

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 06-522V

Filed with redactions: May 19, 2011

[Originally filed: April 29, 2011]

Unpublished

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ROBERT VERYZER,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,

Respondent.

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Decision on remand; Hepatitis A,  
Althen prongs; Cognitive and  
physical injuries; Sufficiency of  
treating physicians' records in  
establishing causation

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*Alan Carl Milstein, Sherman, Silverstein, et al., Pennsauken, N.J., for Petitioner.*  
*Voris Johnson, U.S. Department of Justice, Washington, D.C., for Respondent.*

### DECISION ON REMAND<sup>1</sup>

GOLKIEWICZ, Special Master.

This case is before the undersigned on remand from Judge Christine O.C. Miller.<sup>2</sup> Before the undersigned is the question of whether petitioner's medical records and reports from his treating physician are sufficient to meet petitioner's burden of showing his alleged conditions were caused-in-fact by the Hepatitis A vaccine he received on April 25, 2001. As discussed below, petitioner fails to meet his burden of causation. The undersigned will review petitioner's evidence, primarily petitioner's medical records and the reports from petitioner's treating physician, Dr. Astruc, and evaluate this evidence under the Althen factors; these factors petitioner must meet by a preponderance of evidence in order to prove causation.

Knowledge of Special Master Abell's Decision and the Decision of Judge Miller is presumed. Thus, this decision is limited to discussing issues pertinent to this remand.

#### Legal Standard

<sup>1</sup> The undersigned intends to post this decision on the website for the United States Court of Federal Claims, 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 a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id. Any motion for redaction must be filed by no later than fourteen (14) days after filing date of this filing. Further, consistent with the statutory requirement, a motion for redaction must include a proposed redacted decision, order, ruling, etc.

<sup>2</sup> This case was reassigned to the undersigned upon retirement of the prior special master. Order Reassigning Case, filed December 7, 2010; see also Memorandum Opinion and Order, at p. 21, filed January 28, 2011; redacted Memorandum Opinion and Order, filed February 17, 2011 (hereinafter "Memorandum and Order").

Causation in Vaccine Act<sup>3</sup> cases can be established in one of two ways: either through the statutorily prescribed presumption of causation, Table cases, or by proving causation-in-fact. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.<sup>4</sup> Petitioner's case is a causation-in-fact claim. To demonstrate entitlement to compensation in a causation-in-fact case, petitioner 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, "[petitioner must] show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); see also 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; see also 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; see also Jay, 998 F.2d at 984; Hodges 9 F.3d at 961;<sup>5</sup> see also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

<sup>3</sup> This 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. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) (hereinafter "Program," "Vaccine Act" or "the Act"). Hereafter, individual section references will be to 42 U.S.C. §§ 300aa of the Act.

<sup>4</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, 371-72 (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).

<sup>5</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. 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). See also Cedillo v. Sec'y of Dept. of Health & Human Servs., 617 F.3d 1328, No. 2010-5004, slip op. at 12-14, 2010 WL 3377325 (Fed. Cir. Aug. 27, 2010)(approving the use of the Daubert factors in examining the reliability of expert testimony); Moberly v. Sec'y of Dept. of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010)(citing Daubert; approving of the use of the Daubert factors in determining expert reliability). 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 from, 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 "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 593. However, the Supreme Court has provided guidance to the lower courts in determining the reliability of a novel proposition:

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. Petitioners do not 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. Also, 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 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 (3) 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 petitioner’s 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)( “Capizzano III”). Moreover, the Federal Circuit stated, [t]he 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 legal requirement that petitioners support their proposed causation theory with a “sound and reliable medical or scientific explanation” is undisturbed. Knudsen, 35 F. 3d 543, 548 (Fed. Cir. 1994). As the Federal Circuit recently reiterated:

Although Althen and Capizzano make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it

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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. (citation omitted). 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 v. Sec’y of Dept. of Health & Human Servs., 418 F.3d 1274,1280 (Fed. Cir. 2005)( “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).

in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury. See Daubert, 509 U.S. at 593-97, 113 S.Ct. 2786 (noting that one factor in assessing the reliability of expert testimony is whether the theory espoused enjoys general acceptance within a relevant scientific community). . . . Althen makes clear that a claimant’s theory of causation must be supported by a “reputable medical or scientific explanation.” 418 F.3d at 1278.

Andreu v. Sec’y of Dept. of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); see also Grant, 956 F.2d at 1148 (“A reputable or scientific explanation must support this logical sequence of cause and effect.”). The Federal Circuit further explained in Andreu:

The assessment of whether a proffered theory of causation is “reputable” can involve assessment of the relevant scientific data. Medical literature and epidemiological evidence must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard . . .

Andreu, 569 F.3d at 1380 (citing Bunting, 931 F.2d 867, 873 (Fed. Cir. 1991)).

Furthermore, “[a]lthough a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness.” Moberly v. Sec’y of Dept. of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010)(citing Terran v. Sec’y of Dept. of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999)(holding that the factors set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), may be applied in assessing the reliability of an expert witness’s testimony.)) Special masters, as “finders of fact[,] are entitled - indeed, expected - to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.” Moberly, 592 F.3d at 1326.

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 Cedillo v. Sec’y of Dept. of Health & Human Servs., 617 F.3d 1328 (Fed. Cir. Aug. 27, 2010); 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); de Bazan v. Sec’y of Dept. of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2006) rev’d 539 F.3d 1347 (2008) ( reversed on other grounds).

A finding that petitioners established their *prima facie* burden does not end the inquiry. The Act provides that a petitioner may not receive compensation “if the court finds by a preponderance of the evidence on the record as a whole ‘that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.’” Knudsen, 35 F.3d at 547 (citing §13(a)(1)(B)) (emphasis in original). The question of a factor unrelated is not present in this case. Petitioner’s case is measured against the above standards.

#### Scope of Petitioner’s Claim

Petitioner received both the Hepatitis A vaccine and the Hepatitis B vaccine on April 25, 2011. Prior to filing the Petition *sub judice*, petitioner filed a Petition on September 22, 2003, alleging vaccine-related injuries due to the Hepatitis B vaccination. P Petition, ¶ 6 (hereinafter “Pet.”); P Ex 5.<sup>6</sup> In his 2003 Petition, petitioner alleged vaccine-related injuries caused by “mercury (Thimerosal) toxicity, which directly caused numerous psychological and physical damages for the petitioner.” P Ex 5. The 2003 Petition did not include a claim for the Hepatitis A vaccine as this vaccine was not added to the Vaccine Table until December 1, 2004. Petitioner withdrew the 2003 Petition, which was premised upon receipt of the Hepatitis B vaccine, on November 1, 2004, pursuant to § 21(b) of the Act. See Memorandum and Order at 3 (discussing the withdrawal of petitioner’s Hepatitis B Petition pursuant to 42 U.S.C. § 300aa-12(g), -21(b)). With the addition of the Hepatitis A vaccine to the Table, petitioner filed his current claim on July 17, 2006.

At numerous instances in his Memorandum and in the evidence, petitioner discusses either both vaccinations together or the Hepatitis B vaccine alone as causing his conditions. P Memorandum in Support of Causation at 1, 2, 2 n. 3, 4, 5, 10, 12, 13, 14, filed March 4, 2011 (hereinafter “P Memo”). However, as discussed in the decision of the previous special master, Judge Miller’s decision and respondent’s Response Memorandum, petitioner’s claim for causation related to the Hepatitis B vaccine was filed in a prior Petition, which was withdrawn per petitioner. Memorandum Opinion and Order at 3; R Response Memorandum at 6.

During the course of this case, petitioner attempted to amend his Petition to include the claim for the Hepatitis B vaccine. This attempt was denied. Special Master Order, filed January 30, 2008; see also Veryzer v. Sec’y of the Dept. of Health & Human Servs., No. 06-522V, 2010 WL 5185485, \*2 (Fed. Cl. Spec. Mstr. Aug. 9, 2010). Petitioner did not appeal that decision. See P Memorandum of Objections in Support of Motion for Review at 1-2, filed September 7, 2010 (objecting to an allegedly skewed procedural account of the case but failing to raise objections to previous special master’s decision to deny amendment of the claim to include the Hepatitis B vaccine). Accordingly, the undersigned’s review of the medical records is limited to whether the records support a causative role for petitioner’s Hepatitis A vaccination.

In support of this claim regarding Hepatitis A, petitioner at times attempts to conflate the alleged vaccine reactions with the components of both the Hepatitis B vaccine and those of the Hepatitis A vaccine. Petitioner states directly that petitioner’s “progressive, significant cognitive and physical decline was proximately caused by an adverse reaction to the component parts of the Hepatitis A and Hepatitis B vaccines.” P Memo at 1-2. Dr. Astruc states, “it is my opinion that [petitioner] has suffered an adverse reaction to the component parts of the vaccines he was administered.” Docket 70-1, p. 1. Petitioner refers to the expert report of Dr. Nass, which was filed in support of petitioner’s previous Hepatitis B Petition and before Hepatitis A was covered by the Vaccine Act, and states that the lack of Table coverage for the Hepatitis A vaccine “explains why Dr. Nass only referred to the Hepatitis B vaccine.” Id. at 5. This is pure speculation and highly doubtful. A credible expert would opine to the cause of petitioner’s

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<sup>6</sup> Petitioner filed many documents without exhibit numbers and the numbering for those documents with exhibit numbers is not entirely consistent. For consistency in this Decision, documents other than those filed with the initial Petition will be referenced herein by the Docket entry number and document number, ie. “Docket 17-18” is the document at Docket entry 17, attached document number 18. Documents filed with the Petition are designated by exhibit numbers and those designations will be used for those exhibits only. Of note, many exhibits of petitioner’s medical records are duplicative and when cited, only one citation is provided. It is noted that respondent utilized an exhibit numbering system in her brief.

injury based upon the medical evidence, not based upon which causative agent is covered by the Vaccine Act.

Petitioner also attempts to explain why the treating doctors refer to “vaccines” generally when discussing possible causes as opposed to identifying specifically the Hepatitis A vaccine or the Hepatitis B vaccine. Regarding this, petitioner states that “the physicians opined that it was the common component parts” that caused petitioner’s injuries. P Memo at 5. This is an overly liberal argument considering the medical evidence herein. As will be discussed, a physician, Dr. Astruc, did refer to the common component parts of the vaccinations, however most did not. This is an important point for several reasons; the most important of which is that there is a critical difference evidenced in this record between the Hepatitis A vaccine and the Hepatitis B vaccine. The Hepatitis A vaccine never contained thimerosal, the mercury-based preservative that was an ingredient in petitioner’s Hepatitis B vaccine and that is the basis for many of petitioner’s claims regarding heavy metal toxicity. See, e.g., R Response to Petitioner’s Memorandum (hereinafter “R Response”), Exhibit Tab 1, Thimerosal Content in Vaccines; P Memo at 2, n.3; P Memo at 12; see also U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm096228.htm> (last visited April 18, 2011). There is no evidence in this record that identifies specifically the “common component parts” shared by the two vaccines, much less those responsible for petitioner’s injuries. Petitioner’s assumptions that claims regarding the Hepatitis B vaccine equate to claims regarding the Hepatitis A vaccine are simply unsupported assumptions and petitioner proffered no reliable evidence upon which to rest these assumptions.

Petitioner’s claim regarding causation in this matter is limited to his receipt of the Hepatitis A vaccine. Evidence regarding the Hepatitis B vaccine is disregarded.

#### Procedural History

This Petition for compensation was filed under the Vaccine Act on July 17, 2006. P Pet., filed July 17, 2006. The Petition alleged that petitioner suffered vaccine-related injuries due to a Hepatitis A vaccination petitioner received on April 25, 2001.<sup>7</sup> Included with the Petition were numerous medical records, petitioner’s CV, documents from the prior actions, vaccine prescribing information, and a report from Donald Marks, MD, PhD, which predominately refers to the Hepatitis B vaccination petitioner received on the same day. Additional records were requested from petitioner, but records were not supplied until after the filing of respondent’s Rule 4(c) Report. R Rule 4(c) Report at p. 2, n2, filed October 16, 2006. On October 16, 2006, respondent filed the Rule 4(c) Report, arguing that compensation was not appropriate.

Following the Rule 4(c) Report, petitioner filed a report by Dr. Marc Girard, which also predominately mentions the Hepatitis B vaccination. P Expert Report, filed March 9, 2007. Thereafter, petitioner filed numerous medical records. Response to Discovery Request, filed March 9, 2007; Response to Discovery Request, filed April 11, 2007.

On April 6, 2007, petitioner filed a Motion to Amend Pleadings to include allegations pertaining to the Hepatitis B vaccination. P Motion to Amend Pleadings, filed April 6, 2007.

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<sup>7</sup> As noted earlier, petitioner also received a Hepatitis B [“Hepatitis B”] vaccination on the same day. Petitioner withdrew the 2003 Petition, which was premised upon receipt of the Hepatitis B vaccine, on November 1, 2004, pursuant to § 21(b) of the Act. The present matter is based on petitioner’s allegation that his alleged injuries were caused-in-fact by the Hepatitis A vaccine received on April 25, 2001. Supra p. 5-6.

Petitioner's Motion was denied on January 30, 2008. Petitioner thereafter filed two expert reports. P Expert Report, filed August 26, 2008; P Expert Report, filed August 27, 2008. Respondent filed Motions *In Limine*. R Motion, filed October 17, 2008; R Motion, filed October 20, 2008. These expert reports were subsequently excluded, Order, filed May 19, 2010, and on August 9, 2010, the special master previously assigned to this case dismissed the Petition for want of proof. Decision, filed August 9, 2010.

Petitioner filed a Motion for Review on September 7, 2010, arguing the special master's decision regarding causation was arbitrary and capricious, that the special master erred in excluding the petitioner's experts, and that the special master abused his discretion in denying petitioner an evidentiary hearing related to the excluded experts. P Motion for Review, filed September 7, 2010. Following briefing and oral argument before the U.S. Court of Federal Claims, petitioner's Motion for Review was granted in part and the case was remanded. Specifically, Judge Miller stated, "the special master did not abuse his discretion by excluding petitioner's expert opinions, but that the special master did not make adequate findings concerning petitioner's medical records." Memorandum Opinion and Order, filed January 28, 2011. Discussing § 12 and § 13 of the Act, Judge Miller held that the Act requires a special master to make factual findings, pursuant to § 12, and a ruling on the record as a whole pertaining to whether petitioner has shown eligibility to compensation, pursuant to § 13. Memorandum Opinion and Order at 19. The judge found the previous "special master failed to make factual findings that adequately articulate his reasons for concluding that petitioner's medical records are insufficient to establish" causation under the Act and "failed to explain on any level why petitioner's medical records, 'do not manifestly support the petitioner's claim of vaccine causation.'" Id. at 20. Judge Miller remanded the case for "findings of fact and conclusions of law concerning petitioner's medical records." Id. at 21. The Memorandum and Order directed that a decision on remand be filed by May 2, 2011. Id. at 22.

A status conference was held on February 2, 2011. Minute Entry, filed February 2, 2011. Petitioner expressed the desire to file additional medical records and suggested possibly taking testimony from one of petitioner's treating physicians. Order, filed February 3, 2011. Additional records were filed on February 3, 2011, and February 7, 2011. Another status conference was held on February 8, 2011, wherein respondent voiced concerns that petitioner's submissions, medical reports utilized in a district court case concerning petitioner's long-term disability claim, exceeded the scope of the remand, which was to consider petitioner's medical records. Order, filed February 9, 2011. Some of the filed reports appeared to be from treating physicians and another report was from a physician familiar in this Program, Dr. Geier. During the status conference, petitioner affirmatively stated he would not be relying upon Dr. Geier's report. Id. A schedule was established to proceed.

In belated compliance with the February 9, 2011 Order, petitioner filed his Notice of Intent to Rely on Letter Report of Petitioner's Treating Physician, Manuel Astruc, M.D. P Notice, filed February 28, 2011. The Notice stated that unless requested by the special master, "petitioner does not intent to take Dr. Astruc's live testimony, which petitioner anticipates would simply reiterate the information contained in the previously filed medical records and report." Id. Respondent filed a Status Report on March 2, 2011. The undersigned's previous Order directed respondent to file a responsive medical opinion if petitioner presented the opinion of a treating physician. Order, filed February 9, 2011. Respondent's status report noted a change in Dr. Astruc's causation opinion, referencing petitioner's exhibits 45 and 70. Respondent stated that she could not determine whether a responsive expert was necessary as petitioner's letter from Dr. Astruc lacked "critical information necessary to establish petitioner's claim." Id. In

order to make the determination of whether respondent needed to file a responsive medical opinion, respondent posed four questions to Dr. Astruc. *Id.* A status conference was held on March 3, 2011, and to respondent's four questions, the undersigned added two. Order, filed March 3, 2011. During the status conference, petitioner's counsel asserted that answers to the questions posed to Dr. Astruc would be explained in petitioner's brief discussing his medical records. *Id.* However, the undersigned emphasized to petitioner's counsel that the "lawyer's explanations are not a substitute for the expert's elucidation of causation." *Id.* Thereafter, the parties filed their memoranda regarding petitioner's medical records and other evidence, including Dr. Astruc's supplemental report and medical literature filed by petitioner. P Memorandum in Support of Causation at 2, filed March 4, 2011 ("P Memo"); P Supplemental Report of Dr. Astruc, filed March 18, 2011; P Notice of Filing Published Articles in Support of Claim, filed March 18, 2011; R Response, filed March 25, 2011.

A status conference was held on April 1, 2011, wherein the undersigned offered the parties the opportunity for further proceedings. Both sides agreed that further proceedings, including the taking of testimony from Dr. Astruc, were unnecessary. Minute entry, filed April 1, 2011.<sup>8</sup> At this point, the parties agreed this case is ripe for a decision on remand pursuant to Judge Miller's Memorandum Opinion and Order.

#### Petitioner's Affidavit

Petitioner's affidavit was filed on November 25, 2008.<sup>9</sup> P Aff, filed November 25, 2008. Petitioner describes his life prior to the vaccinations, including his career achievements and scholarly pursuits. *Id.* at 1-2. Based upon upcoming international travel, petitioner explains that he received the vaccinations per his doctor's recommendations. *Id.* at 2. He states he began experiencing physical, cognitive and emotional symptoms within hours of receiving the vaccination.<sup>10</sup> He states he experienced chills, mild joint aching, fatigue, disorientation and forgetfulness on the day of the vaccines. P Aff at 2. He explains that symptoms worsened over the next days, to include symptoms of [REDACTED] constipation, rashes and skin outbreaks, itching and fever. *Id.* He states his primary care doctor diagnosed him with a urinary tract infection and that this doctor did research on vaccine reactions and found a case of a vaccine causing permanent nerve damage.<sup>11</sup> Petitioner lists doctor visits wherein no causation was identified for his symptoms. *Id.* Petitioner claims additional damage was done to [REDACTED]

<sup>8</sup> After some review of the materials, the undersigned identified a possible discrepancy regarding Dr. Astruc's board certification. Although petitioner stated Dr. Astruc was board certified in psychiatry and neurology, the undersigned found Dr. Astruc was only certified in psychiatry according to the certifying entity's website. On April 18, 2011, petitioner was asked to clarify this issue. Order, filed April 18, 2011. Petitioner responded to this Order on April 20, 2011, stating Dr. Astruc holds board certification in psychiatry only. P Response to April 18, 2011 Order, filed April 20, 2011.

<sup>9</sup> In petitioner's Memorandum in Support of Causation at p. 8, filed March 4, 2011, petitioner cites the affidavit as Docket 42, Exhibit A. This document is actually Docket 41-2, also labeled Exhibit A.

<sup>10</sup> Of note, petitioner's contemporaneous medical records only note petitioner's complaints of chills and generally not feeling well on the day of his vaccinations, which he reported improved. *E.g.*, P Ex 10 at p. 32.

<sup>11</sup> Petitioner's primary care doctor and others seem to have first relied upon petitioner's alleged research with the vaccine manufacturer, *see, e.g.*, P Ex 13; P Ex 15; P Ex 21, p. 1. However later, through his own investigation, the treating doctor failed to find cases of vaccine reactions similar to petitioner's. P Ex 14 (telephone message indicating Dr. Marinello spoke to a representative of the vaccine manufacturer indicating there were no reports of [REDACTED]; P Ex 11 (letter from Dr. Marinello to petitioner stating no reports of [REDACTED] have been reported in association with either vaccine petitioner received); P Ex 16 (telephone notes relating to the lack of reports of [REDACTED] related to the vaccinations).



Minnesota. Petitioner recalls two visits to the emergency room in July 2001 for extreme pain.<sup>12</sup> Petitioner also describes a plastic surgery consult for an infection on his face that was “due to impairment of the immune system post-vaccinations.”<sup>13</sup> Petitioner also notes his parents’ efforts to take care of him during his struggles. Several other visits to treating physicians are discussed, noting issues with petitioner’s thyroid and potentially his pituitary. P Aff at 4. He describes an incident in January 2002, where he was transported to a hospital in an unconscious state.<sup>14</sup> Following this, petitioner discusses undergoing testing that “suggested heavy metal intoxication as the likely cause of my medical problems.” *Id.* at 5. Finally, petitioner describes professional, emotional and social struggles he faced thereafter.

### The Parties Briefs on the Medical Records

As noted by Judge Miller, “[t]he medical records offer inconsistent indications of possible causation . . .” Memorandum Opinion and Order, p. 19. The purpose of this remand is to determine whether petitioner’s medical records offer preponderant evidence that petitioner’s Hepatitis A vaccination is responsible for his alleged injuries. Specifically, the parties were ordered to file briefs discussing evidence found in petitioner’s medical record pertaining to vaccine causation. Order, filed March 3, 2011. Upon review of the medical records and the parties’ briefs, an overarching observation the undersigned makes is that petitioner engaged numerous doctors shortly after vaccination and there was no consensus that petitioner’s complaints were vaccine-related. Specialists, in discussing medical information pertinent to their specialty, found little or no objective evidence of a vaccine-related reaction. While several did raise a possibility of vaccine relatedness, such possibility was rejected or discounted after reviewing the clinical data. At other times, specialists operating outside of their specialty noted a possible vaccine reaction. These references are by doctors of one specialty raising the possibility that the alleged condition or dysfunction is attributable to a mechanism that is the subject of another medical specialty. That is, the doctor raising the possibility is likely not qualified to make the link and is not in fact doing so; the doctor is merely raising the possibility that petitioner’s answers lie with another specialist. Petitioner many times relies upon such speculative statements, fails to acknowledge the unsupportive statements of the same doctors and patently overstates language in the doctors’ reports. The undersigned finds such efforts unpersuasive. A detailed account of the relevant records follows.

In many instances, petitioner claims he was in excellent health, physically and mentally, prior to receipt of the Hepatitis A vaccination on April 25, 2001. P Memorandum in Support of Causation at 2, filed March 4, 2011 (“P Memo”). However, as noted by respondent, petitioner experienced similar physical and emotional difficulties prior to immunization. R Response at 9-11, Docket 17-1. Petitioner begins his brief by discussing the initial reaction evidenced in Dr. Marinello’s records. Petitioner states he “developed significant symptoms such as nausea,

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<sup>12</sup> These visits appear, from the medical records, to have been initiated due to petitioner’s [REDACTED], P Ex 23, and also a visit for nausea and a tingling sensation, P Ex 24. The visits also evolved into psychological evaluations due to petitioner’s concerned condition over these symptoms.

<sup>13</sup> Petitioner’s [REDACTED], which some treating physicians opined may have been the cause of some of petitioner’s symptoms that he attributed to the alleged vaccine reaction. P Ex 15, p. 3 (noting petitioner’s symptoms, with the exception of the [REDACTED], may be attributable to an atypical manifestation of [REDACTED]); P Ex 18 (Dr. Marinello note that he agreed with Dr. Saririan that petitioner’s presentation may be attributable to the prodrome of that infection).

<sup>14</sup> Per the medical records, petitioner’s unconscious state and emergency room visit was due to [REDACTED] P Ex 25, filed July 17, 2006.

rashes, neuralgia, as well as cognitive impairments, extreme mood swings and persistent fatigue” “[o]ver the two days following the injections.” P Memo, p. 2-3. The undersigned reviewed each of the records petitioner cited for these initial symptoms. Of note, petitioner suspected a vaccine reaction almost immediately when he was not feeling well and when he first noted [REDACTED] [REDACTED]. E.g., P Ex 10 (noting telephone call with petitioner on April 28, 2001, wherein petitioner expressed concern of a vaccine reaction after not feeling well after vaccination and developing [REDACTED]). It was often the first question or statement recorded in histories given by petitioner in the medical records. This is noteworthy because, unlike many cases where treating physicians are not investigating causation, petitioner presented his many treating physicians with the question of whether this was vaccine-related. Even with this question presented contemporaneously with petitioner’s alleged reaction, treating physicians still did not identify the Hepatitis A vaccine as being causative and only entertained a possibility of a vaccine reaction. Clearly, Dr. Marinello’s records do not support petitioner’s claim.

The medical records at Docket 17-2 have some records previous to the vaccine but pick up at May 15, 2001, after the April 25, 2001, vaccines. The symptoms described in the May 15, 2001, record include lack of [REDACTED], chills, generally feeling ill and [REDACTED]. Docket 17-2, p. 3. It is during a call with Dr. Marinello on May 15, 2001, that petitioner says he spoke with a representative of the vaccine manufacturer and was told there were other reports of [REDACTED] following vaccination. *Id.* This information was later found to be incorrect or inaccurate. *Id.* (May 17, 2001, call between Dr. Marinello and a vaccine manufacturer representative); *id.* at 2 (May 18, 2001, call between petitioner and Dr. Marinello); *id.* (May 18, 2001, call between Dr. Marinello and second vaccine manufacturer representative); Docket 17-3, p. 18 (letter from Dr. Marinello to petitioner). In a letter dated April 30, 2001, Dr. Marinello stated he had done research and there were “no reports from the manufacturer of any [REDACTED] associated with either vaccine.” Docket 17-1, p. 10. Dr. Marinello further stated, “I would think that this [REDACTED] is more of a coincidence than a side effect . . . .” *Id.* However, the doctor continued, “[a]s I previously stated . . . you probably should not receive any further Hepatitis B because of the initial reaction that you experienced.” *Id.* In an even earlier letter, dated April 30, 2001, Dr. Marinello stated “[t]here have been no reports from the manufacturer of any [REDACTED] associated with either vaccine. I would have to think that this is more of a coincidence than a side effect which should resolve spontaneously.” P Ex 11.

A visit on May 16, 2001, evidences the above symptoms plus tingling in his face, a rash and a [REDACTED]. Docket 17-2, p. 4. “Fatigue/malaise” and “Fever/chills” are marked in “Review of Symptoms.” *Id.* Laboratory tests later indicate the [REDACTED] is due to [REDACTED]. See, e.g., Docket 17-2, p. 5; Docket 17-3, p. 4. Docket 17-3 includes a [REDACTED] record from May 7, 2001, wherein petitioner also complained of [REDACTED] [REDACTED] however, petitioner denies a history of fever or chills in this record. Docket 17-3, p. 2.

At an infectious disease consultation on May 17, 2001, petitioner complains of arthralgias, facial tingling, malaise, rash, [REDACTED] hives, dysuria, constipation, swollen glands, nausea but denies urinary frequency or urgency, weakness, parasthesias and dysthesias. *Id.* at 6. Docket 17-5 appears to be telephone messages from Dr. Marinello’s office. Docket 17-7 includes more telephone calls with Dr. Marinello’s office. Docket 17-7, p. 1. Another message relates an [REDACTED] pre-dating the vaccination by approximately six months. *Id.* Other notes from April 30, 2001 and May 7, 2001, are messages wherein petitioner requests vaccine information on the Hepatitis A and Hepatitis B vaccines he received,

but this message does not relate petitioner's specific complaints. *Id.* at 2-3. A second note on April 30, 2001, relays petitioner's complaints of [REDACTED] a flushed face, urinary burning and urgency and arthralgias. *Id.* at 3. Docket entry 64 includes seven sets of records and reports.

Dr. Alboum's records appear to represent this physician's opinion regarding petitioner's condition as of 2008 and 2009. Docket 64-1, pp. 1-2, 7. Dr. Alboum's opinion was that petitioner's condition was the result of the Hepatitis B vaccination, and **possibly** the Hepatitis A vaccination. *Id.* at 1. The complaints petitioner relayed to Dr. Alboum are a compilation of those already noted above. Dr. Alboum identifies petitioner's high "Thimerosal (Mercury)" levels as causative of his condition. *Id.* at 2. As noted elsewhere, the Hepatitis A vaccine petitioner received **has never contained thimerosal**. Other records within Docket 64-1 include diagnostics showing petitioner had abnormal levels of mercury, calcium, copper, vanadium, zinc, sodium, potassium, iron, manganese, molybdenum and germanium in diagnostics perform in February 2002, March 2002, and July 2005. *Id.* at 3-6, 8-19.

Docket 64-4 is records of petitioner's evaluation by Dr. Lifrak. It appears that a thorough neuropsychological exam was performed in 2006, approximately five years after vaccination. Docket 64-4, p. 1. Dr. Lifrak references thimerosal toxicity, concluding he suffers from toxic mercury poisoning in a rather conclusory fashion, *id.* at 16; again, the Hepatitis A vaccine is thimerosal free. Docket 64-5 are petitioner's records from Dr. Mansfield, D.O., who petitioner saw in 2010. Dr. Mansfield attributes petitioner's hypothyroidism to mercury poisoning without explanation. Docket 64-5, p. 3. Docket 64-6 includes records from Dr. Mustafa, who petitioner saw starting in 2005, four years after vaccination. Dr. Mustafa associates petitioner's problems with mercury poisoning. Docket 64-6, p. 6. A 2008 letter from Dr. Mustafa details the overall deterioration of petitioner in 2007, again attributed to mercury poisoning without further explanation. *Id.* at 10. Docket 64-7 includes records from Dr. Hyman, who states in a letter that he is treating petitioner for the ongoing illness plaguing petitioner since receipt of the vaccinations. Docket 64-7, p. 1. Dr. Hyman generically references petitioner's test results and symptoms being "consistent with vaccine (inclusive of Thimerosal/Mercury, Aluminum, etc) damage/poisoning." *Id.* Again, Dr. Hyman's letter is conclusory, failing to explain his opinion or how it pertains to the Hepatitis A vaccine specifically. *Id.*

Docket 66 includes nine documents. Docket 66-1, also labeled Exhibit 47, evidences an "attending physician's statement" from Dr. Mustafa regarding petitioner's ability to work and release forms. Docket 66-2 is a letter from Dr. Astruc, who petitioner utilized for a medical opinion on causation, and this letter is discussed elsewhere in this Decision. *Infra* pp. 18-22. Docket 66-3, also referenced as Exhibit 49, appears to be a responsive report from Dr. Alboum regarding petitioner's long-term disability dispute. This report continuously references thimerosal poisoning and the Hepatitis B vaccine. Docket 66-3, p. 3. At one point Dr. Alboum references "substances included in the vaccines" and VAERS reports of adverse reactions, without explanation or citation. *Id.* at 6. Docket 66-4, also Exhibit 50, is another report from Dr. Alboum referencing thimerosal toxicity throughout, a **possibility** of demyelination and neuropathies due to vaccinations generally, Docket 66-4, p. 4, and other toxic responses to the substances in vaccines that **may** cause damage, *id.* at 9.<sup>15</sup>

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<sup>15</sup> Of note, Dr. Alboum references decisions of the U.S. Court of Federal Claims that identified thimerosal as playing a role in vaccine injuries. No cases are cited. Also, Dr. Alboum responsive report references VAERS reports but does not discuss or acknowledge reliability concerns related to such reports. See *Manville v. Sec'y of the Dept. of Health & Human Servs.*, 63 Fed. Cl. 482, 494 (Fed. Cl. 2004)(discussing a special master's review and dismissal of VAERS data proffered by petitioner).

Docket 66-5, also Exhibit 51, is a responsive letter from Dr. Lifrak questioning the long term disability reviewer's assessment of petitioner and does not shed light on causation for this case. Docket 66-6, also labeled Exhibit 52, is another letter from Dr. Alboom regarding petitioner's long term disability dispute and also sheds no light on causation in this case. Docket 66-7, Exhibit 53, another responsive report from Dr. Alboom disagreeing with a toxicology report in petitioner's long term disability dispute case. This report again argues the harmful effects of thimerosal, Docket 66-7, p. 3, which is not present in the Hepatitis A vaccine. At one point though, Dr. Alboom states without explanation, "the Hepatitis A vaccine, and its interaction with the Hepatitis B vaccine, can be damaging as well . . . ." *Id.* at 5. Docket 66-8, the report of Dr. Mark Geier, is not being relied upon by petitioner and also primarily discusses the Hepatitis B vaccination, not at issue here. Order, filed February 9, 2011. Docket 66-9 is the Decision of the U.S. District Court of the Southern District of New York regarding petitioner's long term disability dispute. As this decision is not a medical record, the undersigned finds it unnecessary to credit it for the purpose of this remand. Further, the decision discusses thimerosal toxicity and as the undersigned has repeatedly noted, thimerosal was not a component of petitioner's Hepatitis A vaccine.

Next, petitioner discusses his visits to treating physicians shortly after vaccination. P Memo at 3. Petitioner first references the infectious disease evaluation with Dr. Liebers. Docket 17-18. The portion of Dr. Liebers' report upon which petitioner relies states, "[t]he **possibility** of a post-vaccination polyneuropathy or autoimmune process is very difficult to exclude." Docket 17-18, p. 3 (emphasis added). However, in that paragraph, Dr. Liebers appears to rely upon petitioner's statements that the vaccine manufacturer had reports of [REDACTED] following the Hepatitis B and Hepatitis A vaccinations. *Id.* As respondent points out, R Response at 12, Dr. Liebers questions whether most of petitioner's symptoms, with the exclusion of his [REDACTED], are related to an atypical manifestation of the [REDACTED]. Docket 17-18, p. 3. Other physicians also wondered about this point. *See supra* p. 9, n. 13. Respondent also points out that there is no indication of whether Dr. Liebers was aware of petitioner's pre-existing medical issues. R Response at p. 12 (citing P Ex 11 at 203-205, also found at Docket 17-18). The undersigned finds unpersuasive Dr. Liebers' statement regarding a "possibility" of a vaccine reaction. Further, his explanation following this statement is based upon medical information that was evidently provided by petitioner, which later proved to be inaccurate and was incomplete. *See supra* p. 9, n. 11. A doctor's statement considering a possible vaccine reaction that is premised upon faulty information and is one part of a record that includes questioning whether the majority of the symptoms are attributable to an alternative cause, [REDACTED] does not help petitioner meet his burden. *See Burns v. Sec'y of the Dept. of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993)(affirming the special master's decision that taking testimony of a treating physician was unnecessary when the physician's opinion was based on facts not substantiated by the record).

Petitioner cites his neurological evaluation by Dr. Beesley. Docket 17-19. Petitioner admits that Dr. Beesley found petitioner to be neurologically intact, P Memo at 3, but petitioner relies upon Dr. Beesley's statement that mild anisocoria<sup>16</sup> was present. P Memo at 3; Docket 17-19, p. 2. From this statement, petitioner asserts that anisocoria is "indicative of a neurological problem." P Memo at 3. There is no support for petitioner's statement and this is not noted by Dr. Beesley in his report. Petitioner also relies upon Dr. Beesley's statement that petitioner "may have had an autoimmune reaction from the vaccine. This could have caused some mild

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<sup>16</sup> "[I]nequity in diameter of the pupils." Dorland's Illustrated Medical Dictionary, 92 (30th Ed. 2003).

demyelination.” P Memo at 3, Docket 17-9, p. 2. However, petitioner’s quotation is taken out of context. Petitioner fails to quote Dr. Beesley’s next statement, “I find almost nothing on exam that would suggest this[, demyelination].” Further, the doctor states that he “entertained the possibility of purely autonomic dysfunction as a result of the inflammation from the vaccination but again there are no systemic symptoms. In addition, I find it odd that he has had marked [REDACTED] although he continues to have [REDACTED] full control of his bowel and bladder.” Docket 17-19, p. 2. Finally, Dr. Beesley notes that if petitioner was suffering from mild demyelination, it stabilized or was improving and should resolve within two months. *Id.* The undersigned finds Dr. Beesley’s assessment of petitioner detracts from the evidence of a vaccine reaction. He specifically notes there were no neurologic findings and did not note any importance to petitioner’s anisocoria. It appears that he entertained the possibility of a vaccine reaction but, in the absence of any clinical support, offered no opinion or assessment.

Next, petitioner relies upon a second neurological consultation with Dr. Rapp, who is certified in neurological surgery and saw petitioner in July 2001. Docket 18-1, pp. 3-6. Dr. Rapp reports that petitioner was told by persons at the Mayo Clinic that the vaccinations “did something to his nervous system, causing neuralgias.” *Id.* at 3.<sup>17</sup> Petitioner relies upon Dr. Rapp’s statement that petitioner’s symptoms “may be due to wallerian degeneration.” Docket 18-1, p. 6; P Memo at 4 (emphasis added). It is not found in Dr. Rapp’s report but petitioner states wallerian degeneration is a type of demyelination, citing an internet medical dictionary.<sup>18</sup> Respondent points to Dr. Rapp’s statement that petitioner’s symptoms “are unusual for a Hepatitis A and Hepatitis B reaction.” R Response at 14; Docket 18-1, p. 6. The undersigned notes that Dr. Rapp does not identify the Hepatitis A vaccine as being causative. Dr. Rapp’s examination appears to have elicited normal findings for petitioner. Docket 18-1, pp. 4-5. While Dr. Rapp states that he believes petitioner’s “symptoms may be due to wallerian degeneration,” he does not reference any examination findings, nor does he discuss any relationship to petitioner’s immunizations, specifically the Hepatitis A vaccination. Dr. Rapp is unhelpful to petitioner’s case.

<sup>17</sup> Apparently, this indication from the Mayo Clinic is not relied upon by petitioner as he did not cite the Mayo Clinic records in his Memorandum. Petitioner’s Exhibit 22 is a letter from the Mayo Clinic, wherein a “final diagnosis” is noted as “[REDACTED] following Hepatitis A and Hepatitis B vaccination.” P Ex 22. The undersigned notes that this single page letter, P Ex 22, only notes the [REDACTED] followed petitioner’s vaccinations, a bare temporal relationship. From this letter, it appears that petitioner was seen by five doctors at the Mayo Clinic between June 14, 2001 and June 21, 2001. The underlying records appear to be filed at Docket 18-9. Like petitioner’s Exhibit 22, the most these records comment on causation is to note the [REDACTED] began after the vaccinations. Dr. Edson states, “[i]t is very difficult to say whether or not this is a result of the Hepatitis B vaccine.” Docket 18-9 at p. 2. This physician acquired “scattered case reports” of [REDACTED] and “the vaccination.” *Id.* Presumably, Dr. Edson was referring to the Hepatitis B vaccine. Dr. Mynderse referenced these case reports as well and noted, “I am questioning the true benefit of reviewing the six or eight cases out of these three databases as they are a small number of total cases out of many, many doses of vaccinations that have been given.” *Id.* at 3. Dr. Mynderse also cautioned petitioner about making interpretations from these case reports. *Id.* A later note of Dr. Wonski referencing the Mayo Clinic visit states, “[t]he [REDACTED] today clearly states that at Mayo they did not say that this was related to the Hepatitis A or B shots.” Docket 17-21, p. 6. The affirmative piece of information petitioner apparently took from the visit to the Mayo Clinic was that his [REDACTED] was not related to [REDACTED] Docket 18-9, at p. 4.

<sup>18</sup> According to Dorland’s Illustrated Medical Dictionary, wallerian degeneration is “fatty degeneration of a nerve fiber that has been severed from its nutritive centers.” Dorland’s Illustrated Medical Dictionary, 483 (30<sup>th</sup> Ed. 2003). The Dorland’s entry also references “dying back,” which is defined as “degeneration of an axon beginning distally and progressing to more proximal areas.” *Id.* at 572 (emphasis added). As demyelination is defined as “destruction, removal, or loss of the myelin sheath of a nerve or nerves,” the two processes do not appear totally identical. Petitioner’s definition, found in an online medical dictionary, does discuss segmentation of myelin. P Memo at 4 (citing <http://medicaldictionary.thefreedictionary.com/wallerian+degeneration>). And Dr. Rapp’s report discusses remyelination. Docket 18-1, p. 6. However, without a medical explanation, the undersigned can give little weight to petitioner’s counsel’s interpretation of Dr. Rapp’s statement on wallerian degeneration.

Petitioner also relies upon the records of Dr. Limeri, an internal medicine specialist. Docket 18-3. Petitioner notes Dr. Limeri's assessment that petitioner had a reaction to the vaccinations. P Memo at 4 (citing Docket 18-3 at p. 3). It is clear from reading Dr. Limeri's report that the information Dr. Limeri was relying upon was provided by petitioner. Under "assessment," Dr. Limeri writes that he will have petitioner get his records from the Mayo Clinic and his last neurologist. Docket 18-3. Dr. Limeri does not note what in his examination or otherwise explain what leads to this opinion.<sup>19</sup> As noted by respondent, Dr. Limeri does not describe any possible mechanism by which this alleged vaccine reaction happened. R Response at 14. It is noted that when Dr. Limeri saw petitioner later in September, Dr. Limeri wrote that petitioner "**allegedly** had side effects from the vaccine." *Id.* at 4 (emphasis added). Dr. Limeri's bald statement made in July 2001 does not help petitioner's case.

Petitioner relies upon a statement by a psychiatrist, Dr. Wright, in August of 2001, suggesting a possible vaccine reaction. Docket 18-4. This examination appears to be solely for psychiatric reasons, with no investigation made regarding causation. Dr. Wright discusses a vaccination reaction as a reiteration of the history and current status petitioner discusses during this session. In his "Diagnosis" note, Dr. Wright states, "[m]ust consider the **possible** reaction to the vaccines that he received." Docket 18-4, p. 2 (emphasis added). However, Dr. Wright also states that "we will ask for clarification from possibly the physicians who have seen him; several specialists have been involved in this at the current time." *Id.* There is no indication in the record of any follow-up visit or note from Dr. Wright, which may have been due to petitioner visiting this doctor while visiting his parents. *Id.* at 1. How petitioner relies upon this record as proof of a reaction to the Hepatitis A vaccine, the undersigned does not understand. There is nothing probative gained from this evaluation regarding the alleged vaccine reaction. Dr. Wright is simply unqualified to opine on vaccine causation and did not do so.

Petitioner discusses a third neurological evaluation by Dr. Seth Wharton. P Memo at 4; Docket 18-6. Petitioner states that Dr. Wharton identified demyelination from the vaccinations as the cause of his complaints. P Memo at 4. However, Dr. Wharton's report states he spent the consultation going over petitioner's records and "[t]he upshot is that at some point [petitioner] was told that demyelination was the explanation for his residual complaints of [REDACTED]" Docket 18-6. Dr. Wharton does not specifically attribute this information to another treating physician. The undersigned could not find a record wherein petitioner was actually diagnosed with demyelination. Drs. Beesley and Rapp suggested it as a possibility but petitioner's examination was essentially normal and no objective evidence of demyelination was found. *Supra* pp. 13-14. Dr. Wharton also notes a brain MRI performed on petitioner was normal. *Id.* Dr. Wharton continues by stating, "I explained to the patient that the diagnosis of demyelinating neuropathy in his case was a **possible diagnosis, not based on any objective evidence.**" *Id.* (emphasis added). He concluded by recommending a psychiatric consultation for petitioner. *Id.* This treating physician specifically stated demyelination was not supported by any objective evidence. It is clear from the record that Dr. Wharton found no support in the records for such a conclusion. He suggested that petitioner see a "[REDACTED]" for any objective evidence of a demyelinating condition. *Id.* There is no record of such a visit. Raising a possible diagnosis without objective support is unpersuasive. Again, the undersigned is uncertain how this record helps meet petitioner's burden as possibility is not probability.

<sup>19</sup> Also, in this record, Dr. Limeri notes that petitioner stated [REDACTED] Docket 18-3, p. 5. Dr. Limeri noted this was not accurate when he consulted with [REDACTED] *Id.*

Dr. Jameson, an endocrinologist, is referenced by petitioner in that this treating physician concluded petitioner had a neurological event following vaccination. P Memo at 4; Docket 18-8. Dr. Jameson did state that he believed petitioner “had a neurological event following immunization.” He stated further that petitioner’s “████████████████████” if present, is due to neurological rather than endocrine etiology.” Docket 18-8, p. 1. However, the statement relied upon by petitioner, regarding a neurological attack on the hypothalamus in small percentage of cases, relates to receipt of the Hepatitis B vaccination. *Id.* There is no discussion of the Hepatitis A vaccine, which is the subject of this Decision. Following the one-page record from Dr. Jameson are multiple pages of what appears to be vaccine information on the Hepatitis B vaccine, which apparently are support for Dr. Jameson’s conclusions. Thus, Dr. Jameson’s findings are unhelpful to petitioner’s Hepatitis A claim. In addition, as respondent notes, Dr. Jameson is not a neurologist and would be less qualified than Drs. Wharton, Beesley and Rapp to opine regarding demyelination or another neurological reaction to the vaccination. R Response at 15.

In February 2002, ten months after petitioner’s vaccinations, petitioner consulted Dr. Lava, another neurologist. P Memo at 4; Docket 18-15. According to petitioner, Dr. Lava suggested endocrine issues have been associated with the alleged vaccine reactions. P Memo at 5. However, petitioner had seen Dr. Jameson, the endocrinologist who noted no endocrine issues. Docket 18-8. Further, it appears that the suggestion of possible endocrine issues was taken from petitioner’s recitation of his history, not from an examination of the records or other diagnostics. Dr. Lava also states that any ongoing neurological attack would be expected to have worsened and that he did not see evidence of any other peripheral nerve problem. Docket 18-15, pp. 3-4. Petitioner’s reliance upon Dr. Lava’s statement regarding endocrine issues related to the vaccinations is misplaced. Dr. Lava is not an endocrinologist. Endocrine issues were ruled out by the endocrinologist, Dr. Jameson. Mere mentioning of the immunizations or reciting a history mentioning immunizations is not evidence of causation. Petitioner repeatedly pulls out of context any reference to the immunization as evidence of causation. Even a cursory examination of the statements in his records dispels this notion.

Next in his Memorandum, petitioner moves to Dr. Alboum’s records and his opinion that petitioner suffered from mercury toxicity. P Memo at 5. Portions of Dr. Alboum’s opinions and records were discussed earlier in this decision. *See supra* pp. 11-12. Petitioner notes Dr. Alboum’s opinion on the mechanism of injury and three diagnostic tests that support Dr. Alboum’s opinion that petitioner suffers from mercury toxicity. P Memo at 5. As noted numerous times, the Hepatitis A vaccine that petitioner received did not contain thimerosal, presumably the mercury component Dr. Alboum references. Thus, Dr. Alboum’s records are not supportive of petitioner’s Hepatitis A claim.

Similar to petitioner’s reliance upon Dr. Alboum’s opinion regarding mercury toxicity, petitioner discusses the 2004 expert report of Dr. Nass, which was submitted in petitioner’s first Vaccine Act petition regarding his Hepatitis B vaccination. P Memo at 5; Docket 75-2, filed March 4, 2011 (also referenced as “Exhibit A”). Dr. Nass opines petitioner’s complaints are caused by the Hepatitis B vaccine, not at issue in this case. Petitioner states, “[a]t the time of this report, reactions to [Hepatitis A] were not subject to this Court’s jurisdiction, which explains why Dr. Nass only referred to the Hepatitis B vaccine.” Without a supplemental report from Dr. Nass, petitioner’s conjecture is unfounded. Petitioner tries to bolster his assumption by stating, “none of [petitioner’s] physicians asserted that it was one vaccine as opposed to the other which caused the adverse reaction, nor could they be expected to point to one over the other; to the contrary, the physicians opined that it was the common component parts of the vaccines which

were the likely cause of the adverse reaction.” P Memo at 5-6. Beyond petitioner lacking grounds to say the opinion of Dr. Nass is applicable the Hepatitis A vaccine and ignoring the fact that the Hepatitis A vaccine has never contained thimerosal, petitioner offers no evidence of the commonality in “component parts” of the Hepatitis A and Hepatitis B vaccines. Petitioner is making an unfounded assumption and, as respondent states, “[t]here is no basis for such an assumption.” R Response at 17. The undersigned agrees. The record is devoid of evidence that the doctors equated the Hepatitis A vaccine with the Hepatitis B vaccine for purposes of causation.

In 2006, a neuropsychological evaluation was performed by Maria Lifrak, PhD. Docket 23-1; also found at Docket 64-4. Petitioner states that Dr. Lifrak concluded petitioner “developed a significant toxic reaction to Hepatitis A and B inoculations . . . .” P Memo at 6; Docket 23-1, p. 16. First, the undersigned notes that Dr. Lifrak is not a medical doctor and thus is highly unlikely to be qualified to diagnose a vaccine reaction. Second, Dr. Lifrak’s evaluation of petitioner did not occur until 2006, five years after vaccination. Upon review of the statement that petitioner quotes, the undersigned finds Dr. Lifrak appears to be reiterating what she was told by petitioner. The objective of petitioner’s evaluation was never to determine vaccine-related causation. The purpose of the examination was to evaluate petitioner’s cognitive and emotional state at that present time. Docket 23-1, p. 1. Petitioner has no grounds to say Dr. Lifrak “concluded” petitioner suffered a toxic reaction to the Hepatitis A vaccine. Or, if that is in fact Dr. Lifrak’s conclusion, she is unqualified to give such an opinion.

The undersigned notes another medical record that could be interpreted as supportive of petitioner’s case concerning the Hepatitis A vaccine, which was not cited by petitioner. Petitioner’s Exhibit 21, filed with the Petition, is a record from Dr. Craig Boss, dated May 31, 2001. Dr. Boss takes a relatively thorough history and it appears that he discussed petitioner’s case with other treating physicians who had seen petitioner. P Ex 21, p. 1. He notes that an infectious disease specialist related petitioner’s initial, transient myalgias and arthralgias, but not ██████████ to the vaccinations. *Id.* He notes a neurologist concurred with this conclusion. It appears that Dr. Boss was given information from petitioner that the vaccine manufacturer confirmed ██████████ was a possible side effect. *Id.* Significant to petitioner’s case, Dr. Boss attributes petitioner’s initial malaise, myalgias and arthralgias to a vaccine-related change. *Id.* In fact, Dr. Boss discussed this possibility with another doctor and identified the Hepatitis A vaccine as most likely to cause these issues. Dr. Boss speculates that the ██████████ is “probably more symptomatic of possible ██████████ vs poss neuropathy like symptoms that may be associated w/ this vaccine.” P Ex 21, p. 1. Dr. Boss also discusses a possible superimposed psychological and anxiety problem for petitioner. *Id.* Dr. Boss later contacts a vaccine manufacturer representative and notes that incidence of reported ██████████ is extremely rare through millions of cases. *Id.* at p. 3. Much concern is expressed about petitioner’s psychological fixation on his condition. *Id.* pp. 1-3. Although Dr. Boss provides some support for petitioner’s initial complaints of myalgias, arthralgias and malaise associated with the Hepatitis A vaccine, this record is unhelpful to petitioner’s broader claims of cognitive, physical and emotional changes due to the vaccine.

Beyond responding to the specific citations petitioner relies upon in the medical records, respondent’s Response notes other portions of the records that call petitioner’s claim into further doubt. Respondent notes that petitioner’s treating physician at the time of the vaccine, Dr. Marinello, noted, “I told him I doubt it very much,” in response to petitioner’s concern that he suffered an episode of ██████████ as a result of his vaccinations.” R Response at 11. Respondent notes petitioner’s consultation with Dr. Saririan, an allergist. *Id.* at 13. Petitioner



saw Dr. Saririan on May 24, 2001. Docket 17-2, p. 27-28; Docket 17-20. Dr. Saririan noted that petitioner's symptoms were "not entirely consistent with immunologic-type sensitivity for the noted vaccines. The onset of symptoms are more or less in line with minor side effects . . . . Continuation of symptoms and development of [REDACTED] could also be, perhaps, related, although [REDACTED] of this duration would be most unusual." *Id.* at 28. Dr. Saririan, assuming petitioner suffered a vaccine reaction, suggested possible serum sickness but noted continuation of this was quite unusual. *Id.* Dr. Saririan suggested petitioner follow up with a [REDACTED] "for management of his [REDACTED] complaints." *Id.* "Dr. Marinello noted that Dr. Saririan noted the [REDACTED] and agreed that the prodrome<sup>20</sup> of that [REDACTED] could have caused many of [petitioner's] symptoms." R Response at 13. Respondent aptly points out that many of petitioner's contemporaneous treating physicians expressed doubt that petitioner's complaints were vaccine-related. R Response at 16.

Respondent summarizes her review of the medical records as:

In short, many of petitioner's treating physicians – particularly those who saw him contemporaneously with the initial onset of his symptoms – attributed his condition to causes unrelated to his vaccinations, such as [REDACTED] or simply expressed doubt that his symptoms were vaccine-related. Of those physicians who entertained the idea that the vaccine played a causal role, it appears that the temporal relationship between vaccination and the onset of petitioner's symptoms was the driving factor. None of the physicians, however, offer a probable medical theory linking the Hep A vaccine specifically to petitioner's symptoms. Rather, they implicate the Hep B vaccination alone, or both the Hep A and B vaccinations.

R Response at 16. The undersigned concurs with respondent's view of the medical records.

The Federal Circuit has instructed the special masters on the importance of treating physician information. Evidence from a treating physician can be "quite probative since treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect shows that the vaccination was the reason for the injury." Andreu v. Sec'y of the Dept. of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009)(internal quotations omitted). However, from experience and practical knowledge, we know to be careful in weighing treating physicians' statements. As aptly stated in Snyder v. Sec'y of the Dept. of Health & Human Servs., 88 Fed. Cl. 706, 746, n. 67 (Fed. Cl. 2009), "there is nothing in Andreu that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted."

This case presents a good case study on why one should carefully evaluate treating physicians' statements prior to leaping to the conclusion that those statements are probative evidence of causation. As seen from the above discussion, many of the physician statements are based upon information supplied solely by petitioner himself, and not on the doctor's independent assessment of the medical records. Several of the statements are made by doctors operating far outside their specialties. Other statements are later undermined by the doctor's own assessment and finding of no objective evidence of the proposed cause. Lastly, many

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<sup>20</sup> Prodrome is defined as, "[A] premonitory symptom or precursor; a symptom indicating the onset of a disease." *Dorland's Illustrated Medical Dictionary*, 1513 (30th Ed. 2003).

statements are couched in terms of possibilities and lack any explanation or support for such a possibility.

In the Remand Decision in Capizzano, the undersigned found that statements from treating physicians tied the case together – these statements bound “the various pieces of circumstantial evidence into a coherent, consistent, medical package” – to prove causation under Althen. In that case, the undersigned agreed with petitioner’s explanation of the role of treating physician records that:

Treating physicians, through their statements in the medical records, establish that [petitioner]: (1) was healthy; (2) had an immediate reaction to her Hepatitis B vaccine; (3) was advised against receiving another vaccine . . . ; (4) had an appropriate temporal relationship between the vaccine and her joint pain; and (5) continues to suffer symptoms of RA[, rheumatoid arthritis]. They also establish: (6) that her physicians believed her RA was associated with her Hepatitis B vaccine; and (7) that there was no likely alternative cause. This evidence, along with the Chief Special Master’s finding that Hepatitis B vaccine **can** cause RA, clearly demonstrate[s] a logical sequence of cause and effect between her vaccine and her RA.”

Capizzano v. Sec’y of the Dept. of Health & Human Servs., No 00-759V, 2006 WL 3419789, \*9 (Fed. Cl. Spec. Mstr. Nov. 8, 2006)(Decision on Remand)(citing petitioner’s Brief at 20).

However, in my experience, treating physicians alone seldom offer enough explanation in their medical records to fulfill petitioner’s burden under the Althen standards of causation. As noted by the petitioner in Capizzano, “in general, treating physicians do not elaborate on medical theories of causation in medical records because they are not relevant to the clinician’s agenda, which is to identify, treat, and heal.” Capizzano v. Sec’y of the Dept. of Health & Human Servs., No 00-759V, 2006 WL 3419789, \*6 (Fed. Cl. Spec. Mstr. Nov. 8, 2006)(Decision on Remand)(internal quotations omitted). Thus, it is generally necessary to either have the treating physician expand in reports and testimony regarding what is stated in the medical records or to have an independent medical expert offer an opinion. In this case, petitioner offered further reports from Dr. Astruc, which are discussed next.

#### Dr. Astruc’s Medical Reports

Dr. Astruc is a board certified psychiatrist<sup>21</sup> who began treating petitioner in 2004, three years after he received the vaccination in question.<sup>22</sup> See, e.g., P Memo at 6. In April 2008, Dr. Astruc provided a letter stating petitioner was diagnosed with [REDACTED] due to heavy metal poisoning. Docket 64-2, p. 1; P Ex 48. In October 2008, Dr. Astruc authored another letter on behalf of petitioner. Docket 64-3, p. 23, filed February 3, 2011. This letter describes petitioner as having a diagnosis of personality change and mental disorder due to brain injury following the Hepatitis A and Hepatitis B vaccinations. Id. Dr. Astruc related petitioner’s story of health and success prior to the April 2001 vaccinations. He also discusses

<sup>21</sup> See supra p. 8, n. 8. Petitioner referred to Dr. Astruc as board-certified in psychiatry and neurology in his Memorandum; however, Dr. Astruc is only board-certified in psychiatry. Docket 81-I (CV of Dr. Astruc).

<sup>22</sup> Docket 64-2, p. 1, 25. Although many of Dr. Astruc’s medical record notes are illegible, petitioner relies upon Dr. Astruc’s reports and these will be focused on by the undersigned. Docket 64-2; Docket 64-3.

the cognitive, emotional and perceptual difficulties he finds petitioner to have since that time. In this October 1, 2008, letter, Dr. Astruc states, “Dr. Veryzer has been quite clear that these symptoms occurred after he received the Hepatitis A and Hepatitis B vaccination[s]. He has attributed this to mercury/heavy metal poisoning.” Docket 64-3, p. 25. Dr. Astruc notes that he does not find a psychiatric reason for petitioner’s condition. Id. He describes the injury as “traumatic injury to the brain” and discusses brain injured patients with similar symptoms following events such as car accidents. He notes, “there has been some focus on mercury and heavy metal poisoning as the causal agent.” Id. Dr. Astruc also notes that petitioner’s problems developed following the vaccine, which, according to him, “implicates the vaccinations as the causal agent.” Id.

On February 28, 2011, following the remand of this case to the undersigned, petitioner filed another letter, an update and summary, from Dr. Astruc. Docket 70-1. Dr. Astruc provides the same diagnoses for petitioner and again recounts petitioner’s difficulties. However, in this letter, Dr. Astruc states petitioner had an adverse reaction to the component parts of the Hepatitis A and Hepatitis B vaccinations. Id. The reasons he gives for this opinion are: the temporal proximity of petitioner’s symptoms to his vaccinations, a lack of other causes for his condition and that petitioner’s symptoms are “consistent with a known potential adverse reaction to such vaccines, namely demyelination . . .” Id. at 2. Dr. Astruc provides no evidence on his last point regarding known vaccine reactions or demyelination associated with the Hepatitis A vaccine; nor does he reference any evidence of demyelination in petitioner’s contemporaneous medical records. Regarding the alleged similarities in the component parts of the vaccination, Dr. Astruc provided no support for this statement. Dr. Astruc characterizes petitioner as suffering from traumatic brain injury “caused by subtle injuries to various parts of the brain.” Id. Without any reference to petitioner’s medical records, Dr. Astruc states that petitioner’s “medical history clearly establishes that his symptoms occurred after he received the Hepatitis A (containing aluminum) and Hepatitis B vaccinations (containing thimerosal and aluminum).”<sup>23</sup> Id. He states, “[t]here have been documented cases evidencing the onset of demyelination in patients shortly after vaccinations” and “medical literature provides support for the link between demyelination and vaccinations.” Id. Again, Dr. Astruc notes the timing between the vaccinations and petitioner’s alleged symptoms. Another point that implicates the vaccinations, per Dr. Astruc, is petitioner’s progressive and significant decline. Docket 70-1. He states petitioner’s cognitive, sensory and movement impairments correlate to nervous system damage attributable to the vaccinations. Additionally, Dr. Astruc states, “I can see no other cause, physiological or emotional, for his impairment.” Id. at p. 1. Given that Dr. Astruc began seeing petitioner three years after vaccination, Dr. Astruc’s specialty in psychiatry and the utter lack of reference to petitioner’s medical records, it is uncertain how Dr. Astruc is qualified to rule out other causes that are not psychiatric. The letter concludes with descriptions of petitioner’s life before and after vaccination.

Given the lack of reference to medical records, a lack of support for the medical opinions he gives and overly broad and vague parts of Dr. Astruc’s opinion, petitioner was ordered to file a supplemental opinion from Dr. Astruc addressing six questions posed by respondent and the undersigned. Order, filed March 3, 2011; see 42 U.S.C. § 300aa-12(d)(3)(B) (allowing the

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<sup>23</sup> Again, Dr. Astruc does not reference petitioner’s medical records and thus does not address the similar issues with which petitioner presented before vaccination. It appears that he relies upon petitioner’s own account regarding the temporal association between the onset of the alleged injury and the vaccine. Docket 70-1, p. 1 (“Dr. Veryzer reported being in good health until April 25, 2001 . . . ;” “Dr. Veryzer advised that within hours of receiving the vaccines . . . .”); Docket 64-3, p. 25 (“Dr. Veryzer has been quite clear that these symptoms occurred after he received the Hepatitis A and Hepatitis B vaccination[s]. He has attributed this to mercury/heavy metal poisoning.”).

special master to require evidence as may be reasonable and necessary). These questions focused on: what evidence Dr. Astruc sees in the medical records to support his opinion that petitioner suffered from demyelination; what evidence Dr. Astruc relies upon for his statement that petitioner's conditions are consistent with "known potential adverse reactions" and symptoms consistent with a demyelinating injury; what scientific support does Dr. Astruc rely upon to find the Hepatitis A vaccine or its component parts cause demyelination in areas of the nervous system related to the symptoms suffered by petitioner; what evidence supports a finding that petitioner's symptoms following vaccination began in a medically appropriate time frame following the Hepatitis A vaccine; how does demyelination cause brain damage resulting in cognitive impairment; and what is the medically acceptable time period, Althen prong III, for demyelination to occur following immunization, what is the time period in which this occurred with petitioner and upon what does Dr. Astruc rely for this opinion. Order, filed March 3, 2011.

On March 18, 2011, petitioner filed the supplemental opinion from Dr. Astruc. In response to the **first** question regarding evidence in petitioner's medical records supportive of a diagnosis of demyelination, Dr. Astruc states generically that petitioner's symptoms began within hours of the vaccine and petitioner's current symptoms are consistent with a neurological condition. Dr. Astruc does not reference petitioner's medical records; he simply states, "[o]ne of the **possible** causes of this condition is demyelination." Docket 76-1, filed March 18, 2011 (emphasis added). **As noted previously, several of petitioner's treating physicians found no evidence of demyelination.** Supra pp. 13-15. Regarding the **second** question concerning what evidence exists that petitioner's alleged reaction is consistent with other known adverse events following the Hepatitis A vaccine, Dr. Astruc merely references petitioner's medical records generally and the reports of petitioner's treating physicians who discussed demyelination as a "probable" event, to which citations or physician's names are not referenced. Id. **The undersigned's review of the medical records did not reveal other treating physicians who stated demyelination due to the Hepatitis A vaccine was probable.** Concerning the **third** question, evidence supportive of the theory that the Hepatitis A vaccine or its component parts can cause demyelination, Dr. Astruc references the temporal association between vaccination and petitioner's alleged symptoms. He again states that demyelination is "a **possible** pathway" and relies upon his "training in Medical School that demyelination as a result of vaccines is a known side effect of vaccines." Id. **Dr. Astruc provides no citations or support for his statements. This is critical as Dr. Astruc is not a neurologist.** Supra p. 8, n. 8. In response to the **fourth** question, what evidence supports petitioner's time from vaccine to onset of symptoms was medically appropriate, Dr. Astruc references petitioner's medical records, with no specific reference, to state he was in good health before vaccination and suffered a degenerative process thereafter. Again without citation, Dr. Astruc states that demyelination is typically a progressive degenerative condition and again, he references the bare temporal proximity between the Hepatitis A vaccine and petitioner's complaints. Id. Dr. Astruc's answer to this question is curious given that his answer to the sixth question, which is similar and related to the medically appropriate time for onset, is that it is outside of his area of expertise to respond. To the **fifth** question, regarding how demyelination causes brain damage resulting in cognitive impairment, Dr. Astruc gives a general description of how demyelination disrupts the myelin sheath of nerve cells, impairing nerve conduction. Finally, the **sixth** question, when asked what the medically acceptable time frame for demyelination to occur following vaccination, Dr. Astruc states that petitioner's symptoms started within hours of the vaccinations and "[c]learly the human body may show the results of a toxic exposure within this time frame."<sup>24</sup> Id. at 2. He also references

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<sup>24</sup> Considering evidence the undersigned hears with other cases involving demyelination, the undersigned has not heard of demyelination referred to as a toxic exposure; it is discussed as an autoimmune process. See Hodges v. Sec'y of the Dept. of

responses of fever and fussiness in babies within hours of vaccination to support his opinion on the temporal association. Id. However, he states, “[i]t is outside of my area of expertise to speculate as to the time frame during which demyelination may specifically occur.” Id. Dr. Astruc was provided every opportunity to explain the basis for his opinion that the Hepatitis A vaccine was the cause of petitioner’s injuries. He failed to do so.

In her Response to Petitioner’s Memorandum in Support of Causation, respondent argues that Dr. Astruc’s opinion is patently insufficient to satisfy petitioner’s burden. R Response at 20. She notes that Dr. Astruc references both the Hepatitis A and the Hepatitis B vaccinations throughout his opinions. Id. at 19. Respondent points out that Dr. Astruc inexplicably references two different theories of injury: a brain injury due to heavy metal toxicity and demyelination. R Response at 20. She states that Dr. Astruc fails to link the Hepatitis A vaccine with petitioner’s specific injuries and provides no basis for the finding that Hepatitis A vaccine specifically can cause demyelination, thus failing to show evidence of Althen prong I. Also, respondent notes that Dr. Astruc himself says demyelination is only a “possible” mechanism. Id. at 21 (citing Moberly v. Sec’y of the Dept. of Health & Human Servs., 592 F.3d 1315, 1322 (holding that “[a] petitioner must provide reputable medical or scientific explanation that pertains specifically to the petitioner’s case,” and noting “proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury . . . is not the statutory standard.”)). Respondent remarks that Dr. Astruc’s opinion identifies no support, from the medical records or medical literature, for his assertions. R Response at 21-22 (citing General Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)(holding that when confronted with “opinion evidence that is connected to existing data only by the *ipse dixit* of the expert,” a “court may conclude that there is simply too great an analytical gap between the data and the opinion proffered”)). Finally, respondent notes that Dr. Astruc admits being unqualified to discuss the appropriate timing for demyelination and thus argues Dr. Astruc is similarly unqualified to opine that demyelination is the cause of petitioner’s condition. Id. Respondent asserts that Dr. Astruc’s reports are no more reliable than the previously excluded reports of Drs. Moulden and Tenpenny and that Dr. Astruc’s reports should either be excluded or given no evidentiary weight.

The undersigned agrees with respondent’s contentions regarding the vagueness and insufficiency of Dr. Astruc’s reports. Most alarmingly, Dr. Astruc fails to reference any of petitioner’s medical records that were created contemporaneously to the Hepatitis A vaccination and alleged reaction. Dr. Astruc failed to reference petitioner’s medical records even when specifically asked in the March 3, 2011, Order. Overall, Dr. Astruc’s opinion is simply unsupported and unclear. Whether Dr. Astruc opines petitioner suffered from demyelination or metal toxicity from the Hepatitis A vaccine is uncertain. Also, whether Dr. Astruc believes petitioner’s alleged injuries were caused by the Hepatitis A vaccine, its component parts or thimerosal, a mercury preservative that was never present in the Hepatitis A vaccine, is also unclear. When examined, Dr. Astruc’s opinion is primarily premised upon temporal association and his unsupported belief that petitioner’s symptoms are similar to reported vaccine reactions. Any explanation or theory as to how the Hepatitis A vaccine can cause heavy metal toxic exposure or demyelination is lacking. Without reference to petitioner’s medical records, Dr. Astruc fails to show how petitioner’s presentation fits a logical sequence of cause and effect showing the vaccination caused his alleged injuries. Also, Dr. Astruc provides no evidence or explanation why the time from vaccination to onset of symptoms is consistent with toxic exposure to the vaccine or its parts. Regarding demyelination and as noted above, Dr. Astruc

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Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (discussing the intent of Congress to assign the Vaccine Act cases to a group of specialists, the special masters, to judge the merits of a case based upon their accumulated expertise in the field).

states he is not qualified to opine on the appropriate time from vaccine to onset of petitioner's symptoms in the case of demyelination. The simple fact that Dr. Astruc is admittedly unqualified to opine regarding the timing of demyelination calls into question whether he is qualified to opine regarding a theory and logical sequence of cause and effect regarding demyelination. Dr. Astruc's reports add very little qualitatively to petitioner's evidence on causation, but instead amount to a vague opinion, unsupported by references to petitioner's medical records or other reliable evidence.<sup>25</sup>

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<sup>25</sup> On March 4 and 18, 2011, petitioner filed several pieces of medical literature. It appears that petitioner filed these articles without critical review for their relevance. None of these pieces were referenced or explained by Dr. Astruc. Nor did petitioner explain their application in his Memorandum. Without the benefit of an expert's explanation, the undersigned finds none of these articles relevant or instructive on petitioner's case and will briefly review these filings for completeness.

First, Hepatitis B Virus Infection – Natural History and Clinical Consequences, by Ganem and Prince, is irrelevant as it is the Hepatitis A vaccine at issue herein. Docket 75-5, p. 1, filed March 4, 2011. Second, Immunologic Hazards Associated with Vaccination of Humans, by Rose, is also irrelevant as it discusses autoimmunity generally and focuses on the autoimmune consequences of immunization with an anti-fertility vaccine. Docket 75-5, p. 13. Third, Vaccination and Autoimmunity, by Nossal, also is irrelevant as it again is a general discussion of autoimmunity, discusses the Hepatitis B vaccine and does not touch upon how Hepatitis A vaccine could cause petitioner's condition. Docket 75-5, p. 15. Third, Stimulation of the Developing Immune System Can Prevent Autoimmunity, by Singh, is irrelevant again because it discusses autoimmunity in general and the abstract appears to be the only portion included. Docket 75-5, p. 17. Fourth, Mechanistic Bases for Adverse Vaccine Reactions and Vaccine Failures, by Roth, is a piece of veterinary medical literature primarily regarding animal vaccination and, since there was no discussion of how this article is pertinent to human medicine, it is also irrelevant. Docket 75-5, p. 18. Fifth, Weighing the Risks and Benefits of Vaccination, by Glickman, is another piece of veterinary medical literature and is not relevant for the same reason. Docket 75-5, p. 28.

Sixth, Vaccinations and multiple sclerosis, by Gout, is also inapplicable because petitioner was not diagnosed with multiple sclerosis and the vaccination discussed in the article, Hepatitis B, is not at issue in this case. Docket 75-4. Seventh, Is CFS Linked to Vaccinations?, by Shepherd, is irrelevant as petitioner was not diagnosed with chronic fatigue syndrome. Docket 75-4, p. 5. Also, this article primarily discusses the Hepatitis B vaccine and only references the Hepatitis A vaccine being associated with "very few cases" that are unpublished. Id. The article also notes that Hepatitis A "does not seem to cause any problems in CFS patients." Id. at p. 6. Eighth, Monitoring signals for vaccine safety, by Collet, et al., is also not relevant to petitioner's burden regarding causation. Docket 75-4, p. 8. Ninth, Hepatitis B Vaccination Safety, by Geier, is irrelevant as the Hepatitis B vaccine is not at issue here. Tenth, Infection, mimics, and autoimmune disease, by Rose, is irrelevant as petitioner was not diagnosed with Chagas' disease, which is discussed specifically, nor does the article link Hepatitis A with molecular mimicry and autoimmunity in humans. Docket 75-4, p. 21.

Introduction to Immunology and Autoimmunity, by Smith and Germolec, only gives brief instruction on autoimmunity and does not further petitioner's causation burden. Docket 75-3. It does not appear that the entire article is included. This observation continues for the following articles relating to schizophrenia, tinnitus, permanent audiovestibular damage and immunity, which are only PubMed abstracts and concern diagnoses petitioner does not have. Docket 75-3, pp. 2-5. Next, the article on the anthrax vaccine from the Institute of Medicine, is also irrelevant here. Docket 75-3, pp. 6-10. The Complicated Task of Monitoring Vaccine Safety, by Ellenberg et al., concerns the interpretation of data in the ongoing surveillance of vaccine safety and is irrelevant as it does not further petitioner's specific case. Docket 75-3, pp. 11-24. Adverse Drug Reactions, by Pirmohamed et al., is irrelevant for the same reason. Docket 75-3, p. 25. Rheumatic disorders developed after Hepatitis B vaccination, by Maillefert et al., is not relevant because the Hepatitis B vaccine is not at issue and petitioner has not alleged a rheumatic disorder. Docket 75-3, p. 29.

Aluminium Toxicokinetics: An Updated MiniReview, by Yokel and McNamara, references aluminium in vaccinations, but does not discuss the Hepatitis A vaccine specifically. Docket 78-1. Activation of methionine synthase by insulin-like growth factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal, by Waly et al., is a highly technical piece of medical literature that the undersigned can only guess was filed due to the discussion of thimerosal on neurodevelopment. Docket 78-2. Without reliable medical expert explanation, the article does not assist petitioner with his burden. Neonatal Administration of Thimerosal Causes Persistent Changes in Mu Opioid Receptors in the Rat Brain, by Olczak et al., deals with thimerosal added to pediatric vaccines and, again, without further evidence or explanation it is not relevant to petitioner's burden regarding causation. Docket 78-3. Thimerosal Induces DNA Breaks, Caspase-3 Activation, Membrane Damage, and Cell Death in Cultured Human Neurons and Fibroblasts, by Baskin et al., again deals with thimerosal and does not relate to the Hepatitis A vaccine. Docket 78-4. The final article, Uncoupling of ATP-Mediated Calcium Signaling and Dysregulated Interleukin-6 Secretion in Dendritic Cells by Nanomolar Thimerosal, by Goth et al., also is irrelevant as it does not pertain to the Hepatitis A vaccine. Docket 78-5. Most notably regarding these articles and as discussed by respondent, the Hepatitis A vaccine never contained thimerosal. R Ex Tab 1, attached to R Response; see also U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm096228.htm> (last visited April 18, 2011). The medical literature offered by petitioner does not further his case.

## Theory of Causation

Under the first prong of Althen, petitioner “must ‘show a medical theory causally connecting the vaccination and the injury.’” Althen, 418 F.3d at 1278 (quoting Grant v. Sec’y of the Dept. of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992)). This entails petitioner showing a proffered theory is medically or biologically plausible. E.g., Andreu v. Sec’y of the Dept. of Health & Human Servs., 569 F.3d 1367 (Fed. Cir. 2009). It has been referred to as the “can cause” prong: can the vaccine cause the alleged injury. E.g., Doe/11 v. Sec’y of the Dept. of Health & Human Servs. 87 Fed. Cl. 1 (Fed. Cl. 2009); Pafford v. Sec’y of the Dept. of Health & Human Servs., No. 01-165V, 2004 WL 1717359 (Fed. Cl. Spec. Mstr. 2004).

Regarding his theory of causation, it appears that petitioner puts forth two theories: one is that petitioner suffered demyelination due to the vaccination; the other is that petitioner suffered mercury toxicity due to the vaccinations. In his Memorandum, petitioner relies upon Dr. Astruc to state petitioner suffered from both “heavy metal poisoning and demyelination.” P Memo at 10.

Importantly, petitioner has not offered evidence, through Dr. Astruc or the otherwise, that the Hepatitis A vaccine can cause demyelination. The Federal Circuit concluded that to support petitioner’s theory of causation, there is no requirement in the Vaccine Act’s preponderant evidence standard that petitioners submit “objective confirmation,” such as medical literature. Althen, 418 F.3d at 1279. However, petitioners must support their proposed causation theory with a “sound and reliable medical or scientific explanation.” Knudsen, 35 F. 3d 543, 548 (Fed. Cir. 1994). Dr. Astruc simply relies upon his “training in Medical School that demyelination as a result of vaccines is a known side effect of vaccines.” This does not equate to a preponderant evidence of a plausible theory by which the Hepatitis A vaccine can cause demyelination. Some treating physicians do entertain the idea that one or both of his vaccinations may have caused demyelination. But this possibility was undercut by the absence of objective evidence of demyelination upon examination. See supra pp. 13-15, 20. Further, and far more basically, none of these treating physicians discussed a theory by which the Hepatitis A vaccine can cause demyelination, the possibility was merely mentioned. Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984). This record contains no persuasive evidence of a medical theory for the Hepatitis A vaccine causing demyelination.

Regarding petitioner’s other theory of heavy metal toxicity, the reports and literature discussing metal toxicity primarily reference thimerosal and its injurious effects on the human body. The Hepatitis A vaccine has never contained thimerosal. Supra p. 6; p. 22-23, n. 25. Beyond this, petitioner provided no evidence to show how the Hepatitis A vaccine can cause heavy metal toxicity. Regarding this theory, there is a complete and total lack of evidence to support its plausibility.

The undersigned finds that petitioner failed to present preponderant evidence of a theory of causation that was legally probable. This finding makes discussion of the other two Althen prongs unnecessary but it will be had nonetheless. The undersigned approaches a discussion of the second and third prongs with some suspension of belief since petitioner’s failure to show the Hepatitis A vaccination can cause demyelination or heavy metal toxicity logically means that prongs two and three of Althen cannot be met.

### Logical Sequence of Cause and Effect

The second prong of Althen is sometimes referred to as the “did cause” test: in petitioner’s case, did the vaccine cause the alleged injury. E.g., Doe/11 v. Sec’y of the Dept. of Health & Human Servs. 87 Fed. Cl. 1 (Fed. Cl. 2009); Pafford v. Sec’y of the Dept. of Health & Human Servs., No. 01-165V, 2004 WL 1717359 (Fed. Cl. Spec. Mstr. 2004). Petitioner’s showing of a logical sequence of cause and effect primarily rests upon the temporal association between the vaccination and his condition. Although the petitioner’s evidence may overlap between the second and third prongs of Althen, the medical records and reports that discuss a possible reaction seem to rely solely upon a temporal association. In fact, several of petitioner’s treating physicians noted petitioner’s symptoms are not typical vaccine reactions and that there was no objective evidence of a reaction when petitioner was examined.

Petitioners do not 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.

As was shown above discussing the treating physician records, petitioner medical condition was complicated. The treating doctors entertained a variety of conditions and potential causes. At various times, petitioner was tested and sometimes treated for [REDACTED]. Based upon a temporal association - not a proven medically appropriate time frame but merely following the immunization – petitioner contends that “[c]learly, something happened to alter [petitioner’s] condition beginning in April 2001.” P Memo at 11. That may be true, but it is also true that such evidence alone is legally insufficient. Grant, 956 F.2d at 1148. No treating doctor found the Hepatitis A vaccine to be the cause of petitioner’s condition. No test results showed an abnormal immunological reaction to the Hepatitis A vaccine. Dr. Astruc provided no reliable support for his opinion that the Hepatitis A vaccine was the causative culprit. Based upon a complete and objective analysis of the medical records, it is illogical to conclude that the Hepatitis A vaccine caused petitioner’s medical condition.

### Appropriate Temporal Relationship

The third prong of Althen is that petitioner must show that onset occurred “in a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury.” Althen, 418 F.3d at 1281. As stated previously, petitioner filed his Memorandum in Support of Causation on March 4, 2011. Petitioner asserts that Judge Miller found he satisfied his burden regarding the third prong of Althen, which is a showing of a proximate, temporal relationship between the vaccination and the alleged injury. Althen, 418 F.3d at 1278. Therefore, on remand, petitioner avers that he need only show a theory of causation “connecting the vaccination and the injury” and a “logical sequence of cause and effect showing that the Hepatitis A and Hepatitis B vaccinations, and their component parts, were the reason for his injuries,” P Memo at 1 (citing Althen, 418 F.3d at 1278).



Respondent disagrees with petitioner regarding Judge Miller's finding regarding prong three of Althen. R Response at 18. Respondent argues that petitioner had yet to present his most recent theory of causation, demyelination, when Judge Miller noted a temporal association. Respondent asserts the decision "cannot possibly be read as concluding petitioner has established by a preponderance of the evidence the third prong of Althen." Id. Respondent notes petitioner's allegations that the onset of symptoms was within hours of receiving the vaccination. "Given this short time frame, and given that petitioner is alleging that his condition is the result of demyelination caused by his vaccinations, he has not shown that the onset occurred within a **proper** temporal relationship to his vaccines." Id. at 18-19 (emphasis in original)(citing DeBazan v. Sec'y of the Dept. of Health & Human Servs., 539 F.3d 1347 (Fed. Cir. 2008)(reversing Court of Federal Claims and upholding special master's original finding that onset of ADEM, an immune-mediated demyelinating condition, could not occur as early as eleven hours after vaccination)).

Although the undersigned does not perceive petitioner is only relying upon the theory of demyelination, as timing refers to that theory, respondent's view that the onset of symptoms occurred too quickly is in line with testimony the undersigned hears in other cases pertaining to demyelination. See, e.g., Mueller v. Sec'y of the Dept. of Health & Human Servs., No. 06-775V, slip op., 23-24 (discussing the earliest medically appropriate time frame for an immune-mediated response in a proposed case of demyelination to be five days); Hargrove v. Sec'y of the Dept. of Health & Human Servs., No. 05-694V, 2009 WL 1220986, \*25 (Fed. Cl. Spec. Mstr. Apr. 14, 2009)(quoting a medical expert who states, "typically the onset of an immune-mediated disorder takes five days or more to become apparent."); Rego v. Sec'y of the Dept. of Health & Human Servs., No. 04-1734V, 2008 WL 1990844, 6 (Fed. Cl. Spec. Mstr. Jan. 30, 2007)(discussing petitioner's expert's opinion that five days after vaccination was "a little bit too soon for a T-cell response to come up and actually start producing damage" in a case concerning demyelination and multiple sclerosis).

Based upon testimony from numerous qualified experts, petitioner's theory of demyelination with onset within a few hours of receipt of the Hepatitis A vaccine appears too soon to be causally related to the vaccination. Beyond the undersigned's reliance on testimony heard in other cases, see Hodges, 9 F.3d at 961, petitioner failed to show any evidence that such a rapid onset is medically appropriate in a case of demyelination, nor was his expert able to opine on the appropriate time for onset. Docket 76-1, p. 2 (noting onset occurred within hours of the vaccination and stating it is outside of Dr. Astruc's area of expertise to speculate as to the time frame during which demyelination may specifically occur).

However, petitioner also offered undeveloped theories of metal toxicity to the vaccine or its component parts. First, petitioner failed to show the Hepatitis A vaccine is capable of inducing mercury or other heavy metal toxicity. Dr. Astruc, in his final report, likened petitioner's onset within hours to a baby's fever and fussiness within hours of vaccination. The undersigned grants petitioner that such transient responses, fevers and myalgias, are commonplace with vaccination. However, petitioner's claims of "physical, cognitive and emotional symptoms," shortly after vaccination are not similar to such transient reactions. P Aff, p. 2. In his affidavit, petitioner alleges chills, mild joint aching, fatigue, disorientation, forgetfulness, [REDACTED] constipation, rashes and fever within days of the vaccination. Id. Other than Dr. Astruc's metaphor to transient reactions, petitioner provided no evidence that metal toxicity can occur from the Hepatitis A vaccine and further failed to provide evidence on the medically appropriate timing of such a reaction.

“[T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” DeBazan, 539 F.3d at 1352. If petitioner is correct and Judge Miller found that he satisfied prong three of Althen with the metal toxicity theories hinted at prior to this remand, then the third prong is established. Admittedly there is a temporal relationship between the vaccine and the initial symptoms petitioner alleged. However, based upon my review of the record, it is found that petitioner failed to provide preponderant evidence that onset of a toxic reaction was within a **medically appropriate** timeframe.

Without more explication from petitioner’s treatment records or Dr. Astruc, the undersigned is unable to find petitioner offered preponderant evidence that an onset of symptoms of heavy metal toxicity within a few hours of vaccination is medically appropriate for the processes causing his myriad symptoms. As stated previously, petitioner also fails to show onset within a few hours of vaccination is medically appropriate in regard to a theory of demyelination.

### Conclusion

A review of the record shows petitioner has failed to provide preponderant evidence that he suffered a vaccine-related injury due to the Hepatitis A vaccine. The Act at 42 U.S.C. § 300aa-13(a) provides that the special master “may not make a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” This Petition remains unsupported by either medical records or medical opinion. In accordance with section 13(a), petitioner’s claim fails for want of proof. Judgment shall enter accordingly.

**IT IS SO ORDERED.**<sup>26</sup>

s/ Gary J. Golkiewicz  
Gary J. Golkiewicz  
Special Master

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<sup>26</sup> Judge Miller stated the decision on remand shall be issued by May 2, 2011. This document constitutes a final “decision” in this case. Vaccine Rule 28.1. Unless a motion for review of this decision is filed within 30 days, the Clerk of the Court shall enter judgment in accord with this decision. Id.