

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 03-2016V

Filed: October 24, 2005

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CLAUDIA CARRERA-MEZA, \*

Petitioner, \*

v. \*

UNPUBLISHED

SECRETARY OF THE DEPARTMENT \*  
OF HEALTH AND HUMAN SERVICES, \*

Respondent. \*

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*Lisa A. Roquemore, McQueen & Ashman, LLP, Irvine, California, for Petitioner.*

*David L. Terzian & Ann K. Donohue, United States Department of Justice, Washington, D.C., for Respondent.*

### MEMORANDUM ENTITLEMENT RULING<sup>1</sup>

GOLKIEWICZ, Chief Special Master

#### I. PROCEDURAL BACKGROUND

On August 29, 2003, petitioner, Claudia Carrera-Meza, filed a petition pursuant to the National Vaccine Injury Compensation Program<sup>2</sup> (“the Act” or “the Program”) alleging that she

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<sup>1</sup>Because this decision contains a reasoned explanation for the undersigned’s action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims’s website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, “the entire” decision will be available to the public. Id.

<sup>2</sup> The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended,

suffered Guillain-Barre Syndrome (“GBS”) as a result of the rubella vaccination she received on May 16, 2001. Petition (“Pet.”) at 4. On November 24, 2003, respondent filed a Rule 4(b) Report contesting the sufficiency of the evidence and recommending that compensation be denied. Respondent’s Report (“R. Report”), filed Nov. 24, 2003.

To resolve outstanding factual questions and elicit expert testimony, a hearing was held on October 25, 2004. Petitioner, Ms. Carrera-Meza, testified as a fact witness. Petitioners also presented Charles K. Jablecki, M.D., as an expert witness. Respondent presented Thomas P. Leist, M.D., Ph.D., as an expert witness.

Following the hearing, the undersigned issued an order on October 29, 2004, requesting respondent’s counsel to file the IOM report to which he referred and petitioner’s counsel to file Dr. Jablecki’s October 21, 2004 report and the two articles that Dr. Jablecki discussed regarding urinary tract infections. Also, as discussed with the parties at the close of the hearing, the undersigned directed the parties to confer and decide whether they would like to wait for the outcome of two cases currently on appeal, Althen v. Secretary of HHS, No. 00-170V, and Capizzano v. Secretary of HHS, No. 00-759V, before proceeding further in this case. On November 22, 2004, petitioner filed a joint status report, relating the parties’ agreement to defer resolution on the above-captioned matter until such time as Althen and/or Capizzano are decided.

On July 29, 2005, the U.S. Court of Appeals for the Federal Circuit issued a decision in Althen v. Secretary of HHS, 418 F.3d 1274 (Fed. Cl. 2005). On August 29, 2005, the undersigned held a status conference with the parties and stated that, based on the causation-in-fact principles set forth in the Federal Circuit’s decision in Althen, petitioner has establish by a preponderance of the evidence her entitlement to compensation. Accordingly, this memorandum ruling explains the basis for the undersigned’s ruling.

## II. FACTUAL BACKGROUND

Petitioner, Ms. Carrera-Meza, was born on August 4, 1973. Pet. at 1. On May 14, 2001, Ms. Carrera-Meza gave birth to her second child via vacuum extracted vaginal delivery. Petitioner’s Exhibit (“P. Ex.”) 1 at 207-379. Because she was Rh negative and rubella non-immune, Ms. Carrera-Meza received RhoGam and rubella vaccines on May 16, 2001. Id. at 228, 235, 380. Five to seven days after receiving the vaccinations, she developed nonpruritic red spots on her body that had almost disappeared five days later. Id. at 397.

On June 4, 2001, Ms. Carrera-Meza presented at the Sharp Medical Center Emergency Room with a five day history of intermittent and worsening numbness in her hands, feet, tongue and around her mouth. P. Ex. 1 at 392. The weakness continued to the point that she could not

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42 U.S.C.A. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) (“Vaccine Act” or the “Act”). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

walk and she was evaluated in the emergency room. Id. The examination revealed weakness in her lower extremities, mild ataxia, diminished sensation to her face, sensory deficits to the upper extremities, diminished motor function to the upper extremities, hypoactive deep tendon reflexes and neck pain on flexion without stiffness. Id. at 393, 395, 398. Ms. Carrera-Meza was admitted to the hospital for further evaluation, with symptoms consistent with an idiopathic polyneuropathy of the Guillain-Barre type. Id. at 396.

A urinalysis performed on June 7, 2001, revealed the presence of *Escherichia coli* and *Proteus mirabilis*. P. Ex. 1 at 450. During Ms. Carrera-Meza's hospitalization, she experienced a worsening in her ability to swallow and speak with subsequent slow improvement. Id. at 644. She began to regain her strength and on June 15, Ms. Carrera-Meza was transferred to Grossmont Rehabilitation Center. Id. at 640. After six weeks of physical and occupational therapy, petitioner continued to experience bowel, bladder, and some swallowing deficits. Id. at 638-39. She also had diffuse weakness and some deficits in her transfer, but continued to make gradual progress in all areas of care. Id. On discharge, Ms. Carrera-Meza was scheduled for follow-up appointment with various physicians. Id. at 639. Neurologist, Dr. Raffer, later diagnosed her with ataxic GBS. Id. at 606.

In her August 21, 2003 affidavit, Ms. Carrera-Meza attested that she continued to suffer from substantial disability, including sensation loss in her hands, feet and part of her tongue, as well as loss of proprioception. Declaration of Claudia Carrera-Meza, filed Aug. 29, 2003.

### III. DISCUSSION

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.<sup>3</sup>

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). GBS is not an injury listed on the Vaccine Injury Table and thus does not benefit from the Act's presumed causation. Id. Thus, petitioner must prove that the vaccine in-fact caused her injury, a so-called "off-Table" case.

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<sup>3</sup>A preponderance of the evidence standard requires a trier of fact to "believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, *CIVIL PROCEDURE*, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

To demonstrate entitlement to compensation in an off-Table case, petitioners must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See, e.g., Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Secretary of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Secretary of HHS, 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, “[petitioners must] show a medical theory causally connecting the vaccination and the injury.” Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Secretary of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Secretary of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Secretary of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by “[a] reputable medical or scientific explanation” which is “evidence in the form of scientific studies or expert medical testimony.” Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960.<sup>4</sup> See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

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<sup>4</sup>The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that “Daubert is useful in providing a framework for evaluating the reliability of scientific evidence.” Terran v. Secretary of HHS, 41 Fed. Cl. 330, 336 (1998), aff’d, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge “connotes more than subjective belief or unsupported speculation.” Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert’s opinion. Id. In other words, the “testimony must be supported by appropriate validation – i.e., ‘good grounds,’ based on what is known.” Id. Factors relevant to that determination may include, but are not limited to:

Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it’s been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication

While petitioners need not show that the vaccine was the sole or even predominant cause of the injury, petitioners bear the burden of establishing “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. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Nor do petitioners satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating “inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation”)); Hodges, 9 F.3d at 960. Finally, petitioners do not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

Recently, in Althen v. Secretary of HHS, 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioner’s burden is to produce “preponderant evidence” demonstrating: “(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 (2) a showing of a proximate temporal relationship between the vaccination and injury.” The Federal Circuit stated further that “requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court’s well established precedent.” Id. at 1281. The Federal Circuit concluded that to support petitioners theory of causation, there is no requirement in the Vaccine Act’s preponderant evidence standard that petitioners submit “objective confirmation,” such as medical literature.

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“does *not* necessarily correlate with reliability,” because “in some instances well-grounded but innovative theories will not have been published.” Daubert, 509 U.S. at 594. However, the Supreme Court’s only guidance to lower courts in determining the reliability of a novel proposition is that

. . . submission to the scrutiny of the scientific community is a component of “good science,” in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Gall v. Secretary of HHS, No. 91-1642V, 1999 WL 1179611, at \*8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

Id. at 1279. The Federal Circuit explained that requiring medical literature “prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants.” Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)). Moreover, the Federal Circuit stated, “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.

However, the Federal Circuit’s decision in Althen does not preclude the use of medical literature in evaluating expert testimony. In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593 (1993), the Supreme Court stated that whether a theory or technique has been subjected to peer review and publication is a “pertinent consideration.” The Court continued, “[t]he fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.” Id. at 594. In Terran v. Secretary of HHS, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, 531 U.S. 812 (2000), the Federal Circuit approved of the special master’s use of Daubert as “a tool or framework for conducting the inquiry into the reliability of evidence” and affirmed the special master’s rejection of a proposed theory that did not meet Daubert standards. Thus, petitioners’ proposed causation theory must be supported by a “sound and reliable medical or scientific explanation.” Knudsen, 35 F.3d 543, 548 (Fed. Cir. 1994).

In petitioner’s expert’s report, Dr. Jablecki argues that the rubella vaccination petitioner received on May 16, 2001, two days after the birth of her child, caused her GBS, which first manifested on May 31, 2001. Charles K. Jablecki, M.D., Declaration in Support of Petition for Compensation (“P. Expert Report”), filed Aug. 29, 2003. Petitioner’s expert, Dr. Jablecki, opines that the rubella vaccination can cause GBS by activating the host’s immune system to generate antibodies against the virus. Id. at 3. Thus, he believes that it is biologically plausible for an adverse immune response to occur and to result in autoimmune reactions that affect the host’s peripheral nerves, causing GBS. Id. Dr. Jablecki finds that there is a strong temporal relationship between petitioner receiving the vaccination and developing GBS. Id. at 14. He also rules out a list of possible alternative causes of petitioner’s GBS. Id. at 14-18.

Respondent argues that even if petitioner proves that the rubella vaccine can cause GBS, she has not shown that the rubella immunization she received is the cause of her condition in this case. R. Report at 6. Further, respondent finds that “there is absolutely no support in the medical literature, other than a few anecdotal case reports, linking rubella immunization and GBS.” Id. Moreover, respondent avers that neither of the neurologists who provided affidavits for petitioner offered, “a credible theoretical basis or mechanism for a proposed causal relationship between rubella immunization and GBS.” Id. Respondent contends that Dr. Raffer’s opinion is insufficient at law to establish a causal relationship between Ms. Carrera-Meza’s May 16, 2001 immunization and her GBS, as he “has opined nothing more than he diagnosed Claudia with ataxic/sensory type GBS and that certain viral infections can be linked to GBS which Dr. Raffer

failed to detect in Claudia.” Id.<sup>5</sup> Respondent further argues that Dr. Jablecki “essentially relies on the temporal relationship and his inability to find another cause as the bases for his opinion.” Id. at 7. Respondent also finds Dr. Jablecki’s opinion insufficient at law to support the finding of a causal relationship between the rubella immunization and GBS. Id.

In respondent’s expert’s report, Dr. Leist opines that the risk for autoimmune manifestation increases in the early postpartum period. R. Report, Tab A at 3. Further, he states that it is possible for an E. Coli infection to serve as a trigger of immune events underlying an acute demyelinating disorder of the peripheral nervous system. Id. Dr. Leist also indicates that there is no epidemiologic data linking the rubella vaccine to GBS and GBS is not listed on the Vaccine Injury Table. Id. Accordingly, Dr. Leist concludes that a causal relationship between petitioner’s condition and the vaccine “can neither be established nor refuted with **certainty** based on the specifics of the case.” Id. (emphasis added).

At the October 25, 2004 hearing, both Drs. Jablecki and Leist provided very strong expert opinions. Both possess outstanding credentials and provided credible testimony. However, measured against the standards espoused in Althen, it is clear that Dr. Jablecki provided medical evidence of causation far beyond the required preponderance standard of proof, while it is equally clear that Dr. Leist simply required an impermissibly higher quantum of proof than required to meet the legal standard for causation.

Dr. Jablecki presented a clear medical theory connecting the rubella vaccination petitioner received to her development of GBS. Dr. Jablecki opined that the rubella vaccine can cause GBS. Transcript (“Tr.”) at 96. He explained that GBS is an immune response which causes the body to attack its own peripheral nerves. Id. The immune response is triggered by an event, which is often a viral infection. Id. The virus stimulates the immune system and the immune system responds by proliferation of cells and proteins to fight the virus. Id. However, aberrant or normal cells and proteins may be made during this process. Id. These cells then cross-react with the antigens, proteins in the peripheral nervous system, causing injury. Id. at 96-97. Dr. Jablecki further explained that because the rubella vaccine is an attenuated, live virus, “there are several lines of evidence which support the conclusion that rubella vaccine rarely can cause Guillain-Barre syndrome.” Id. at 97.

Dr. Jablecki opined that the timing between Ms. Carrera-Meza receiving the vaccination and developing GBS also lead him to believe that the vaccination caused her injury. Tr. at 116. Dr. Jablecki explained that there is increased risk of developing GBS during the postpartum period. Id. at 155-56. In other words, one becomes more susceptible to the triggering event within the 30-day postpartum period. Id. Thus, Ms. Carrera-Meza was more susceptible to GBS postpartum and a specific trigger, the rubella vaccination, “set off” her development of GBS. Id. at 116. Further, Dr. Jablecki opined that petitioner began to have neurological symptoms consistent with GBS within 10 days of receiving the vaccine. Id. at 124. Thus, Ms. Carrera-Meza

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<sup>5</sup>Dr. Raffer did not testify at the October 25, 2004 hearing.

met the appropriate medical, as opposed to literal, temporal criteria, as the onset of symptoms occurred within the five- to 30-day time period that has been reported with the onset of GBS associated with a live virus and the immunizations. Id.

Dr. Jablecki also ruled out possible alternative causes for Ms. Carrera-Meza's GBS. Dr. Jableck further testified that "Dr. Raffer conducted a very careful search to look for alternative explanations for the Guillain-Barre syndrome, including cytomegalic virus, Campylobacter, hepatitis, AIDS, and these studies were all negative." Tr. at 124. Moreover, Dr. Jablecki stated that he personally "went through the literature - the medical records to look for other conditions which have been reported to trigger Guillain-Barre, and I found that she did not meet the criteria for the diagnosis of those particular conditions." Id.

Contrary to Dr. Jablecki, Dr. Leist opined that the rubella vaccination did not cause Ms. Carrera-Meza's injury. Tr. at 173. Similar to Dr. Jablecki, Dr. Leist testified that during the postpartum period there is an increased risk for developing autoimmune diseases. Id. at 177. However, his opinion differed from Dr. Jablecki's in that Dr. Leist believes that "very often there is no direct proof of an inciting reason why somebody has something." Id. Dr. Leist brought up the possibility of multiple alternative causes to the vaccine for petitioner's GBS. Id. at 178-83. Dr. Leist further testified that there are "no real population-based studies that can tell us what the incidence of rubella-associated GBS is; it's all based on case reports." Id. at 184. Dr. Leist explained that the fact that in approximately 40 percent of GBS cases there is no known cause "means that there is no test to really say what this cause is...you cannot prove the negative." Id. at 189. Dr. Leist disagreed that one could never rule out all possible pathogens. Id. at 190. He stated, "[y]ou need to rule out what you can rule out, and you need to have - prove in a positive way what you can prove in a positive way." Tr. at 190. Dr. Leist explained that positive proof in petitioner's case would be, for example, a high IGM titer during the acute phase. Id. However, when asked whether evidence of such would be sufficient for him to opine that the vaccine was the cause of petitioner's GBS, Dr. Leist replied, "**[I]n a biological mechanistic way, in a laboratory, I would have to see more than that. I would have to see an immune response that is actually directed against a nerve that is caused by the pathogen.**" Id.

Dr. Leist opined that he could not make a decision that there is an association between the vaccination and petitioner's GBS "because important pieces of information are missing." Id. at 191. Additionally, in contrast to Dr. Jablecki, Dr. Leist found petitioner's postpartum state to be a negative factor, since she would be at an increased risk for GBS during the postpartum period independent of receiving the vaccination. Id. at 192. Dr. Leist argued that to view the postpartum state as a positive factor for the vaccine causing petitioner's GBS, would require performing statistical studies to demonstrate the link. Id. at 192-93. Accordingly, the undersigned asked Dr. Leist, "So isn't that the essence of your opinion, though, that there is not an epidemiological study that supports this case in there?" Id. at 194. Dr. Leist replied, "**Correct.**" Id. However, Dr. Leist also conceded that there are no population based studies to support each item on his laundry list of other potential causes of GBS. Id. at 200.



Dr. Leist was questioned about whether, in his expert opinion as an immunologist, “the mechanisms that Dr. Jablecki has outlined with respect to rubella causality of GBS” are relational ones. Tr. at 196. Dr. Leist answered that “there are mechanisms by which on a theoretic - or, on a - that we can put together by which a live vaccine can cause a neurological injury, yes.” Id. However, he noted that “[w]hat afterwards comes into play is how frequently this event [is] observed.” Id. Dr. Leist further averred, “the rubella virus by itself is only in very rare cases a cause of GBS or where we can - where we can accept it.” Id. at 197. Dr. Leist opined that the rubella virus was not more likely the cause of petitioner’s GBS. Id. at 199. When asked whether he believed that all possible causes of petitioner’s GBS are in “equipoise,” Dr. Leist stated:

Equilibrium means that you have a balance of equal forces on both sides. My testimony has been that there is an absence of proof over here that the - that the rubella vaccine has caused this disease other than the fact that there was a temporal coincidence.

Id. at 204. Dr. Leist explained that he thinks that the cause of petitioner’s GBS is weighted against rubella,

[b]ecasue you have a very likely event. The very likely event is an increased risk of GBS after pregnant - after delivery. You have a highly unlikely event. And that’s the potential of GBS after a rubella vaccination. So I have a more likely and a very unlikely event.

Id.

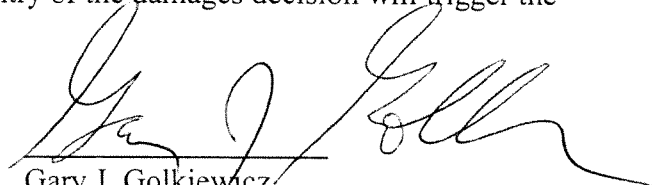
Dr. Jablecki provided clear and credible testimony supporting his medical theory that the rubella vaccination caused Ms. Carrera-Meza’s GBS. He demonstrated a medical theory causally connecting the vaccination and the injury, a logical sequence of cause and effect showing that the vaccination was the reason for the injury, and a proximate temporal relationship between the vaccination and injury. The undersigned was particularly impressed with the depth of Dr. Jablecki’s knowledge, the amount of research and preparation put into his report and testimony, and his cogent presentation. The undersigned finds that petitioner’s evidence far surpassed the preponderance standard.

Dr. Leist, while an extremely qualified and credible witness, essentially required that petitioner provide “objective confirmation” that the rubella vaccination caused her GBS, see Tr. at 190, or epidemiological studies, see Tr. at 194, to support causation. However, as stated by the Federal Circuit, this requirement “prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants.” Althen, 418 F.3d at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)). Accordingly, the stringent standard of proof required by respondent’s expert, Dr. Leist, does not comport with Althen, and thus failed to persuasively rebut petitioner’s evidence provided through Dr. Jablecki.

#### IV. CONCLUSION

Based on the foregoing, the court finds, after considering the entire record in this case, that petitioner is entitled to compensation under the Vaccine Act. The parties are currently working towards resolving the damages in this case. The entry of the damages decision will trigger the parties' further rights under the Act.

**IT IS SO ORDERED.**



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Gary J. Golkiewicz  
Chief Special Master