In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. 04-1734V

Filed: January 30, 2008

Not To Be Published

PENNY PIVA REGO,	*	
	*	
	*	Multiple Sclerosis; MMR Vaccination;
Petitioner,	*	Credibility of Expert Witness
	*	
v.	*	
	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Thomas P. Gallagher, Somers Point, New Jersey for petitioner.

Lynn E. Ricciardella, United States Department of Justice, Washington, DC, for respondent.

DECISION[1]

GOLKIEWICZ, Chief Special Master.

[1] 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' 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.

I. PROCEDURAL BACKGROUND

On December 3, 2004, petitioner, Penny Rego (Mrs. Rego), filed a petition pursuant to the National Vaccine Injury Compensation Program[2] ("the Act" or "the Program") alleging that she suffers multiple sclerosis (MS) "which was 'caused-in-fact'" by a Measles Mumps Rubella (MMR) vaccination on February 16, 2003. Petition (Pet.) at 1. On May 23, 2005, respondent filed a Report pursuant to Vaccine Rule 4 contending that compensation was inappropriate and the petition should be dismissed. Respondent's Report, filed May 23, 2005. To elicit expert testimony, a Hearing was held on March 29, 2007 (hereinafter "Hearing"). Petitioner presented Vera Byers, M.D., Ph.D. as an expert witness. Respondent presented Thomas Leist, M.D., Ph.D. as an expert witness. Ms. Rego also provided fact testimony. Petitioner and respondent filed Post-Hearing Briefs on July 17, 2007 and August 16, 2007, respectively. The case is ripe for resolution.

II. FACTUAL BACKGROUND

The factual background in this matter is largely undisputed.[3] Penny Rego was born on December 25, 1966. Pet. at 1. Ms. Rego received childhood vaccinations without incident, including: a measles vaccination on October 3, 1967 and July 15, 1974; a mumps vaccination on February 28, 1969; and a rubella vaccination on June 16, 1970. Petitioner's Exhibit (Pet. Ex.) 1 at 4.

Ms. Rego saw her primary care physician, Dr. Cathleen Hood on November 12, 2002. At that visit Dr. Hood authorized Ms. Rego to go on medical leave and notes she was experiencing headaches, nausea, and depression. Pet. Ex. 7 at 2-3. Ms. Rego saw Dr. Hood again on January 20, 2003 at which time Ms. Rego complained of headaches, nausea, and depression; Dr. Hood extended Ms. Rego's medical leave. Id. at 4-5. Dr. Hood's notes also reflect Ms. Rego had the flu and questioned "how much [petitioner's gastrointestinal symptoms were secondary] to viral illness." Id. at 4.

On February 16, 2003, Ms. Rego received an MMR vaccination as required by Johnson & Wales, where Ms. Rego was enrolled in a pastry arts course. Pet. Ex. 1 at 3, Transcript (Tr.) at 14. Ms. Rego testified she reported to a friend on February 20, 2003 that her hand and arm felt

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[2] 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, 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.

[3] As discussed, *infra* p. 13 footnote 9, there is a question as to when the symptoms began, anywhere from 3-5 days following vaccination. As found in this decision, that determination is not necessary for resolving this case.

"tingly" and "kind of numb," Ms. Rego further clarified that she had first experienced these symptoms prior to February 20, 2003, but did not remember the exact date. Tr. at 16-17. Ms. Rego wrote in her journal that she reported to a classmate on February 23, 2003 that her hand was numb and her arm had "been sore all week." Pet. Ex. 1 at 5. On February 28, 2003, Ms. Rego saw her primary care physician, Dr. Cathleen Hood for a routine gynological examination. Id. at 97-98. Dr. Hood recorded that Ms. Rego complained of "numbness 'L' hand x 1. week - sts. started 8D ago . . . ." Id. Ms. Rego also reported to Dr. Hood her buttocks got "tingly" when she looked down. Id. Dr. Hood referred Ms. Rego to a neurologist for an MRI.

Brain and cervical MRI scans of Ms. Rego performed on March 3, 2003 indicated Ms. Rego's likely diagnosis to be a "demyelinating disease." Id. at 143-144. Ms. Rego's treating neurologist, Alvin Marcovici, M.D., wrote in a letter to Dr. Hood that the MRI imaging showed "intrinsic lesions of the brain stem and spinal cord" and that this is "most suspicious for MS." Id. at 10. Ms. Rego consulted with Dr. Jonathan W. Martin at the MS Center in Sturdy Memorial Hospital on March 27, 2003. Dr. Martin's impression after examining Ms. Rego was that she suffered "clinically possible multiple sclerosis based on the presence of a single demyelinating episode." Id. at 156-157. Petitioner followed up with Dr. Martin on June 26, 2003 at which time Dr. Martin noted that while Ms. Rego was continuing her life as usual "[i]t seems reasonable at this point to proceed with the presumptive diagnosis of multiple sclerosis and to initiate therapy." Id. at 154. Petitioner saw Dr. Martin on February 5, 2004, at which time Dr. Martin noted an "exacerbation of multiple sclerosis" consisting of "numbness of the tongue and face in December of last year." Id. at 146.

The findings from petitioner's most recent MRIs in the record, taken on January 17, 2007, indicate "likely consistent with clinical diagnosis of multiple sclerosis." Pet. Ex. 10 at 3, 10, 11. Finally, in a letter dated March 26, 2007, Dr. Martin confirmed "Ms. Rego has clinically definite relapsing-remitting multiple sclerosis and is currently undergoing treatment for this disease." Id. at 1.

III. DISCUSSION

A. Summary of Experts' Positions

The following is a brief overview of the experts' testimony.

Vera Byers, MD.

Dr. Byers is board-certified in internal medicine and completed a clinical fellowship in immunology. Pet. Ex. 6 at 5. After voir dire, the undersigned found Dr. Byers qualified as an expert in immunology, however as Dr. Byers is neither a neurologist, nor is board certified in neurology, the undersigned limited Dr. Byers testimony to discussing the "mechanism of causation but not the diagnosis" of MS. Tr. at 34-40. Dr. Byers herself conceded she would

refer patients to a neurologist to have an MS diagnosis "confirmed" and to treat the patient. Tr. at 38. Dr. Byers worked with MS patients while doing her residency and internship, as well as in her private practice from 1981-1997. Tr. at 38-39; Pet. Ex. 6 at 4-5. More recently, Dr. Byers has been involved with at least three clinical trials for pharmaceutical companies with patients "usually" with MS. Tr. at 35-36. However, she has not maintained a clinical practice for many years and in fact describes herself as a "druggie" working for pharmaceutical companies. See Tr. at 35.

Dr. Byers testified that Ms. Rego's MS "symptoms were triggered by the MMR vaccination." Tr. at 42. Dr. Byers testified that Ms. Rego had demyelinating lesions or asymptomatic plaques[4] prior to her February 16, 2003 MMR vaccination. Id. at 43. Dr. Byers' causation theory is that the MMR vaccination interacted with Ms. Rego's "innate immune system" which produced "inflammatory cytokines . . . which then cause activation of lesions and produce inflammatory foci that were asymptomatic before this, and then they go on to produce T-cells which can cross-react with various proteins in the brain . . . and then exacerbates the lesions and activates the immune disease so that now you start seeing the symptoms." Id. at 43-44. Dr. Byers elaborated:

> [t]he measles virus can be anticipated to continue to replicate for at least two days after it's given, because, of course, this is a live virus, until it's engulfed by the innate immune system, and after - and that can then produce symptoms of inflammation and disruption of the neural pathways, which would then explain the - both the painful injection site, but more likely the numbness of the hand. It then stimulates T-cells which would interact with the **existing lesions** and then continue on to start the whole cascade of multiple sclerosis so it would continue to progress.

Id. at 59-60 (emphasis added).

Thomas Leist, M.D.

Dr. Leist is an associate professor of neurology, chief of the division of clinical neuroimmunolgy, and director of the Comprehensive MS Center at Thomas Jefferson University. Respondent's Exhibit (Resp. Ex.) B at 1: Tr. at 97. Dr. Leist is board-certified in neurology, has a clinical practice which services approximately 2000 patients with ongoing MS, and sees approximately 240 MS patients per month. Resp. Ex. B at 1; Tr. at 98-99. Dr. Leist testified without objection as an expert in immunology and neurology. Id. at 100.

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[4] "A sharply defined zone of demyelination characteristic of multiple sclerosis." Stedman's Medical Dictionary 1393 (27th ed 2000); see also Tr. at 134 (Dr. Leist defined plaques as "an area of tissue disturbance . . . where brain tissue got injured.")

After reviewing the medical records of Ms. Rego, Ms. Rego's personal journal, the expert reports submitted by Dr. Byers, as well as listening to the testimony of Ms. Rego, Dr. Leist opined that Ms. Rego's MMR vaccination and MS "were two independent contemporaneous events." Id. at 100-102. Dr. Leist testified that in his opinion the numbness and "tingly" feeling Ms. Rego developed within days of her MMR vaccination which evolved into "Lehrmitte's phenomenon" were symptoms "that were in line with a lesion in the cervical spine" and that more likely than not "this lesion that was later visualized on an MRI was new at the time of occurrence." Id. at 103-104. Dr. Leist bases this opinion on the fact that there is no indication anywhere in the medical records or from Ms. Rego's testimony that she experienced any prior symptoms. Id. at 104. Dr. Leist concedes he cannot know the cause of Ms. Rego's MS, although he notes her symptoms could have been triggered by the viral illness she suffered on January 20, 2003. Id. at 105-106.

Dr. Leist further testified that he dismissed the MMR vaccination as a potential cause of Ms. Rego's MS as the time span of four days is too short "to raise a primary response or to raise an anamnestic response, essentially a response to an antigen that somebody has been exposed to previously." Id. at 106-107. Dr. Leist explained that for a first time response, it would take a minimum of 3-4 weeks for an individual to develop neurological symptoms, and for an anamnestic response it would take approximately 8-12 days. Tr. at 112-113. Dr. Leist elaborated that if he were to assume Ms. Rego had pre-existing lesions, the only way he would expect to see a reaction in a three or four day time period would be if you have a high fever at the same time, or a urinary tract infection, but in that event he would expect the symptoms to recede once the fever goes away. Id. at 139-142.

B. Legal Standard

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.[5]

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). Petitioner do not allege a table injury. Thus, petitioner must prove that the vaccine in-fact caused Ms.

[5] 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).

Rego's injury, a so-called "off-Table" case.

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 or significantly aggravated the injury alleged. See, e.g., Bunting v. Sec'y of Dept. of Health & Human Servs., 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Sec'y of Dept. of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Sec'y of Dept. of Health & Human Servs., 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. Sec'y of Dept. of Health & Human Servs., 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. Sec'y of Dept. of Health & Human Servs., 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Sec'y of Dept. of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Sec'y of Dept. of Health & Human Servs., 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.[6] See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986

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[6] 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. Sec'y of Dept. of Health & Human Servs., 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.

U.S.C.C.A.N. 6344.

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.

In Althen v. Sec'y of Dept. of Health & Human Servs., 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioners' 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 (3) a showing of a proximate temporal relationship between the vaccination and injury." The Federal Circuit stated further that "requiring that the

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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 "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 Althen, 418 F.3d at 1280 ("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."); see also, Gall v. Sec'y of Dept. of Health & Human Servs., No. 91-1642V, 1999 WL 1179611, at *8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

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. 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)); see also Capizzano v. Sec'y of Dept. of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) [hereinafter "Capizzano III"]. 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.

The Federal Circuit affirmed Althen's three-part test in Capizzano III and in Pafford v. Sec'y of Dept. of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006). The panel in Pafford, however, explained that the three prongs in Althen "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." Pafford, 451 F.3d at 1355. Fairly interpreted, the Pafford court held that it is petitioner's burden to rule out other competing possible causes of the injury in establishing that the vaccine was the "but-for cause of the harm." Id. at 1355, 1357; see also Althen at 1281. ("[T]he elimination of other causes [] is merely a recitation of this court's well-established precedent."). But see, Walther v. Sec'y of Dept. of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007) ("[W]e conclude that the Vaccine Act does not require petitioner to bear the burden of eliminating alternative causes when the other evidence on causation is sufficient to establish a prima facie case.").

However, the legal requirement that a petitioner support her proposed causation theory with a "sound and reliable medical or scientific explanation" is undisturbed. Knudsen, 35 F. 3d 543, 548 (Fed. Cir. 1994); see also Grant, 956 F.2d at 1148 ("A reputable or scientific explanation must support this logical sequence of cause and effect."). Thus, when considering the evidence in a case, the special master is to "consider all relevant and reliable evidence, governed by the principles of fundamental fairness to both parties." Vaccine Rule 8(c); see also DeBazan v. Sec'y of Dept. of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2000) ("A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness's testimony regarding causation;" Campbell v. Sec'y of Dept. of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006). (Althen's requirement of a "reputable medical or scientific explanation" "[l]ogically [ ] requires a special master to rely on reliable medical or scientific evidence . . . ."); Manville v. Sec'y of Dept. of Health & Human Servs., 63 Fed. Cl. 482, 491 (2004) ("Daubert adequately serves the gatekeeping function for analysis of the admissibility of evidence; once evidence has passed that test, the trier of fact's process, simply, is to determine the probativeness of that evidence."). Ms. Rego's case is measured against these standards.

C. Analysis

Petitioner has not alleged a table injury in this case. Pet. at 1. Thus, the issue to be resolved is whether petitioner has demonstrated by a preponderance of the evidence that the MMR vaccination Ms. Rego received on February 16, 2003 more likely than not caused, or significantly aggravated her MS. For the following reasons the undersigned finds petitioner failed to establish a "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Sec'y of Dept. of Health & Human Servs., 165 F.3d 1344, 1353 (Fed. Cir. 1999).

The medical theory presented by Dr. Byers is that Ms. Rego had lesions or plaques which were pre-existing and asymptomatic prior to her February 16, 2003 MMR vaccination. "The clinical picture in the case of Ms. Rego is consistent with the fact that the demyelinating lesions were already present prior to the vaccination, and up to the time of the vaccination were asymptomatic." Pet. Ex. 3 at 3; see also Tr. at 43, 59, 61-62, 65, 75, and 91. Dr. Byers testified that in Ms. Rego's case "the temporal relationship as well as the data that has accumulated indicates that [] - she probably had those plaques before and she was asymptomatic with those plaques, [before] she received the MMR vaccination." Tr. at 43. Dr. Byers opined that the "strong inflammatory response which, can be considered to be a nonspecific adjuvant-like effect of the vaccination and triggered the onset of symptoms of multiple sclerosis." Pet. Ex. 3 at 3. Dr. Byers explained that inflammation causes the release of cytokines and nitric oxide "which have been shown to have an important role in producing CNS damage" and "an important role in 'short circuiting' neuronal communication and causing axonal degeneration," respectively. Id.

Dr. Byers testified that vaccination can cause or exacerbate autoimmune diseases. Tr. at 42. Dr. Byers opined in her expert report:

> [m]ultiple sclerosis is an autoimmune disease characterized by demyelination of CNS neurons. These demyelinating lesions are seen by MRI, as occurred in this patient. For many years the principal mechanism of action was thought to be molecular mimicry, in which a foreign antigen - such as an infectious disease - was unusually "seen" by the immune system as being very similar to the "self" myelin, causing an attack by the T cells mount an assault on the myelin sheath of the neurons in the CNS.

Pet. Ex. 3 at 2. However, in the instant case, Dr. Byers testified that Ms. Rego's symptoms "began five days after the vaccination" which "is a little bit too soon for a T-cell response to come up and actually start producing damage." Tr. at 65. In essence, the time frame for the vaccination to cause initial neurological damage was too short. Dr. Leist agreed. See Tr. at 112-113.

Therefore, Dr. Byers theorized that Ms. Rego had asymptomatic plaques which were exacerbated by the inflammatory response to the vaccines resulting in the display of symptoms. Tr. at 44. Thus, what is central and essential to Dr. Byers' opinion in this case is the existence of plaques prior to Ms. Rego's MMR vaccination. See Tr. at 43, 59, 61, and 75. The undersigned engaged in the following question and answer with Dr. Byers:

> THE COURT: Your opinion hinges on the fact that these lesions predated the vaccination?
>
> DR. BYERS: Yes, it does.

Id. at 65-66. Accordingly, resolution of the existence of plaques prior to immunization is central to the determination of the viability of Dr. Byers' opinion. If the evidence does not support the existence of plaques in Ms. Rego prior to immunizations, Dr Byers' opinion necessarily fails. What is the evidence to support the existence of the plaques? Dr. Byers relied upon two pieces of evidence:

- the MS medical community, relying upon autopsy data, is finding lesions in otherwise asymptomatic individuals, and
- the rapid onset of Ms. Rego's symptoms supports the existence of plaques.

Dr. Byers readily conceded that she cannot "say in Ms. Rego specifically [whether she had preexisting plaques] because she never had an MRI before." Tr. at 63; see also Id. at 75. When asked by the court what evidence supports the plaques being present prior to the MMR vaccination, Dr. Byers testified:

> when you have a diagnosis of MS it - the first symptoms are actually pretty subtle or can be pretty subtle. But if you do an MRI you find that there's an awful lot of lesions there, and so therefore the MS community is realizing that these lesions actually are presently in an asymptomatic fashion prior to the symptoms actually starting.

Tr. at 62. However, in later testimony, Dr. Byers stated that in reviewing autopsies only about "20 percent of the people will have these same lesions that are characteristic of MS, but they've never had any symptoms." Tr. at 92. Dr. Leist agreed that autopsies have shown plaques in otherwise asymptomatic individuals, but the percentage "is a much lower number" than represented by Dr. Byers. Tr. at 133. When pressed further by the court for evidence of the pre-

existing plaques, Dr. Byers conceded that she could not "tell you that Penny Rego herself had those lesions." Tr. at 75; see also Id. at 63. Having considered the minimal evidence presented on this issue, the undersigned sides with Dr. Leist. The undersigned finds these reports to show that it is possible to have asymptomatic lesions; however the literature reporting autopsy findings does not support the fact that Ms. Rego had asymptomatic lesions prior to her MMR vaccination. It is simply intellectually unreasonable to conclude otherwise. Thus, the undersigned agrees with respondent and finds the fact that while autopsy reports have indicated some individuals have lesions despite not having experienced MS symptoms, this does not demonstrate that Ms. Rego more likely than not had pre-existing lesions. See respondent's Post Hearing Brief filed August 16, 2007 (Resp. Brief) at 16.

Then why does Dr. Byers opine to the existence of the plaques? Dr. Byers testified that the lesions in this case predated the vaccination because the symptoms "began fairly rapidly." Tr. at 62. Dr. Byers elaborated:

> I don't have the ability to say in Ms. Rego specifically because she never had an MRI before, but in MS patients in general, the **rapidity** with which the symptoms appears in cases where you know what causes it, especially like a viral infection, where that's pretty well established that a viral infection can precede MS, the rapidity with which the lesions, with which the symptoms begin . . . there's a discordance between the relative mildness of the onset of the symptoms and the number of the demyelinating lesions have caused the community to realize that in fact the symptoms are being triggered by initial inflammation.

Id. at 63 (emphasis added); see also Id. at 76 ("the fact that she started having symptoms probably within five days would indicate that she already had the lesions beforehand but they were just inactive.") Thus, since the symptoms began rapidly after vaccination, Dr. Byers believes the plaques were pre-existent but asymptomatic until Ms. Rego had her MMR vaccination "and that's when they became symptomatic," as a result of inflammation caused by the vaccination. Id. at 63-64.

Dr. Leist testified cogently that there is no basis for Dr. Byers' medical theory. In addition to Dr. Leist opining that there is no support in the medical community for the MMR causing inflammatory or demyelinating injuries, tr. at 117-18, Dr. Leist testified convincingly that the clinical picture of Ms. Rego's disease process is inconsistent with the existence of pre-existing plaques and, even if possible, the timing of onset was too soon to implicate the immunization.

Dr. Leist testified that Ms. Rego's lesion was new at the time of its occurrence, not pre-existing as postulated by Dr. Byers. Tr. at 104. Dr. Leist noted it appeared Ms. Rego had

symptoms of dysesthesia[7] starting around February 18-20, 2003. Tr. at 103. Dr. Leist explained, per the testimony of Ms. Rego and the medical records, these symptoms evolved into "Lehrmitte's phenomenon, that is when she flexed her neck she felt tingling going down her spine," which Ms. Rego reported to her primary care physician on the 28th of February. Id. Dr. Leist opined:

> [t]hese symptoms are at that point in time in line with a lesion in the cervical spine, because with the stretching, . . . of the fibers that are denuded, as so there is inappropriate discharges from these fibers occurring. So more likely than not, it appears this lesion that was later visualized on an MRI was new at the time of occurrence, because at least to the records that I have, there was no report and we haven't heard any testimony to the contrary today, that there was any event beforehand where she would have had similar Lehrmitte's-like symptoms or symptoms at all.

Id. at 103-104.

Dr. Leist acknowledges that since an MRI was not performed prior to Ms. Rego's MMR vaccination, there is a "theoretical possibility" that a lesion existed prior to the vaccination. Id. at 152; see also Id. at 136. However, the fact that Ms. Rego's medical records contain "no history of an event" to support a pre-existing lesion argues against the possibility that there was a pre-existing lesion **based on the location of the lesion itself**. Id. at 152-153. Dr. Leist explained:

> the fact that this is a C-2 lesion or a lesion at where essentially everything that goes into the spinal cord leads to - this is like at the entry into a development, you know where there is building site at the entry into a development, because everybody that needs to go there needs to pass through. So this is a high cervical lesion. **It's very unlikely that high cervical lesions are not clinically manifest, just by the mere fact of where they are located**. You will know about it.

Id. (emphasis added); see also Id. at 130, 136. Finally, Dr. Leist opined that the gradual evolution of the cervical lesion argues that it was a new lesion, as the symptoms were not "stroke-like." Id. at 153, 155. "Initially there was numbness, then the numbness went to the point where essentially it was there all the time, . . . then came the Lehrmitte's." Id. at 153. Dr. Byers offered no rebuttal to Dr. Leist's testimony; in fact it is highly doubtful that she is qualified to counter Dr. Leist's testimony on this issue. See Tr. at 35-41 ("I'm a druggie"). Based upon Dr.

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[7]Dr. Leist defines dysesthesia as "[t]hat's funny feeling, numbness, tingling, in her hand about two to three days." Tr. at 103.

Leist's considerable experience in the field of neuroimmunolgy and his extensive experience with MS patients, tr. at 99, the undersigned finds his testimony regarding the unlikelihood of Ms. Rego's lesions pre-existing her MMR vaccination to be extremely persuasive. This finding effectively eviscerates Dr. Byers' opinion in this case. Dr. Byers' opinion "hinged" on the pre-existing plaques. The undersigned finds based upon Dr. Leist's convincing testimony that Ms. Rego's plaques were new lesions; not pre-existing. Accordingly, Dr. Byers' opinion necessarily fails.

Even without Dr. Leist's testimony regarding the new lesions, Dr. Leist maintained that the timing of onset of Ms. Rego's symptoms was too soon to implicate the immunization. Dr. Byers bases her contention that there were pre-existing plaques on the "rapidity" of Ms. Rego's symptoms. Again, the undersigned was far more impressed with Dr. Leist's testimony on this issue.

There is an issue whether Ms. Rego's symptoms began at three days following vaccination or at five. However, whether it is three or five is ultimately of no matter.[8] Dr. Leist explained that for a neurologic reaction to a vaccine received for the first time would take three to four weeks. Tr. at 113. However, this was not the first measles, mumps, or rubella vaccination received by Ms. Rego, although her previous vaccinations were received nearly 30 years prior to the immunization in question. Dr. Leist testified that, assuming that Ms. Rego still had immunity from that earlier vaccine (there was no way to know since no titers were drawn), it would take 8-12 days for a neurologic response. Tr. at 113-114. This is called an anamnestic response. Dr. Leist explained:

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[8]Petitioner argues at some length in her post hearing brief that Dr. Leist's opinion, that the time period is to short in this case to support an amnestic response to the MMR vaccination, is based upon a less contemporaneous medical record that indicated the time period was three days as opposed to petitioner's contention of a five day time period based upon an earlier record. As noted in the factual background of this decision, on February 16, 2003 Ms. Rego received an MMR vaccination. Ms. Rego testified she reported to a friend on February 20, 2003 that her hand and arm felt "tingly" and "kind of numb," Tr. at 16-17. Ms. Rego wrote in her journal that she reported to a classmate on February 23, 2003 that her hand was numb and her arm had "been sore all week." Pet. Ex. 1 at 5. Dr. Hood recorded on February 28, 2003, that Ms. Rego complained of "numbness 'L' hand x 1 week - sts. started 8D ago . . . ." Id. at 97-98. Ms. Rego also reported to Dr. Hood her buttocks got "tingly" when she looked down. Id. Based upon the medical records and the fact testimony presented in this case it is unclear exactly when Ms. Rego's initial MS symptoms appeared, however it is evident that the symptoms appeared between Ms. Rego's February 16 MMR vaccination and February 20, 2003. Based upon the testimony of Dr. Leist, whether the time frame is three days or five days is of no critical difference, the time period is too short to support an anamnestic or primary response. Tr. at 106-107, 139-142.

> In order to have an anamnestic response you need to have exposure to the antigen and then afterwards you have to have a raising of the T-cell response, and that takes some period of time, too. And so that's why a reasonable period of time is outside of the time window in which her symptoms . . . occurred.

Tr. at 113. Dr. Byers testified that even accepting the onset at the earlier date of three days would be an acceptable time frame because:

> number one, she had already been vaccinated twice, so she had had plenty of memory cells built up for T-cells, but more importantly, she also had the vaccine, had the opportunity to activate the innate immune system.

Tr. at 59. Dr. Byers made no effort to address the 30 year period that had elapsed since Ms. Rego's last MMR and the effect on her immunity. Dr. Byers offers no support for the anamnestic response occurring in such a short period of time, contrary to Dr. Leist's testimony. Based upon Dr. Leist's far superior background and experience, and considering his cogent testimony in this case, the undersigned accepts his testimony that the time frame for an initial or anamnestic response in this case is too short.

The undersigned is compelled to note that the testimony of Dr. Byers was in this case was unimpressive. Dr. Byers testimony was confusing, speculative, and frankly suspect as it not supported by the record in this case or other reliable sources. Dr. Byers' testimony includes a broad overview of how the vaccine could cause neurological injury, but notably lacks any reliable discussion of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. See Althen. Dr. Byers concedes that she has no way of knowing if plaques were present in Ms. Rego prior to vaccination. She proceeds to rely on autopsy information that implicates a mere 20% of the population; yet draws a correlation to Ms. Rego to a level of probability, that is greater than 50%. Dr. Byers utilized a slide show to support her theories that was taken from others, put together months prior for purposes of other litigation and was quite frankly confusing and incomplete to all present. See Tr. at 78-83. Most egregiously was Dr. Byers' failure to address the location of the lesions. Dr. Leist showed convincingly that the location of the lesions made it almost certain that the lesions were nascent, not preexisting. Dr. Byers failed to even mention that critical piece of information.

The undersigned notes to support her theory of causation in this case Dr. Byers repeatedly attempted to force the facts of Ms. Rego's injury into a review by Douglas R. Jeffery on The Use of Vaccinations in Patients with Multiple Sclerosis, Pet Ex. 3 at 3, which concluded

> patients should be informed that vaccination can, on rare occasion, trigger an MS

> relapse but that the risk of infectious illness poses a far greater threat. In patients with MS who exhibit evidence of active disease as manifested by rapidly evolving neurologic deficits or in those who show active disease by MRI criteria, vaccination should be withheld until the disease activity can be brought under control with appropriate immunomodulating therapy.

Pet. Ex. 3 at 12. After an extensive and thoroughly confusing discussion attempting to analogize this article to her own theory of causation as it pertains to Ms. Rego's injury, tr. at 66-73, Dr. Byers finally conceded Jeffery's is discussing individuals who have been diagnosed with MS, whose symptoms recede and then post-vaccination have a relapse. Id. at 93-94. The undersigned notes this is not the case under Dr. Byers' theory of causation because her theory relies upon asymptomatic lesions being present at the time of vaccination, as opposed to "patients with MS who exhibit evidence of active disease as manifested by rapidly evolving deficits or in those who show active disease by MRI criteria" as described by Jeffery. As there is no reliable evidence that Ms. Rego had either erythematous injection site reaction or pre-existing lesions, the undersigned echoes the sentiment of my colleague, Special Master Millman, who in another case noted, "Dr. Byers created a theory and then tailored the facts to suit it." Lawson v. HHS, No. 90-2455V, 2000 WL 246234 at *8 (Fed. Cl. Spec. Mstr. Feb. 14, 2000); see also Walther v. HHS, No. 00-426V at 4-5 (Fed. Cl. Spec. Mstr. July 29, 2005)(unpublished)(criticized Dr. Byers' role as an expert witness)(vacated and remanded on other grounds). The undersigned concurs and finds that Dr. Byers was ineffectual and unpersuasive as an expert in this case.

In the final analysis, petitioner failed to present reliable, reputable evidence that Ms. Rego had lesions prior to her MMR vaccination. Dr. Leist persuasively showed that the "clinical picture" supports there were no pre-existing lesions. As Dr. Byers conceded, her medical theory of causation hinges upon the existence of lesions prior to the MMR vaccination. Since petitioner's medical theory relies upon a fact she was unable to establish, petitioner's theory must fail. As respondent noted in their post hearing brief, "[t]he conclusions of experts are only as sound as their factual predicate." Respondent's Post Hearing Brief at 14 brief citing Castillo v. HHS, 1999 WL 605690 at *13 (Fed. Cl. Spec. Mstr. July 19, 1999) (citing Davis v. HHS, 20 Cl. Ct. 168, 173 (1990)); Loesch v. United States, 645 F.2d 905, 915 (Ct. Cl. 1981) (citing State of Washington v. United States, 214 F.2d 33, 43 (9th Cir. 1954), cert. denied, 348 U.S. 862 (1954)). Thus, petitioner has failed to establish "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury," nor has petitioner demonstrated by a preponderance of the evidence that Ms. Rego's MMR vaccination was the "but for" cause of her injury as required by the Federal Circuit. Althen at 1278, Capizzano III at 1352, Pafford, 451 F.3d at 1355.

Accordingly, the undersigned finds that petitioner has not established by a preponderance of the evidence that Ms. Rego's February 16, 2003 MMR vaccination was the legal cause of Ms. Rego's MS. Petitioner's claim is denied. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master