby article, and the multiple occurrences of Guillain-Barré Syndrome, the challenge/rechallenge, in the forty-two-year-old man described in that report after he received tetanus toxoid. The Special Master wrote:

> Challenge/rechallenge in the Vaccine Program generally pertains to Prong 2 [of the Althen test], as it may furnish evidence that there was a logical chain of cause and effect linking vaccination to injury. In this case, Dr. Tornatore testified that the case of challenge/rechallenge reported by Pollard and Selby supported his theory of molecular mimicry pertaining to Prong 1. I agree in general that evidence that an injury did happen (even to someone other than the vaccinee) makes it more likely that it could happen. This is consistent with the principle established by the Federal Circuit that evidence adduced under one prong of the Althen test may be applied to satisfy the other prongs. See Capizzano v. Sec'y of Dep't of Health & Human Servs., 440 F.3d 1317, 1325-26 (Fed. Cir. 2006). The problem, as discussed herein, is that it no longer appears that the Pollard and Selby case report represents a case of challenge/rechallenge.

(internal citations omitted).

In finding Dr. Tornatore's testimony and expert report unreliable, Special Master Lord also noted that Dr. Tornatore failed to provide evidence to rebut Respondent's "science-based evidence," provided by Dr. Leist, and which countered Dr. Tornatore's theory of causation. Special Master Lord indicated that "Dr. Leist pointed out that the medical literature Dr. Tornatore submitted involved a cross-reaction based on a particular component of an organism known to cause GBS. Evidence that *C. jejuni* causes GBS by molecular mimicry does not constitute preponderant evidence that molecular mimicry is a possible explanation for vaccine causation." Therefore, Special Master Lord stated, "[i]n these circumstances, Dr. Tornatore needed to present rebuttal evidence to show that, contrary to Dr. Leist's testimony, the evidence supported possible vaccine causation by the process of molecular mimicry. Dr. Tornatore's presentation failed in this respect. Instead, as noted above, he [Dr. Tornatore] shifted ground and relied on the notion of challenge/rechallenge."

Therefore, Special Master Lord concluded:

> I find that Dr. Tornatore's evidence is not sufficient to preponderate under Althen Prong 1. The theory that Td vaccination could cause GBS by molecular mimicry was effectively challenged by Respondent's expert, without meaningful response. Seemingly unable to explain the basis for the theory of molecular mimicry as it might pertain to Td vaccination and GBS, Dr. Tornatore relied instead on the concept of challenge/rechallenge. That phenomenon, with respect to Td vaccination and GBS, no longer is accepted by scientific experts as a link between Td

and GBS, as Dr. Leist indicated at hearing, and as was shortly thereafter confirmed by the IOM.

Finally, Special Master Lord found Dr. Tornatore's expert report and testimony in Petitioner's case unreliable because he relied on Dr. Winkelmann's admission note to show causation. Dr. Winkelmann's October 13, 2005 admission note to Methodist Rehabilitation Center stated: "It was felt that immunization series had been the trigger for the development of the Guillain-Barré." (emphasis added). Special Master Lord explained that given Dr. Winkelmann's specialty as a physiatrist, not a neurologist or an immunologist, "it seems odd that Dr. Tornatore would consider Dr. Winkelmann's opinion of vaccine causation 'important.'" As a physiatrist, Dr. Winkelmann is a specialist in the branch of medicine that deals with rehabilitation, "using physical agents such as light, heat, cold, water, electricity, therapeutic exercise, and mechanical apparatus, and sometimes pharmaceutical agents.'" (quoting Dorland's Illustrated Medical Dictionary 1443). Special Master Lord also noted that Dr. Winkelmann was not Petitioner's treating physician when she fell ill. Special Master Lord noted that, "[i]t would appear that at the time he [Dr. Winkelmann] made the statement on which Dr. Tornatore places importance, which was the time of Petitioner's admission to the rehab facility, Dr. Winkelmann had not yet had a treating relationship with the Petitioner," and "Dr. Winkelmann treated Petitioner only after this 'important' note concerning the cause of Petitioner's condition was created." (emphasis in original).

Special Master Lord concluded that Dr. Tornatore had improperly relied "on an isolated, ambiguous statement by a Physiatrist," Dr. Winkelmann. Moreover, Special Master Lord also questioned Dr. Tornatore's reliability based on his speculation that Dr. Winkelmann examined the Petitioner's medical history prior to writing the note, when "this assumption is not based upon any evidence of record." (footnote omitted). As indicated above, Special Master Lord found that Petitioner had failed to prove the first prong of the Althen test, demonstrating "a medical theory causally connecting the vaccination and the injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278. The Special Master, therefore, concluded that Petitioner did not qualify for relief under the Vaccine Act.

"[T]o provide additional context," to her decision, Special Master Lord also examined the second prong of Althen, "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278. Special Master Lord concluded that Petitioner had failed to establish cause and effect. She stated that, based on the evidence in the record before her, Petitioner's attempt to prove cause and effect again revolved around Dr. Tornatore's testimony. First, she reasoned that, while Dr. Tornatore ruled out *C. jejuni* as a cause for Petitioner's Guillain-Barré Syndrome, his testimony "still left two possible causes of Petitioner's GBS – virus and vaccine. Ruling out a bacterial infection did not logically make vaccine causation more likely than viral infection." Furthermore, Special Master Lord found unpersuasive Dr. Tornatore's dismissal of Dr. Moore's conclusions

as one of Petitioner's treating neurologists, and Dr. Moore's "clear"[14] notation that Petitioner's injury was "likely related to gastrointestinal illness," as compared to Dr. Tornatore's reliance on the physiatrist, Dr. Winkelmann's "ambiguous notation." Therefore, finding "scant medical record evidence one way or the other, no meaningful treating physician opinions, and two qualified experts who disagree concerning the evidence," Special Master Lord's decision was based on which expert testimony she found more reliable. Special Master Lord found Dr. Leist's expert report and expert testimony in Petitioner's case more reliable than Dr. Tornatore's because, according to the Special Master, "Dr. Leist's testimony was clearer, more consistent, more logical, and more closely tied to the facts of this case."

Turning to the third prong of the Althen test, "a showing of a proximate temporal relationship between vaccination and injury," Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278, Special Master Lord concluded that, regarding "Prong 3 of the Althen test," "[t]he timing of the onset of Petitioner's illness in relation to vaccination…is deemed appropriate. This factor alone does not determine entitlement to compensation." Special Master Lord also noted that at the hearing, the "Secretary conceded Prong 3 of the Althen test." Special Master Lord determined that "Petitioner has not presented preponderant evidence to support her claim under the Vaccine Act that the Td vaccination was the cause of her injuries. Accordingly, she is not entitled to compensation under the Vaccine Act," and dismissed the petition for compensation.

Before this court, Petitioner objects to the decision of Special Master Lord on three grounds. First, Petitioner contends that Special Master Lord abused her discretion by arbitrarily and capriciously mischaracterizing Dr. Tornatore's testimony as "predominatly [sic] reliant" on the 1994 Institute of Medicine Report. Petitioner argues that Dr. Tornatore only briefly mentioned the 1994 Institute of Medicine Report once in his expert report, and only referred to the 1994 Institute of Medicine Report three times during his testimony. Petitioner alleges that Dr. Tornatore showed a plausible theory of causation between the Petitioner and the tetanus vaccine even by relying on three of the articles referred to in his expert report, namely, R. Lahesmaa et al., Molecular Mimickry between HLA B27 and *Yersinia*, *Salmonella*, *Shigella* and *Klebsiella* within the Same Region of HLA α_1-helix, Clin. Exp. Immunol. 1991, vol. 86, Tomoko Komagamine and Nobuhiro Yuki, Ganglioside Mimicry as a Cause of Guillain-Barré Syndrome, CNS & Neurological Disorder – Drug Targets, 2006, vol. 5, and 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.

Second, Petitioner claims that Special Master Lord abused her discretion by finding that the Institute of Medicine reversed its position on causation from the 1994 Report to the 2011 pre-publication Report, and then used this allegedly mistaken belief

[14] In this respect, the Special Master may have overstated the facts, although her decision remains valid overall, given the other factors on which she relied. As noted above, although Dr. Moore described Petitioner's AIDP as "likely related to related to gastrointestinal illness." The next day he also indicated that the nerve study was "consistent with early GBS."

that the Institute of Medicine had reversed its position as a reason to find Dr. Tornatore's testimony unreliable. Petitioner argues that the 2011 pre-publication Institute of Medicine Report never reversed its position from the previous 1994 version of the Institute of Medicine Report conclusion that, "'[t]he evidence favors a causal relationship between tetanus toxoid and GBS." Rather, according to Petitioner, the 2011 pre-publication Institute of Medicine Report took a neutral stance[15] on causation between the tetanus vaccination and Guillain-Barré Syndrome, as opposed to its earlier conclusion in the 1994 Institute of Medicine Report, which stated: "The evidence favors a causal relationship between tetanus toxoid and GBS." Petitioner argues that the 2011 pre-publication Institute of Medicine Report's finding as "evidence is inadequate to accept or reject a causal relationship" between the tetanus vaccine and Guillain-Barré Syndrome. According to Petitioner, "[t]his abuse of discretion led directly to the Special Master requiring Lakeysha to prove an elevated evidentiary burden expressly rejected in *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), a requirement that was not in accordance with law." (footnote omitted). Petitioner acknowledges that the 2011 pre-publication Institute of Medicine Report may not be an objective confirmation of causation, but argues that special masters cannot require Petitioner to prove causation through "objective confirmation."

Moreover, Petitioner alleges that Dr. Tornatore did not rely on the 1994 Institute of Medicine Report to prove his plausible theory of causation. Rather, according to Petitioner, to conclude that the tetanus vaccination caused Petitioner's Guillain-Barré Syndrome, Dr. Tornatore relied on the specific facts of Petitioner's case, the absence of another cause, and the three articles discussed in his expert report: R. Lahesmaa et al., Molecular Mimickry between HLA B27 and *Yersinia*, *Salmonella*, *Shigella* and *Klebsiella* within the Same Region of HLA α_1-helix, Clin. Exp. Immunol., 1991, vol. 86, Tomoko Komagamine and Nobuhiro Yuki, Ganglioside Mimicry as a Cause of Guillain-Barré Syndrome, CNS & Neurological Disorder – Drug Targets, 2006, vol. 5, and 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. Petitioner also alleges that Dr. Tornatore explained how molecular mimicry causes Guillain-Barré Syndrome in his testimony.

Third, Petitioner alleges that "[r]ejecting an expert's opinion based on whether his theory of causation is supported by the weight of epidemiological evidence is an *erroneous legal standard*." (emphasis in original). Petitioner quotes from the Federal Circuit's decision in Andreu ex rel. Andreu v. Secretary of Department of Health & Human Services, 569 F.3d 1367 (Fed. Cir. 2009), to argues that "'[w]hile considerable deference must be accorded to the credibility determinations of special masters, see Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993), this does not mean that a special master can cloak the application of an erroneous legal

[15] Petitioner argues that "[a]fter improperly characterizing Dr. Tornatore's theory of causation as *emphatically relying* upon the 1994 IOM report's conclusion, she then takes the 2011 IOM's incremental step away from a direct statement of causation to basically a position of neutrality and finds that Dr. Tornatore's theory is therefore unreliable." (emphasis in original).

standard in the guise of a credibility determination, and thereby shield it from appellate review. A trial court makes a credibility determination in order to assess the candor of a fact witness, not to evaluate whether an expert witness' medical theory is supported by the weight of epidemiological evidence.'" (quoting Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1379). Therefore, Petitioner alleges that although Special Master Lord used the term "reliability determination" in her decision, rather than "credibility determination," it does not change the fact that Special Master Lord actually did use epidemiology to determine the credibility of Dr. Tornatore. Petitioner argues that:

> In the instant matter the Special Master repeatedly denigrates Dr. Tornatore's testimony due to what is characterized as a "lack of reliability," in particular because the articles he submitted may not say that a causal relationship to a degree of scientific certainty has been established, or because articles they have submitted indicate either that there is not enough evidence or that there is no association, and most significantly that the 2011 IOM report that the Court submitted "reversed" its position on causation between the Td vaccination and GBS.

Petitioner also contends that, "[d]espite the Federal Circuit's *clear* directive that Petitioners are not required to submit literature, the standard of scientific certainty in medical journal articles is still being inappropriately foisted on petitioners." (emphasis in original). Therefore, Petitioner claims:

> Epidemiology *cannot* be used to disprove causation. Yet, the Special Master used the ambivalent conclusions of the 2011 IOM report to attack Dr. Tornatore, and to hold that since his theories are not generally accepted in the medical community, they are not "reliable." This argument was also in front of the Federal Circuit in *Althen* in the guise of Prong 2 of *Stevens*. This argument was also explicitly *rejected* by the Circuit as contrary to law and imposing an impermissible burden of proof on Mrs. Althen. By requiring this objective confirmation the Special Master in *Althen* acted contrary to law.

(emphasis in original).

Petitioner argues that Special Master Lord erroneously changed the legal standard by requiring Dr. Tornatore to rebut Dr. Leist's testimony with objective medical theories in order to be found credible. Petitioner also takes issues with Special Master Lord's finding that Dr. Tornatore's "'reliance' on the statements of Dr. Winkelmann in LaKeysha's contemporaneous medical records is 'misplaced.' Dr. Tornatore did find it important that Dr. Winkelmann related the Td vaccination to LaKeysha's GBS. He never testified that it was *necessary* for his opinion." (emphasis in original). Petitioner, therefore, moves for this court to set aside Special Master Lord's decision, to enter a decision in her favor, and to remand her case for a determination of damages.

In response, Respondent asks the court to dismiss Petitioner's Motion for Review. According to Respondent, "Petitioner has not shown that the special master's determination was arbitrary, capricious, or an abuse of discretion. Thus, she has not established reversible error, and the special master's decision must be affirmed." First, Respondent argues that Special Master Lord did not mischaracterize Dr. Tornatore's reliance on the 1994 Institute of Medicine Report when he tried to establish causation. Rather, Respondent emphasizes:

> Dr. Tornatore relied upon the 1994 IOM report and its prior endorsement of Pollard & Selby as the linchpin to support his conclusion that tetanus-toxoid containing vaccines can cause GBS. He offered no other evidence to support this assertion (including his own knowledge of Td vaccine, his experience with other GBS cases, or other case reports, studies, or medical literature), and otherwise failed to explain the putative link between Td vaccine and GBS (whether by molecular mimicry or otherwise) when offered the opportunity to do so at the hearing and thereafter.

(internal citations and footnote omitted).

Respondent continues: "Indeed, the special master acknowledged that, if she were to have found that Dr. Tornatore's testimony supplied preponderant reliable evidence of a causal connection between Td vaccine and GBS, she would have held that petitioner satisfied *Althen* prong 1, 'notwithstanding the lack of supporting evidence elsewhere in the record.'" Therefore, Respondent argues that Special Master Lord was warranted in finding Dr. Tornatore's expert report and testimony unreliable because he depended on the 1994 Institute of Medicine Report to support his theory, and based his theory in such general terms, that it "'seemed to be that any vaccine can cause any demyelinating disorder.'" Respondent also argues that "[th]e special master found Dr. Tornatore's inability to independently express or explain the concept of molecular mimicry in the context of Td vaccine as illustrative of the tenuous and circular nature of his opinion in this case."

According to Respondent, although Special Master Lord used the Institute of Medicine Report to explain inconsistencies in Dr. Tornatore's theory, she never concluded that the Institute of Medicine had reversed its position from their 1994 Report to the 2011 pre-publication version of the Report. Respondent contends, "the special master was careful to articulate that her discussion of the 2011 IOM report [2011 pre-publication Institute of Medicine Report] was to explain the contradiction between Dr. Tornatore's reliance on Pollard & Selby at the hearing, and the IOM's re-evaluation of the 'significance' of that evidence – not to raise the bar of what is required to establish compensation under the Act to the scientific standard." Rather, Respondent notes:

> [T]he special master acknowledged that "the standard of proof to demonstrate causation in the scientific community requires more and different evidence than is required in the Vaccine Program." Thus, she did

> not simply adopt the IOM's new findings, or find that "the absence of evidence" is "evidence of absence," as petitioner contends. Rather, the special master was careful to articulate that her discussion of the 2011 IOM report was to explain the contradiction between Dr. Tornatore's reliance on Pollard & Selby at the hearing, and the IOM's re-evaluation of the "significance" of that evidence -- not to raise the bar of what is required to establish compensation under the Act to the scientific standard.

(internal citations omitted).

Accordingly, Respondent argues Special Master Lord did not use epidemiology studies to establish credibility between the expert witnesses, but instead found Dr. Tornatore's testimony unreliable because it was "essentially unsupported by other evidence in the record." Respondent notes that, although Petitioner argues that it was "absolutely appropriate" that Dr. Tornatore relied "on other evidence in reaching his conclusion that the Td vaccine caused her GBS, including that the timeframe between vaccination and the onset of symptoms," and that testing ruled out other causes, "it is well settled that 'neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.'" (quoting Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1323-24 (citing Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278).

Furthermore, the Respondent points out that Special Master Lord concluded that Dr. Tornatore's entire testimony was filled with "'apparent contradictions, gaps, vagueness and illogic.'" Respondent contends that for numerous reasons, Special Master Lord properly did not find Dr. Tornatore's expert report and testimony in Petitioner's case reliable, and more heavily relied on Dr. Leist's expert report and testimony, when she held that Petitioner failed to meet her burden of proof. Accordingly, Respondent requests that this court deny Petitioner's Motion for Review, and dismiss her petition for compensation.

DISCUSSION

When reviewing a Special Master's decision, the assigned Judge of the United States Court of Federal Claims shall:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
> (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); see also Vaccine Rule 27. The legislative history of the Vaccine Act states: "The conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Rep. No. 101-386, at 517 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3120.

In order to recover under the Vaccine Act, a petitioner must prove that the vaccine caused the purported injury. See Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1364-65 (Fed. Cir. 2012); see also Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54 (2011). Regarding the standard of review, articulated in Markovich v. Sec'y of Health & Human Servs., the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1355-56 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007); see also de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1350 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2008); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1277.

As recently noted by the United States Court of Appeals for the Federal Circuit:

> The role of appellate review of a special master's decision under the arbitrary and capricious standard "is not to second guess the Special Master's fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1380 (Fed. Cir. 2012), quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Doe v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010)[, cert. denied, 131 S. Ct. 573 (2010)]. If the special master's conclusion is "based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious." Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010), quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000). Put another way, if the special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Hines [ex rel. Sevier] v. Sec'y of the Dep't of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991).

Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363. Therefore, this court may set aside a Special Master's decision only if the court determines that the "findings of fact or conclusion of law of the special master…[are] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law…." 42 U.S.C. § 300aa-12(e)(2)(B); see also Avera v. Sec'y of Health & Human Servs., 515 F.3d 1343, 1347 (Fed. Cir.) ("Under the Vaccine Act, we review a decision of the special master under

the same standard as the Court of Federal Claims and determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" (quoting 42 U.S.C. § 300aa-12(e)(2)(B)), reh'g and reh'g en banc denied (Fed. Cir. 2008); Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1321; Markovich v. Sec'y of Health & Human Servs., 477 F.3d at 1356-57; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360. The United States Court of Appeals for the Federal Circuit has indicated that:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.

Munn v. Sec'y of Health & Human Servs., 970 F.2d at 871 n.10; see also Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1345) (The Federal Circuit explained that "[w]e do not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder."), reh'g en banc denied (Fed. Cir. 2012). The arbitrary and capricious standard is "well understood to be the most deferential possible." Munn v. Sec'y of Health & Human Servs., 970 F.2d at 870 ("With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The Claims Court owes these findings and conclusions by the special master great deference – no change may be made absent first a determination that the special master was "arbitrary and capricious'" (citing 42 U.S.C. § 300aa-12(e)(2)(B))). Generally, "if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (quoting Hines ex rel. Sevier v. Sec'y of Health & Human Servs., 940 F.2d at 1528); see also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1253-54; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360; Avila ex rel. Avila v. Sec'y of Health & Human Servs., 90 Fed. Cl. 590, 594 (2009); Dixon v. Sec'y of Health & Human Servs., 61 Fed. Cl. 1, 8 (2004) (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (in turn quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962) ("The court's inquiry in this regard must therefore focus on whether the Special Master examined the 'relevant data' and articulated a 'satisfactory explanation for its action including a "rational connection between the facts found and the choice made.'"))). In other words "if the special master's conclusion is 'based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious." Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (citing Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1338 (internal citations omitted)).

As indicated by the Federal Circuit in Althen v. Secretary of Health & Human Services:

> The [Vaccine] Act provides for the establishment of causation in one of two ways: through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ("Table injury"), see 42 U.S.C. § 300aa-14(a); or where the complained-of injury is not listed in the Vaccine Injury Table ("off-Table injury"), by proving causation in fact, see 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I).

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346; Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 551 U.S. 1102 (2007); Fesanco v. Sec'y of Health & Human Servs., 99 Fed. Cl. 28, 31 (2011); Dobrydnev v. Sec'y of Health & Human Servs., 94 Fed. Cl. 134, 144 (2010).

Petitioner claims that, as a result of the tetanus vaccine she received in 2005, she developed Guillain-Barré Syndrome, which is not listed as an injury on the Vaccine Table. See 42 U.S.C. § 300aa-14. Under the off-Table theory of recovery, a petitioner is entitled to compensation if she can demonstrate, by a preponderance of the evidence, see 42 U.S.C. § 300aa-13(a)(1)(A), that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine that is listed on the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); see also Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Hines ex rel. Sevier v. Sec'y of Health & Human Servs., 940 F.2d at 1525.

Since Petitioner's condition does not meet the requirements of a presumptively on-Table, vaccine-related condition, to prove entitlement for an off-Table injury, petitioner must

> prove causation-in-fact. Grant [v. Sec'y of Health & Human Servs.], 956 F.2d [1144,] 1147-48 [(Fed. Cir. 1992)]. [The United States Court of Appeals for the Federal Circuit has] held that causation-in-fact in the Vaccine Act context is the same as the "legal cause" in the general torts context. Shyface v. Sec'y of Health and Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "a substantial factor in bringing about the harm."

de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting the Restatement (Second) of Torts § 431(a)). A "'substantial factor' standard requires a greater showing than 'but for' causation." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at

1352). "However, the petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351.

The petitioner must prove her case by a preponderance of the evidence. See 42 U.S.C. § 300aa-13(a)(1)(A). According to the United States Court of Appeals for the Federal Circuit, the preponderance of evidence standard is "one of proof by a simple preponderance, of 'more probable than not causation.'" Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80 (citing concurrence in Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). Decisions of the Federal Circuit permit the use of circumstantial evidence, which the court described as "envisioned by the preponderance standard," and by the vaccine system created by Congress in which "close calls regarding causation are resolved in favor of injured claimants" without the need for medical certainty. Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280. The Althen court further noted that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id. (citing Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 549). When proving eligibility for compensation for an off-Table injury under the Vaccine Act, however, Petitioner may not rely on her testimony alone. According to the Vaccine Act, "[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." See 42 U.S.C. § 300aa-13(a)(1).

The court in Althen defined a three-prong test which a petitioner must meet to establish causation in an off-Table injury case:

> To meet the preponderance standard, [petitioner] must "show a medical theory causally connecting the vaccination and the injury." Grant v. Sec'y of Health & Humans Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]" Grant, 956 F.2d at 1148. [Petitioner] may recover if she shows "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant, 956 F.2d at 1149. Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a

> showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (brackets in original); see also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1249; Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322; Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355; Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1324; Contreras v. Sec'y of Health & Human Servs., 107 Fed. Cl. 280, 291 (2012).

With regard to the first Althen prong, "a medical theory causally connecting the vaccination and the injury," Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278, the Althen court analyzed the preponderance of evidence requirement as allowing medical opinion as proof, even without scientific studies in medical literature that provide "objective confirmation" of medical plausibility. Id. at 1278-80; see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. 353, 358 (2012). In rejecting a requirement that a claimant under the Vaccine Act prove confirmation of medical plausibility from the medical community and medical literature, the Althen court turned to the analysis undertaken in Knudsen ex rel. Knudsen v. Secretary of Heath & Human Services, 35 F.3d at 549. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80. In Knudsen ex rel. Knudsen v. Secretary of Health & Human Services, the United States Court of Appeals for the Federal Circuit wrote, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 549. Further,

> [t]he Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. The special masters are not "diagnosing" vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury or that the [petitioner's] injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury. See 42 U.S.C. § 300aa-13(a)(1), (b)(1).

Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 549 (brackets added). The Federal Circuit recently indicated that:

> Although a finding of causation "must be supported by a sound and reliable medical or scientific explanation," causation "can be found in

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

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

The second prong of the Althen test requires the petitioner to demonstrate "a logical sequence of cause and effect, showing that the vaccination was the reason for the injury" by a preponderance of the evidence. Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; see also Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355. In order to prevail, the petitioner must show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). In Capizzano v. Secretary of Health & Human Services, 440 F.3d at 1326, the Federal Circuit stated, "'[a] logical sequence of cause and effect' means what it sounds like – the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326 (quoting 42 U.S.C. §§ 300aa-11(c)(1) – 13(a)(1) (2006)).

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

> [i]f, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination

> is at least a factor. Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury.

Id. at 1358.

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

At oral argument, Petitioner stated that "even if there had never been a Pollard and Selby article, even if there had never been a 1994 [Institute of Medicine] report, this case would be on all fours with the Althen decision." As noted above, the Federal Circuit in Althen defined the three-prong test by which a petitioner must meet to establish causation in an off-Table injury case. Although Petitioner in this case has claimed, on multiple occasions, that Petitioner's case was "on all fours" with the Federal Circuit's decision in Althen, as Respondent correctly observes, "Althen's a different case. It's a different injury. It's a different medical presentation, a different clinical presentation, just different evidence, different expert."[16] Indeed, the Althen case is not on "all fours" with the Petitioner's case.

[16] At oral argument, counsel for the Respondent elaborated on the differences between Althen and the above captioned case, stating:

> There's no collateral estoppel in the program because each case is unique. Even though the injuries may be the same, each patient's or petitioner's medical presentation is different. The Federal Circuit in Althen was not opining as to the theory. The Federal Circuit in Althen took issue with the Special Master's sort of styled Stevens [v. Secretary of Health & Human Services, No. 99–594V, 2001 WL 387418 (Fed. Cl. March 30, 2001)], test where the Special Master required objective evidence of the petitioner and found that was inappropriate, and the Special Master basically said unless you can show me epidemiological studies or some proof in the medical literature, you automatically lose. That's not what Special Master Lord did here. In fact, she was very clear in her opinion.

In Althen, the petitioner, a forty-nine-year-old woman with pre-existing diagnoses of hypothyroidism and Duane's Syndrome,[17] received tetanus toxoid and hepatitis A vaccinations, and subsequently sought medical treatment for an incessant headache, painful eye movements, and blurred vision in her right eye, which progressed in four days to a complete loss of sight in that eye. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1276. The Federal Circuit noted that "[a]fter subsequent complaints of vision impairment in her right eye and numbness in her right hand, she was diagnosed with significant right optic neuritis on May 23, 1997. On June 4, 1997, Althen was admitted to the hospital after suffering from fever, confusion, and neck stiffness. After several days of testing, she was discharged with a diagnosis of acute disseminated encephalomyelitis, right optic neuritis and congenital Duane's syndrome." Id. at 1276-77 (internal citation and footnote omitted). She was again admitted to the hospital due to dizziness and gait instability and subsequently "experienced optic neuritis in her left eye. On August 6, 2000, she suffered a brain seizure. A brain biopsy showed evidence of inflammation in the central nervous system, and she was diagnosed with vasculitis with secondary tissue destruction and demyelination consistent with primary angiitis." Id. at 1277 (footnote omitted). The Special Master in Althen found that, "[d]espite the testimony of Dr. Derek R. Smith, a board-certified neurologist with a subspecialty in neuroimmunology, that the TT [tetanus toxoid] shot caused her injury and that the onset of her optic neuritis occurred within a medically-accepted time period for causal connection," the tetanus toxoid vaccination did not cause Ms. Althen's illness. Id.

The United States Court of Federal Claims reversed, concluding that Ms. Althen had proven causation in fact under the preponderant evidence standard set forth in the Vaccine Act, and the Federal Circuit affirmed the Court of Federal Claims decision. Aside from the fact that the petitioner in Althen and the current petitioner are both female, and that both received tetanus toxoid and hepatitis A vaccinations, it is difficult to draw many other comparisons between the two cases. A footnote to the original Althen decision by the Special Master did note that Dr. Smith referenced the "IOM's 1994 findings of a probable causal relation between tetanus toxoid and two injuries, brachial neuritis and acute inflammatory demyelinating polyradiculoneuropathy, also known as Guillain–Barre Syndrome." Althen v. Sec'y of Health & Human Servs., 2003 WL 21439669, at *4 n.7 (Fed. Cl. Spec. Mstr. June 3, 2003), rev'd, 58 Fed. Cl. 270 (2003), aff'd 418 F.3d 1274 (Fed. Cir. 2005). Given the reassessment in the pre-publication excerpts of the 2011 Institute of Medicine Report, which Special Master Lord entered into the record, regarding which she gave the parties an opportunity to comment, this footnote in Althen may not be entitled to the same weight as it would have been before the issuance of the 2011 pre-publication Institute of Medicine Report and the final version in 2012 of that same Report.

[17] The Federal Circuit in Althen explained that "Duane's Syndrome is a hereditary eye movement disorder which limits the ability to move the eye outward toward the ear (abduction) and, in most cases, the ability to move the eye inward toward the nose (adduction). This ailment caused Althen to experience double vision when looking to the left." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1276 n.1 (citing Dorland's Medical Dictionary 1816 (30th ed. 2003)).

Moreover, the discussion in Althen was focused on the Special Master's use of the test from Stevens v. Secretary of Health & Human Services, 2001 WL 387418. In Althen the Federal Circuit wrote:

> The disputed *Stevens* test requires that a claimant provide proof of: (1) medical plausibility; (2) confirmation of medical plausibility from the medical community and literature; (3) an injury recognized by the medical plausibility evidence and literature; (4) a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury; and (5) the elimination of other causes.

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279. The Special Master in Althen, interpreting this test, found that, '"[w]ithout some objective confirmation that the vaccine administered is potentially associated with the injury alleged, petitioner's causal claims are mere speculation and thus insufficient.'" Id. (quoting Althen v. Sec'y of Health & Human Servs., 2003 WL 21439669, at *12). By contrast, as discussed below, Special Master Lord properly applied the Althen test, and not the Stevens test, to Petitioner's claims when she found that "Petitioner has not presented preponderant evidence to support her claim under the Vaccine Act that the Td vaccination was the cause of her injuries."

Petitioner alleges that she has met her burden of proving by a preponderance of the evidence that the tetanus vaccination in fact caused her Guillain-Barré Syndrome injury by providing a sound medical theory of causation through Dr. Tornatore's expert report and testimony.[18] In cases in which a petitioner relies upon expert testimony to prove causation, the expert testimony must rest upon an objective and reliable scientific basis and must prove causation to a degree of legal certainty, but not to a medical or scientific certainty. See Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322 ("A petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be "legally probable, not medically or scientifically certain.'" (quoting Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 548–49)); see also Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1339; Terran ex rel. Terran v. Sec'y of Health & Human Servs., 195 F.3d at 1316. Although a petitioner may rely solely on expert testimony, "[a]n expert opinion is no better than the soundness of the reasons supporting it." Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994). Therefore, a Special Master does not need to credit "expert opinion testimony that is connected to the existing data or methodology 'only by the *ipse dixit*[19]

[18] Dr. Tornatore, has testified as an expert in roughly sixty cases regarding the Vaccine Act. Among those cases, Dr Tornatore's testimony has been both helpful to prove some claimants' claims, but his expert opinion also has been found insufficient or unreliable as support in other petitioners' cases.

[19] As a Judge of the United States Court of Federal Claims noted: "*Ipse dixit* is Latin for 'he himself said it.' Black's Law Dictionary 847 (8th ed. 2004). The term means

of the expert,' or where 'there is simply too great an analytical gap between the data and the opinion proffered.'" Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. at 61 (quoting Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1339).

Petitioner argues that "Special Master Lord arbitrarily and capriciously mischaracterized Dr. Tornatore's testimony as being predominantly reliant upon findings of the [1994 Report issued by the] Institute of Medicine." Petitioner claims that Special Master Lord "then abused her discretion by finding that the IOM had reversed its position on causation related to the Td vaccine and GBS when, in fact, the IOM's finding was that 'the evidence is inadequate to accept or reject a causal relationship.' This abuse of discretion led directly to the Special Master requiring Lakeysha to prove an elevated evidentiary burden expressly rejected in *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), a requirement that was not in accordance with law." (footnote omitted). At oral argument, however, Petitioner conceded that this court should review Special Master Lord's finding under an arbitrary and capricious standard, to which the Respondent agreed. The Federal Circuit has stated that in vaccine cases, the abuse of discretion standard "will rarely come into play except where the special master excludes evidence." Munn v. Sec'y of Health & Human Servs., 970 F.2d at 870 n.10.[20] Petitioner has not argued, nor does the record reflect, that Special Master Lord excluded any evidence. Indeed, Special Master Lord took the initiative to introduce into the record an excerpt of the 1994 Institute of Medicine Report, two excerpts from the 2011 pre-publication version of the Institute of Medicine Report, and to give the parties an opportunity to address the new materials. Therefore, the court considers whether Special Master Lord's findings were arbitrary and capricious.

In his expert report, Dr. Tornatore concluded that, "[i]t is my opinion, to a reasonable degree of medical certainty, that the vaccinations of September 15, 2005, specifically the tetanus vaccination, resulted in the development of Ms. Isaac's inflammatory neuropathy." He also stated that, "there is a biologically plausible mechanism that occurred in temporal relationship to the vaccine that resulted in a logical sequence of cause of effect to explain the onset of an inflammatory demyelinating polyneuropathy (Guillain-Barre) following tetanus vaccination in Ms. Isaac's case."

Special Master Lord determined in her decision that in Petitioner's case, "none of the medical records support molecular mimicry or any other theory of possible vaccine causation. Petitioner's case therefore rests on the reliability of her [Petitioner's] expert's

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'[s]omething asserted but not proved.'" Banks v. United States, 93 Fed. Cl. 41, 49 n.7 (2010) (quoting Black's Law Dictionary 847).

[20] The abuse of discretion standard is "'ordinarily used where the tribunal under review had a finite range of discretion (e.g. to select a penalty, or to award a specific sum as damages, from within a range of permissible alternatives).'" Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 85 Fed. Cl. 571, 597 (2009) (quoting Hines v. Sec'y of Health & Human Servs., 940 F.2d at 1527), aff'd, 592 F.3d 1315 (Fed. Cir.), reh'g en banc denied (Fed. Cir. 2010).

conclusion." Special Master Lord noted in a footnote that "Petitioner's expert's theory seemed to be that any vaccine can cause any demyelinating disorder. Accordingly, Petitioner submitted evidence of data derived from the 1970s swine flu vaccination campaign to show that that flu vaccination can cause GBS. I find no reliable evidence in this material supporting a broad hypothesis causally linking any and all vaccinations with any and every demyelinating disorder." (internal citation omitted).

After reviewing the expert testimony offered by Dr. Tornatore, the Special Master found it insufficient to support Petitioner's claim to compensation. Petitioner argues that Special Master Lord's mischaracterization of Dr. Tornatore's expert testimony was overly reliant on the 1994 Institute of Medicine Report and that her decision was arbitrary and capricious. Petitioner alleges that Dr. Tornatore demonstrated a plausible theory of causation between the Petitioner's Guillain-Barré Syndrome and the tetanus vaccine by relying on three articles he submitted in addition to the Pollard and Selby article. Petitioner also argues that Dr. Tornatore did not overly rely on the 1994 Institute of Medicine Report because he briefly mentioned it only once during his expert report, and referred to the 1994 Institute of Medicine Report only three times during his testimony, "the last two in the same answer to a single question." Of the four academic articles provided in his expert report, Dr. Tornatore relied on the Pollard and Selby article and the Schonberger et al. article for support that Tetanus is a vaccine "resulting in inflammatory demyelinating polyneuropathies." In his expert report, however, Dr. Tornatore continued: "Indeed, the Institute of Medicine has recognized that tetanus vaccination can be a cause of Guillain-Barre based on the article by Pollard and Selby," without mentioning the Schonberger et al. article, or any other article. In addition, the 1978 Pollard and Selby article is the article on which Dr. Tornatore most extensively relied on during his testimony at the June 27, 2010 hearing.

The other three articles in Dr. Tornatore's expert report were: R. Lahesmaa et al., Molecular Mimickry between HLA B27 and *Yersinia*, *Salmonella*, *Shigella* and *Klebsiella* within the Same Region of HLA α_1-helix, Tomoko Komagamine and Nobuhiro Yuki, Ganglioside Mimicry as a Cause of Guillain-Barré Syndrome, and Lawrence B. Schonberger et al., Guillain-Barre Syndrome following Vaccination in the National Influenza Immunization Program, United States, 1976-1977. These three other articles were used by Dr. Tornatore generally to explain molecular mimicry, how molecular mimicry applies in the general context of Guillain-Barré, and how various vaccines cause molecular mimicry. The entire sum of Dr. Tornatore's reliance on the article titled Molecular Mimickry between HLA B27 and *Yersinia*, *Salmonella*, *Shigella* and *Klebsiella* within the Same Region of HLA α_1-helix, was the general statement in his expert report that "[t]he concept that viral or bacterial antigens share homology with host antigens, also known as molecular mimicry, is a well established concept in immunology." At the July 27, 2010 hearing, the extent of Dr. Tornatore's testimony on the same article was limited to the statement that "this is a paper that was trying to find similarities between those microorganisms and a protein called HLAB27, it's an immune protein." Additionally, under cross-examination, Dr. Toratore explained that although the article he submitted by Tomoko Komagamine and Nobuhiro Yuki, Ganglioside Mimicry as a Cause of Guillain-Barré Syndrome referenced *C. jejuni*. Dr. Toratore stated the article

"was just submitted as, you know, the concept that you can have, just to support the argument that molecular mimicry can be a pathogenetic mechanism in Guillain-Barré. It was not meant, and even in my report, it was not meant to get down to that degree of specificity." Even in his discussion of Guillain-Barre Syndrome following Vaccination in the National Influenza Immunization Program, United States, 1976-1977, Dr. Tornatore related the article back to the Pollard and Selby article. Dr. Tornatore noted that the Schonberger article "looked at the risk of developing Guillain-Barré following the swine flu influenza program 1976 to '77. And I presented this one because it's epidemiologic data that supported the concept that indeed vaccination, in this case influenza vaccination, could result in Guillain-Barré. I also submitted it because it did show the time course when one would expect Guillain-Barré following vaccination, but I guess that's not an issue that we're going to have to deal with so I probably won't go into that." When asked about the relationship between the flu and tetanus vaccines and Guillain-Barré Syndrome, he testified that the

> Schonberger article really was to demonstrate the kinetics of the onset of the Guillain-Barré following a vaccination. It's a large number of patients and so it's our best example of what one might expect as far as timing goes. But in that article the peak time of Guillain-Barré following vaccination was approximately two weeks, and that's about the time frame for the Pollard and Selby article, and in this case is approximately two weeks from when the vaccination occurred to when really the first manifestations of Guillain-Barré happened, so everything kind of fits together.

Dr. Tornatore also used the Pollard and Selby article to develop his theory on challenge/rechallenge and specificity. At the July 27, 2010 hearing Dr. Tornatore testified that "the Pollard and Selby article, although they did not speak to molecular mimicry spoke more to the idea that there is some specificity to this in that somebody who was rechallenged with the same protein developed the same problem on three different occasions, and so that that antigenic stimulus was recognized as the inciting factor for causing the Guillain-Barré. And in the early '90s the Institute of Medicine recognized that concept of challenge rechallenge as a valid biological model for looking at this idea."

Additionally, Dr. Tornatore used the 1994 Institute of Medicine report to bolster his reliance on the Pollard and Selby article, and the 1994 Institute of Medicine Report to indicate that the Institute of Medicine approved of his theory of causation, reasoning that, "[i]ndeed, the Institute of Medicine has recognized that tetanus vaccination can be a cause of Guillain-Barré based on the article of Pollard and Selby." Dr. Tornatore stated at the July 27, 2010 hearing:

> Because you have the Pollard and Selby article where you had the positive rechallenge. And so all you need to know is that it's the vaccine itself. The individual components it would be nice to know what those are specifically. However, that is for this case, that specificity is not required.

> The only specificity is that there was a challenge and positive rechallenge case, the Pollard and Selby case, that the Institute of Medicine said, you don't need to know the absolute molecular component.

Dr. Tornatore further explained that a lack of subsequent studies relating to Guillain-Barré Syndrome and tetanus vaccinations were explained by the fact that "the Institute of Medicine has spoken to this." Dr. Tornatore continued: "Science is science. That's a very interesting case. If it happened and you have a patient that demonstrates a very peculiar process you don't discard it just because, oh that happened some time ago. What difference does that make?"

Special Master Lord's conclusion that Dr. Tornatore "described the Pollard and Selby report as a case of GBS caused by tetanus vaccination and indicated that the IOM recognized it as such" was not a mischaracterization of the testimony of Dr. Tornatore, offered in his expert report and at the hearing. As noted by the Respondent, "Dr. Tornatore relied upon the 1994 IOM report and its prior endorsement of Pollard & Selby as the linchpin to support his conclusion that tetanus-toxoid containing vaccines can cause GBS. He offered no other evidence to support this assertion (including his own knowledge of Td vaccine, his experience with other GBS cases, or other case reports, studies, or medical literature), and otherwise failed to explain the putative link between Td vaccine and GBS (whether by molecular mimicry or otherwise) when offered the opportunity to do so at the hearing and thereafter." (internal citations and footnote omitted). Accordingly, Special Master Lord's finding that Dr. Tornatore relied on the 1994 Institute of Medicine Report and the Pollard and Selby article to support his opinion that Petitioner's tetanus vaccine caused her illness was not arbitrary or capricious.

After the July 27, 2010 hearing Special Master Lord took note of the 2011 pre-publication Institute of Medicine Report, which called into question the conclusions of the 1994 Institute of Medicine Report, and introduced two excerpts into the record as Court Exhibit 1 and Court Exhibit 2, on September 23, 2011 and May 24, 2012, respectively. The Special Master gave both parties an opportunity to address each of the excerpts. In her decision, Special Master Lord noted that, "[b]y order dated September 23, 2011, the pertinent portion of the 2011 IOM report was entered into the record, without objection, and the parties were invited to comment on the new information," and "[o]n May 24, 2012, the parties were invited to comment on and file responses to Court Exhibit 2, the excerpt from the 2011 IOM report on the theory of molecular mimicry."

As indicated by a Judge of the United States Court of Federal Claims, "a special master must act on the record after adequate notice." Davis v. Sec'y of Health & Human Servs., 94 Fed. Cl. 53, 65 (2010), aff'd, 420 F. App'x 973 (Fed. Cir. 2011). The Davis court noted:

> The requirement to decide on the record is specifically stated in 42 U.S.C. § 300aa–13(a)(1), which provides in pertinent part that "[c]ompensation

> shall be awarded under the Program to a petitioner if the special master or court finds *on the record as a whole* [that the petitioner is entitled to relief]." *See also* 42 U.S.C. § 300aa–13(c) (defining "record"); RCFC Appendix B, Rule 8(b)(1) (requiring the special master to consider "all relevant and reliable evidence"). The correlative requirement that a special master provide adequate notice to the parties of evidentiary issues and matters stems from 42 U.S.C. § 300aa–12(d)(3)(B)(iv), (v) (a special master "shall afford all interested persons an opportunity to submit relevant written information" and "may conduct such hearings as may be reasonable and necessary"), as well as RCFC Appendix B, Rule 8(b)(1) (a "[s]pecial master . . . must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties").

Davis v. Sec'y of Health & Human Servs., 94 Fed. Cl. at 65 (footnote omitted). Although Special Master Lord considered the excerpts from the 2011 pre-publication Institute of Medicine Report she introduced into the record, she did so only after offering the parties an opportunity to comment. As Special Master Lord noted, "Dr. Tornatore did not update his testimony when offered the opportunity to do so…. Dr. Tornatore offered no supplementation of his report or his testimony, notwithstanding that the new IOM report indicated that his reliance on Pollard and Selby to bolster his theory of causation in this case was misplaced." (internal citation omitted).

Generally, as to the use of an Institute of Medicine Report, a Judge of the United States Court of Federal Claims appropriately wrote:

> The Institute of Medicine (IOM), a branch of the National Academy of Sciences, was charged by the Vaccine Act with reviewing medical and scientific literature on risks associated with certain vaccines covered by the Act. See Watson v. Sec'y of Health & Human Servs., No. 96–639V, 2001 WL 1682537, at *5 n. 11 (Fed. Cl. Spec. Mstr. Dec. 18, 2001). Special masters "frequently rely" on the IOM's 1994 report, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, (1994 IOM Report) "as a sound source for answering difficult issues of medical plausibility and causation." Althen, 2003 WL 21439669, at *11 n. 28. "Due to the IOM's statutory charge, the scope of its review, and the cross-section of experts making up the committee reviewing the adverse events associated with vaccines, the court considers their determinations authoritative and subject to great deference." Id.

Kelley v. Sec'y of Health & Human Servs., 68 Fed. Cl. 84, 91 n.11 (2005).

The 2011 pre-publication excerpts from the Institute of Medicine Report backed off from the 1994 Institute of Medicine Report's earlier conclusion of a link between the tetanus vaccine and Guillain-Barré Syndrome and concluded that "[t]he evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccines and GBS." (internal citations omitted).

The 2011 pre-publication Institute of Medicine Report reached this result because of changing views on the Pollard and Selby article. Regarding the Pollard and Selby article, Special Master Lord repeated that the man studied in the "Pollard and Selby report no longer is regarded by the IOM as evidence of vaccine causation," because he was "'subsequently diagnosed with a spontaneously relapsing remitting neuropathy and experienced episodes in association with acute viral infections.'" Therefore, it was appropriate for Special Master Lord to conclude that the "IOM no longer characterized the individual reported on as suffering from GBS, but from a recurring/relapsing disorder called CIDP [Chronic Inflammatory Demyelinating Polyneuropathy]." In addition, referring to the concept of challenge/rechallenge, from the Pollard and Selby article, which was relied upon by Dr. Tornatore, Special Master Lord noted that challenge/rechallenge "may furnish evidence that there was a logical chain of cause and effect linking vaccination to injury," but, "[i]n this case, Dr. Tornatore testified that the case of challenge/rechallenge reported by Pollard and Selby supported his theory of molecular mimicry pertaining to Prong 1 [of the Althen test]." Special Master Lord correctly recognized that: "The problem, as discussed herein, is that it no longer appears that the Pollard and Selby case report represents a case of challenge/rechallenge." Moreover, Special Master Lord found that the individual studied in the Pollard and Selby article "was not linked with 'specificity' to [the tetanus] vaccination" because the Institute of Medicine established that his "relapsing/remitting neuropathies had only 'a temporal relationship with vaccine administration.'"

Unlike the 1994 Institute of Medicine Report, the Guillain-Barré Syndrome section of the 2011 pre-publication Institute of Medicine Report does not include any mention of the Pollard and Selby article. Rather, the only mention of the Pollard and Selby article falls in the Chronic Inflammatory Disseminated Polyneuropathy section of the 2011 pre-publication Institute of Medicine Report. That section includes a conclusion that the Pollard and Selby article "did not provide evidence beyond a temporal relationship between administration of the vaccine and development of symptoms after vaccination." Special Master Lord stated in a footnote to her decision that she did "not place undue reliance on the IOM's causality conclusion (which is a non-conclusion, in any event)." In the same footnote, Special Master Lord explained:

> This may be an appropriate point to note that Petitioner and her expert laid great emphasis on the conclusion from the 1994 IOM report of a causal link between Td and GBS. . . . Now that the IOM has withdrawn its previous endorsement of a causal link, Petitioner urges that the IOM's information should not be considered significant. . . . I understand and appreciate the distinction between the proof that is required to establish entitlement to compensation in the Vaccine Program and the greater proof that may be required to satisfy the scientific community of vaccine injury causation, and I do not place undue reliance on the IOM's causality conclusion (which is a non-conclusion, in any event). But I do rely on the IOM's evaluation of the scientific significance of the Pollard and Selby report. That evaluation was undertaken and communicated to the public

by a committee of scientific experts assigned by law to evaluate scientific evidence.

Special Master Lord also specifically noted that, "I agree that the standard of proof to demonstrate causation in the scientific community requires more and different evidence than is required in the Vaccine Program. That is why I do not simply adopt the findings of the IOM but give due consideration to the IOM in reaching my own conclusion, based on the evidence in the record as a whole." Special Master Lord concluded that "[t]he 2011 IOM report thus negated the earlier findings that were based on the Pollard and Selby report, such that Dr. Tornatore's reliance on the IOM to buttress the theory of vaccine injury due to tetanus vaccination must, based on the 2011 IOM Report, be viewed as inappropriate." Accordingly, Special Master Lord's conclusion that the Institute of Medicine no longer viewed the Pollard and Selby article as showing causation between the tetanus vaccination and Guillain-Barré Syndrome is justifiable, and was not arbitrary or capricious. Because of the reexamination of the case study from the Pollard and Selby article, Special Master Lord called into question Dr. Tornatore's reliance on the Pollard and Selby article in reaching his conclusions. As Special Master Lord noted: "Dr. Tornatore's testimony in this case was not reliable. The reasons for reaching this conclusion are discussed below, with no intent to disparage the expert, but rather to elucidate the basis for my decision, so that it can be understood in the first instance and effectively reviewed if appealed." Special Master Lord did not reject Dr. Tornatore's qualifications as an expert, or disregard his entire report when she found Dr. Tornatore's expert opinion less reliable than Respondent's expert, Dr. Leist's expert opinion.

As noted above, Dr. Tornatore has testified extensively for petitioners in vaccine cases. His conclusions have been rejected, but he also has been an expert in several notable cases in which petitioners were deemed entitled to compensation based on the facts of those particular cases. The United States Court of Appeals for the Federal Circuit, sustaining a Court of Federal Claims decision, reversing a special master's decision which criticized Dr. Tornatore, observed: "As the Court of Federal Claims correctly recognized, [Doctor] Tornatore has 'excellent medical credentials.' . . . He is director of the residency program in the neurology department at Georgetown University, has done research at the National Institutes of Health on the toxic effect of bacterial and viral products on cells, and is an expert in the pathogenesis of brain injury." Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1377 n.4 (quoting Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., No. 98-817V, 2007 WL 2706157, at *4-5 (Fed. Cl. Spec. Mstr. Aug. 29, 2007), review granted and remanded by 2008 WL 2009746 (Fed. Cl. Mar. 3, 2008)); see also Kelley v. Sec'y of Health & Human Servs., 68 Fed. Cl. at 90 n.9 (quoting Kelley v. Sec'y of Health & Human Servs., No. 02-223V, 2005 WL 1125671, *7 n. 14 (Fed. Cl. Spec. Mstr. Mar. 17, 2005)) (In which the court recognized the medical reports from the treating doctors and the opinion of "Dr. Tornatore, 'a board-certified neurologist and professor of medicine at Georgetown University Medical Center,' directs the Multiple Sclerosis and Associated Autoimmune Disorders Clinic at Georgetown Hospital and sees an estimated ten to

fifteen CIDP patients every couple of months," together were sufficient to support the claims, although the special master had been critical of Dr. Tornatore).

In the case currently before this court, Petitioner claims that "[a]s is becoming painfully expected in the Vaccine Program the Special Master ultimately reduced her decision to a comparison of experts, specifically the *reliability* of experts. As noted above she favored Dr. Leist's 'science-based' testimony over Dr. Tornatore's 'advocacy.'" (emphasis in original). In a footnote, Petitioner quotes from a footnote in Special Master Lord's decision, in which Special Master Lord indicated that Dr. Tornatore "'appeared to be more of an advocate than an objective expert. . . . To the extent that Dr. Tornatore's opinion appears to be that of a partisan rather than an objective expert, his opinion carries less weight.'" (omission in original). Based on this statement, Petitioner's counsel tries to inflame the issue when stating, "[w]hile Special Master Lord stops short of calling Dr. Tornatore a 'hired gun' as some of her colleagues have done – and been rebuked for doing, she nevertheless attacks his 'credibility' under the guise of his 'reliability.'" In her decision, Special Master Lord, however, acknowledged Dr. Tornatore's credentials when she wrote: "Dr. Tornatore is a neurologist at Georgetown University Hospital in Washington, D.C., and director of the Multiple Sclerosis Center there. He trains residents and interns in neurology. Dr. Tornatore is a member of several neurological organizations, including the American Neurological Association."

Special Master Lord's observation that Dr. Tornatore was "more of an advocate than an objective expert," in the case under review, was based on her conclusion that Dr. Tornatore made assumptions not based on evidence in the record before her. She questioned Dr. Tornatore's reliance on Dr. Winkelmann's statement that, "'[i]t was felt that immunization series had been the trigger for the development of the Guillain-Barré,'" because Dr. Winkelmann was not a neurologist or an immunologist. Special Master Lord wrote: "Dr. Tornatore explained that he credited Dr. Winkelmann's statement because, unlike the physicians who did not identify vaccination as causative, or who identified an infectious cause, 'Dr. Winkelman[n] has the retrospectoscope where he can look back, he knows everything that happened.' . . . Dr. Tornatore assumed that 'obviously he [Dr. Winkelmann] must have gone through the previous records and come up with something.' This assumption is not based upon any evidence of record." (footnote omitted).

Respondent suggests that Special Master Lord found Dr. Tornatore unreliable not only due to the lack of evidence provided by Petitioner, but also because of "'significant weaknesses' in his [Dr. Tornatore's] testimony." In Petitioner's case, Special Master Lord supported her consideration of Dr. Tornatore's testimony as unreliable because his testimony had "apparent contradictions, gaps, vagueness, and illogic." Special Master Lord explained that Dr. Tornatore provided contradictory testimony by identifying Dr. Winkelmann's statement, "'[i]t is felt that immunization series had been the trigger for the development of the Guillain-Barré,'" as important, although dismissing Dr. Moore's statement that petitioner's injury "'is likely related to

gastrointestinal illness.'"[21] For example, in her decision, Special Master Lord noted that "Dr. Tornatore's opinion that Petitioner's report of a stiff neck and sickness at the time of vaccination was symptomatic of GBS, appears to be at variance with his testimony that these symptoms were an immediate allergic reaction to the vaccine. An allergic reaction is not the same condition as GBS. If there is some medical relationship between these two conditions, Dr. Tornatore's testimony did not elucidate it." (internal citations omitted).

In an attempt to bolster the credibility of Dr. Tornatore, Petitioner contends that Dr. Tornatore based his testimony on more than just timing and the elimination of other causes by also relying on clinical facts, such as "statements by her treating doctors [that] certainly add weight to Dr. Tornatore's opinion," including the entry by Dr. Leis, one of Petitioner's treating physicians, which indicates that Petitioner "[h]ad vaccination for DPT [tetanus vaccination] and hepatitis about 2 weeks before onset of altered sensation," similarly, the statement by Dr. Winkelmann that "patient states that she started experiencing the symptoms a couple of weeks after having some injections. . . ."[22] Although these statements were made by Petitioner's doctors, these notes in Petitioner's medical record only provide evidence of timing between the tetanus vaccine and her injury. They do not provide any other evidence of causation. As Special Master Lord noted in her decision, "[o]ther treating personnel noted at various points that Petitioner had received a vaccination a couple of weeks before the onset of her illness, but none stated that vaccination had caused it. A treating physician's recognition of a temporal relationship does not advance the analysis of causation, as Dr. Tornatore agreed."

In his testimony, Respondent's expert, Dr. Leist, who the Special Master noted is an expert in adult neurology," and "is an assistant professor of neurology at Thomas Jefferson University in Philadelphia and chief of the division of neuroimmunology," relied on the facts in Petitioner's medical records to reach his expert opinion that Petitioner's injury was caused by a gastrointestinal illness, including Petitioner's symptoms of nausea and vomiting. Special Master Lord noted that in his expert report, "Dr. Leist opined that the presence of 'nausea and vomiting is compatible with an acquired gastrointestinal illness including a gastrointestinal infection,'" Special Master Lord also observed that "Dr. Leist reviewed Petitioner's medical history, including her Hep A and tetanus vaccinations on September 15, 2005. He noted Petitioner's symptoms when she presented to Baptist Health System on September 28, 2005 – chest pressure, headache, nausea and emesis, as well as numbness and tingling in the fingers and toes…. Dr. Leist pointed out that Petitioner reported 'that she had experienced

[21] The court has noted that Dr. Moore's notes included conflicting information. At first, he indicated that Petitioner's acute inflammatory demyelinating polyneuropathy "is likely related to gastrointestinal illness." The next day, Dr. Moore also noted that the nerve study was "consistent with early GBS."

[22] As described above, Special Master Lord also questioned the reliance on Dr. Winkelmann, given that he was not a neurologist or an immunologist, nor was he Petitioner's treating physician when she fell ill.

headache, stiff neck, nausea and vomiting 2 weeks before which resolved after one week.'"

Special Master Lord correctly concluded that, "[t]he medical record discloses very little by way of treating physician opinions concerning whether vaccination was the cause of Petitioner's GBS." Special Master Lord concluded that "[u]pon careful consideration of the record, I find that none of the notations, other than Dr. Moore's single[23] statement, even constitutes a treating physician 'opinion.' In contrast to cases in which the record reveals extensive analysis of the causation issue, it appears in this case that once the diagnosis of GBS was made there simply was very little medical attention paid by treating personnel to the cause of Petitioner's illness."

In addition, Special Master Lord took issue with Dr. Tornatore's testimony regarding molecular mimicry. Special Master Lord indicated that, "somewhere between what the IOM would require to establish molecular mimicry as a theory of vaccine injury causation, and what we have in this case, which is the bare speculation of an expert, there is scope for a special master to decide whether there is sufficient evidence to preponderate under Prong 1 of Althen." Again, Special Master Lord was not discrediting Dr. Tornatore, rather, she was acknowledging that Dr. Tornatore had relied on the 1994 Institute of Medicine Report and the Pollard and Selby article to support his molecular mimicry argument, with little or no additional support. Special Master Lord explained in her decision:

> Dr. Tornatore stated that molecular mimicry explained how the vaccine could have caused GBS. . . . He said it was not necessary to know which component of the vaccine shared homology with the host antigens that theoretically caused GBS, "Because you have the Pollard and Selby article where you had the positive rechallenge."
>
> Dr. Tornatore's testimony in this respect is essential to my decision in this case. He stated:
>
> > And so all you need to know is that it's the vaccine itself. The individual components it would be nice to know what those are specifically. However, that is for this case, that specificity is not required. The only specificity is that there was a challenge and positive rechallenge case, the Pollard and Selby case, that the Institute of Medicine said, you don't need to know the absolute molecular component but it's teaching us that if something happens one time and you challenge a person a second time with that same entity, that entity is the ca[u]se.

[23] As noted above, Dr. Moore made two conflicting statements on successive days.

> Dr. Tornatore testified that the absence of epidemiological studies showing an association between tetanus vaccine and GBS was not significant, because "epidemiologic studies are not meant to identify rare events." He indicated that there may have been no subsequent case reports in the more than three decades since the Pollard and Selby article was published only because "it's already been reported."

(internal citations omitted, bracket in original). Special Master Lord determined "I find that Dr. Tornatore's evidence is not sufficient to preponderate under Althen Prong 1. The theory that Td vaccination could cause GBS by molecular mimicry was effectively challenged by Respondent's expert, without meaningful response." Special Master Lord also found that Dr. Tornatore had gaps in his testimony, and, therefore, was unreliable. Special Master Lord noted that "[s]eemingly unable to explain the basis for the theory of molecular mimicry as it might pertain to Td vaccination and GBS, Dr. Tornatore relied instead on the concept of challenge/rechallenge." Although Dr. Tornatore did describe the process of molecular mimicry as it relates to Guillain-Barré Syndrome, he failed to show how the tetanus shot in particular could incite molecular mimicry and cause Guillain-Barré Syndrome, other than through the process of challenge/rechallenge found in the Pollard and Selby article. Special Master Lord, therefore, determined that "none of the medical records support molecular mimicry or any other theory of possible vaccine causation. Petitioner's case therefore rests on the reliability of her expert's conclusion."

Special Master Lord observed that Respondent's expert, Dr. Leist provided evidence that ran counter to Dr. Tornatore's theory of causation. Special Master Lord noted that "Dr. Leist pointed out that the medical literature Dr. Tornatore submitted involved a cross-reaction based on a particular component of an organism known to cause GBS. . . . Evidence that *C. jejuni* causes GBS by molecular mimicry does not constitute preponderant evidence that molecular mimicry is a possible explanation for vaccine causation. Further, AIDP [Acute Inflammatory Demyelinating Polyneuropathy], the form of GBS at issue in this case, has been found not to be caused by cross-reaction with *C. jejuni*." Dr. Tornatore admitted that Petitioner was not tested for *C. jejuni* bacteria (or other viruses associated with Guillain-Barré Syndrome such as cytomegalovirus or Epstein-Barr virus), and testified that she was not tested because her symptoms did not warrant it. Respondent further explained that "Dr. Tornatore also conceded that two-thirds of GBS patients have a history of preceding infection, and while campylobacter jejuni is a common prodrome[24] associated with GBS, not all infections associated with GBS are campylobacter infections." Special Master Lord, therefore, concluded that, "[i]n these circumstances, Dr. Tornatore needed to present rebuttal evidence to show that, contrary to Dr. Leist's testimony, the evidence supported possible vaccine causation by the process of molecular mimicry. Dr. Tornatore's presentation failed in this respect." Moreover, because Dr. Tornatore did not demonstrate how molecular mimicry specifically occurs after tetanus vaccinations, or if

[24] According to Dorland's Illustrated Medical Dictionary, prodrome is defined as "a premonitory symptom or precursor; a symptom indicating the onset of a disease." Dorland's Illustrated Medical Dictionary 1522.

a cross-reaction could have caused Guillain-Barré Syndrome, the reliance on molecular mimicry is insufficient to demonstrate causation. See Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 132 (2011) ("'[N]either a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.'" (quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d at 278)), aff'd, 463 F. App'x 923 (Fed. Cir. 2012); see also Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1323-24 (citing Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278); Grant v. Sec'y of Health & Human Servs., 956 F.2d at 1148.

Despite having been given the opportunity, Dr. Tornatore, as Petitioner's expert, did not respond to the excerpts from the 2011 pre-publication Institute of Medicine Report which the Special Master placed in the record and regarding which she offered the parties an opportunity to comment. Although counsel for Petitioner and for the Respondent both responded on behalf of their clients, at oral argument before this court, Petitioner conceded that, although Special Master Lord gave Petitioner multiple opportunities to comment on the excerpts of the 2011 pre-publication Institute of Medicine Report, no comments were received from Dr. Tornatore. Taken as a whole, it was not unreasonable for Special Master Lord to find Dr. Tornatore's expert report and testimony insufficient for Petitioner to prevail, and to determine:

> I find that Dr. Tornatore's evidence is not sufficient to preponderate under Althen Prong 1. The theory that Td vaccination could cause GBS by molecular mimicry was effectively challenged by Respondent's expert, without meaningful response. Seemingly unable to explain the basis for the theory of molecular mimicry as it might pertain to Td vaccination and GBS, Dr. Tornatore relied instead on the concept of challenge/rechallenge. That phenomenon, with respect to Td vaccination and GBS, no longer is accepted by scientific experts as a link between Td and GBS, as Dr. Leist indicated at hearing, and as was shortly thereafter confirmed by the IOM.

Finally, Petitioner argues that Special Master Lord elevated Petitioner's evidentiary burden of proof from a preponderance of the evidence to a scientific certainty, thereby not acting in accordance with the law. In response, Respondent disputes Petitioner's contention that Special Master Lord elevated the required standard of proof. In Respondent's view, Special Master Lord "articulated and applied the proper legal standard," and acted in accordance with the applicable law. Respondent also asserts that Special Master Lord understood the difference between the standard of proof required by the scientific community to show causation and the preponderance evidence standard established in the Vaccine Act.

As noted above, under the off-Table theory of recovery, a petitioner is entitled to compensation if she can demonstrate, by a preponderance of the evidence, see 42 U.S.C. § 300aa-13(a)(1)(A), that the recipient of the vaccine sustained, or had

significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine that is listed on the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); see also Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Hines ex rel. Sevier v. Sec'y of Health & Human Servs., 940 F.2d at 1525. As indicated by the United States Court of Appeals for the Federal Circuit, the preponderance of evidence standard is "one of proof by a simple preponderance, of 'more probable than not causation.'" Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80 (citing concurrence in Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d at 1572-73). In Althen the Federal Circuit noted that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280 (citing Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 549). When proving eligibility for compensation for an off-Table injury under the Vaccine Act, however, petitioner may not rely on her testimony alone. According to the Vaccine Act, "[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." See 42 U.S.C. § 300aa-13(a)(1).

In her decision, Special Master Lord specifically stated that in order to qualify for compensation, Petitioner had to prove causation by the tetanus vaccine and her Guillain-Barré Syndrome, "by a sound and reliable 'medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be "legally probable, not medically or scientifically certain."'" (quoting Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1324 (quoting Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 548-49)).

A Special Master's decision will be upheld if the Special Master acted in accordance with the law, if the Special Master weighed all the evidence submitted by both parties, and if the Special Master did not base his or her conclusion on a lack of medical studies. See Viscontini v. Sec'y of Health & Human Servs., 103 Fed. Cl. 600, 612 (2012) (holding that the Special Master acted in accordance with the law when finding respondent's expert more credible than petitioner's, and was not "cloaking an impermissible burden in the guise of a credibility determination." The Court of Federal Claims found that the special master had "painstakingly reviewed the medical records and journal articles," and did not "base his conclusion on the absence of medical literature or studies, nor require petitioner to submit such evidence.") see also Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1356 (Fed. Cir) (holding that a special master acted in accordance with the law in finding for respondent because "[t]he special master spent significant effort in deciding Lombardi's case, holding three separate hearings, analyzing Lombardi's extensive medical record, resolving conflicting expert opinions, and reviewing a gamut of evidentiary materials submitted by both parties to rule on multiple factual and legal issues in a significantly difficult case"), reh'g en banc denied (Fed. Cir. 2011). Accordingly, "such a comprehensive effort [by the special master] diminishes a claim that a special master is holding a petitioner to an elevated burden . . . ." Viscontini v. Sec'y of Health & Human Servs., 103 Fed. Cl. at

611-12 (holding that the special master did not raise petitioner's evidentiary burden, but rather found petitioner's expert unreliable because he failed to: (1) offer any indicia of reliability; (2) articulate a causative relationship between the vaccine and the injury, other than "identif[ying] a temporal relationship between petitioner's receipt of the vaccine and onset of symptoms" and; (3) counter respondent's expert testimony that persuasively challenged the reliability of petitioner's expert).

In the case currently before this court, Special Master Lord undertook significant efforts to review Petitioner's claim and wrote a lengthy opinion explaining her conclusions. Special Master Lord repeatedly invited the parties to comment on medical information, even after the hearing. As indicated above, although Respondent's and Petitioner's counsel offered responses, Dr. Tornatore did not did not take the opportunity to rebut the information Special Master Lord put into the record, including the excerpts from the 2011 pre-publication Institute of Medicine Report. The Special Master also analyzed Petitioner's medical records, reviewed the medical literature, and considered the testimony provided by both parties before making her decision. Special Master Lord's decision considered all of Petitioner's claims, as well as all of the expert reports and testimony before determining, for the reasons described throughout this opinon, that Petitioner had "not presented preponderant evidence to support her claim under the Vaccine Act that the Td vaccination was the cause of her injuries."

As indicated above, Petitioner's counsel frequently cited to Althen v. Secretary of Health & Human Services, 418 F.3d at 1281, but did not amplify the Althen connection. Petitioner's counsel repeatedly alleged that Petitioner's case is identical to Althen, and that a Special Master acts contrary to law if the Special Master requires a Petitioner "to demonstrate that her specific injury is recognized by said medical documentation of plausibility." Id. Petitioner also alleges that Special Master Lord raised Petitioner's standard of proof by requiring "objective confirmation." As has been discussed above, Petitioner's case and the Althen case are not the same. In Althen, the Federal Circuit explained that the petitioner had met her burden of proof because she proffered evidence that the special master found more convincing than respondent's evidence. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1282. In this case, however, after reviewing the information offered by the Petitioner, Special Master Lord found Petitioner's proffered evidence, including Petitioner's expert testimony, insufficient and less convincing than Respondent's evidence, including Respondent's expert testimony. In fact, Special Master Lord noted that "[i]f reliable, Dr. Tornatore's testimony alone theoretically would be sufficient to satisfy Prong 1 – notwithstanding the absence of supporting medical literature, or evidence in the medical record, or a specific biological mechanism explaining how molecular mimicry could result in AIDP [acute inflammatory demyelinating polyneuropathy]." Special Master Lord, however, stated that she found "Dr. Tornatore's testimony in this case was not reliable." Quoting Cedillo v. Secretary of Health & Human Services, 617 F.3d at 1339 n.3, Special Master Lord noted that more than just the word of the expert is required, and that a Special Master in reaching a decision is "'entitled to require some indicia of reliability to support the assertion of the expert witness.'" Therefore, Special Master Lord did not impermissibly raise Petitioner's burden.

Contrary to Petitioner's suggestion, Special Master Lord did not require objective confirmation of Dr. Tornatore's theory of causation, or that the articles he submitted had to establish that there existed "a causal relationship to a degree of scientific certainty." At oral argument before this court, Petitioner failed to identify where in Special Master Lord's decision she required such objective confirmation. Moreover, as discussed at length above, Special Master Lord did not find Dr. Tornatore's testimony unreliable because she required scientific certainty, instead she found him unreliable because the scientific evidence he heavily relied on to draw a connection between the tetanus vaccine and Petitioner's Guillain-Barré Syndrome had been discredited or at least called into question by the 2011 pre-publication excerpts from the Institute of Medicine Report and because he was unable to articulate and support the basis for molecular mimicry and how it related to Petitioner's Guillain-Barré Syndrome. For all the reasons cited above, Special Master Lord's found that Dr. Tornatore had failed to show causation between the Petitioner's tetanus vaccination and her Guillain-Barré Syndrome, and had failed to rebut Respondent's expert testimony. See generally Viscontini v. Sec'y of Health & Human Servs., 103 Fed. Cl. at 601. Special Master Lord did not raise Petitioner's burden of proof in this case, and did not act contrary to law.

CONCLUSION

Upon review of the record before this court, including the transcripts, medical records, exhibits, conflicting expert reports, and Special Master Lord's decision, this court finds that Special Master Lord employed the proper standard of proof. Despite a few inconsistencies, Special Master Lord's conclusion that Petitioner failed to prove, by a preponderance of the evidence, a medical theory of causation between the tetanus vaccination and Petitioner's Guillain-Barré Syndrome, was not arbitrary or capricious. The Special Master's Ruling on Entitlement denying compensation to Petitioner is **AFFIRMED**.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge