OFFICE OF SPECIAL MASTERS

No. 00-759V

Filed: June 8, 2004

ROSE CAPIZZANO,	*	
Petitioner,	*	
v.	*	
	*	To Be Published
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald Homer and Sylvia Chin-Caplan, Boston, Massachusetts, for petitioner.

Ann Donohue with whom were Melonie McCall and Catharine Reeves, United States Department of Justice, Washington, D.C., for respondent.

ENTITLEMENT DECISION

GOLKIEWICZ*,* Chief Special Master

On December 15, 2000, Rose Capizzano filed a petition for compensation under the National Vaccine Injury Compensation Program (hereinafter the Act or the Program)[1] for injuries resulting from the administration of a hepatitis B vaccination. This petition was one of twenty-one other similar petitions alleging that the hepatitis B vaccination caused rheumatoid arthritis (RA). RA is not listed on the Vaccine Injury Table; thus there is no presumption of causation.[2] Therefore, a petitioner alleging an RA injury is required to prove by a preponderance of evidence that the vaccine in-fact caused the RA. As discussed below, this court finds that petitioner failed

[1]The statutory provisions governing the Vaccine Act are found at 42 U.S.C. §§300aa-10 to 300aa-34 (1991 & Supp. 2002). Hereinafter, for ease of citation, all references will be to the relevant subsection of 42 U.S.C. §300aa.

[2] See 42 U.S.C. §300aa-14(a). See also discussion of causation-in-fact standards, *infra*.

to establish by a preponderance of the evidence that the hepatitis B vaccination caused her RA.

Background

The parties agreed to a litigative procedure by which, from the twenty-two RA cases filed, petitioners' attorneys selected five cases to be litigated as "test cases." Petitioners believed these to be the most representative of all the cases filed. These test cases would be litigated at a hearing to determine the general issue of whether the hepatitis B vaccine can cause RA. Evidence was also heard on the issue of specific causation in each test case. A finding on the issue of general causation would then be used in each of the remaining RA cases as a basis for determining whether or not the vaccine caused the injury alleged in that particular case.

Ms. Capizzano's case was among those selected for litigation.[3] The facts of this case are not in dispute. See Respondent's Status Report, filed Mar. 4, 2004. Petitioner is a thirty-three year-old mother of three. After receiving a second hepatitis B vaccine on May 3, 1998, petitioner asserts that she developed RA. She claims that the temporal relationship between the vaccine and her injuries is strong because she had an immediate reaction after receiving the hepatitis B vaccine; within hours, she had a rash on her abdomen. After several days her ailments increased to include stiff and painful joints. See Petition for Vaccine Compensation, filed on Dec.15, 2000 (hereinafter Petition), Ex. 13, at 1. Several of petitioner's treating physicians attributed her injuries to the vaccine. See, e.g., Pet. Ex.1, at 9. Petitioner continues to suffer from these symptoms and takes daily medication to keep the pain, swelling, and stiffness under control. See Pet. Ex. 13, at 2.

On June 11 and June 12 of 2003, the undersigned conducted a hearing to address the general issue of whether the hepatitis B vaccine can in-fact cause RA. The undersigned also heard evidence specifically relating to petitioner and her alleged injuries. Subsequent to the hearing, on June 20, 2003, the undersigned issued an Order that directed the parties to file various documents introduced and discussed during the hearing. See Capizzano, Ashby, Analla, Ryman and Manville v. HHS, Nos. 00-759V, 01-221V, 99-609V, 99-591V, 99-628V, 2003 WL 21432586, at *1 (Fed. Cl. Spec. Mstr. June 20, 2003). In addition, this court instructed the parties to file post-hearing briefs on the undersigned's criteria for resolving actual causation claims as discussed in Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001) as it relates to the issue of general causation.[4] The court also

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[3] The four other petitions selected for litigation as test cases were: Ashby v. HHS, 01-221V; Analla v. HHS, 99-609V; Ryman v. HHS, 99-591V; and Manville v. HHS, 99-628. On August 11, 2003, petitioner Mary Ashby filed a "Motion for Ruling on the Record." Respondent filed no response. Accordingly, the court issued a Decision dismissing the petition on October 3, 2003. The Clerk subsequently entered judgment in Ashby on October 20, 2003.

[4] As discussed in Stevens, in summary, petitioner must provide (1) proof of theoretical medical plausibility, (2) proof of confirmation of medical plausibility from the medical

requested "any additional information that is more recent than respondent's exhibit HH, a 1967 article, C.G. Barnes and H.L.F. Currey, Carpal Tunnel Syndrome in Rheumatoid Arthritis. A Clinical and Electrodiagnostic Survey, Ann. Rheum. Dis., Vol. 26 at 226-233 (1978)," as well as "additional medical evidence in the form of peer-reviewed literature that discusses whether or not there is a possible association between the Hepatitis B vaccine and rheumatoid arthritis or other evidence that assists the court in determining what the medical community is 'thinking' regarding the alleged association." Capizzano et al., 2003 WL 21432586, at *1.

In that same Order, this court stated that it had made tentative findings with regard to the first prong of the Stevens' test, holding that

> . . . tentatively, the undersigned finds the issue of medical plausibility (Prong 1) moot. That is because respondent's exhibit L, "Rheumatic Disorders Developed After Hepatitis B Vaccination" related four "rechallenge"[5] cases to the Hepatitis B vaccine. R. Ex. L (J.F. Maillefert, J. Sibilia et al., Rheumatic Disorders Developed After Hepatitis B Vaccination, Rheumatology, 1999:38:978-983 at 979). The Institute of Medicine (IOM)[6] has stated that rechallenge is proof of causation. See Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines, 48, 53 (1991). The IOM has also

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community and literature, that is, acceptance by the medical community that the vaccine causes the injury, (3) proof of an injury recognized by the medical plausibility evidence and literature, (4) proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and (5) proof that no reasonable evidence suggesting that an alternate etiology is a more probable cause of the injury. Stevens, 2001 WL 387418, at *23-*26 as clarified in Watson v. Secretary of HHS, No. 96-639V, 2001 WL 1682537, at *8 (Fed. Cl. Spec. Mstr. Dec. 18, 2001), White v. Secretary of HHS, No. 98-426V, 2002 WL 1488764, at *5 (Fed. Cl. Spec. Mstr. May 10, 2002).

[5]A rechallenge case is one where adverse symptoms are noted after a dose of the vaccine, an additional dose of the vaccine is given, and the symptoms worsen. See Pet. Ex. 26, at 17.

[6]The law establishing the Vaccine Program, P.L. 99-660, charged the Institute of Medicine of the National Academy of Sciences to review the medical and scientific literature regarding risks associated with the various vaccines covered under the Program. The specific committee assigned to review the adverse events associated with the hepatitis B vaccine, the Vaccine Safety Committee, published its findings. See Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, (1994)(hereinafter IOM Report on Causality).

Considering the IOM's statutory charge, the scope of its review, and the cross-section of experts making up the committee, the special masters have consistently accorded great weight to the IOM's findings.

> stated that where causation is proven, biologic plausibility is a given. Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, 21 (1994). Therefore, if the court affirms this tentative determination, petitioners will have met Prong 1 of Stevens and any rechallenge rheumatoid arthritis case, if proven successfully to be a rechallenge case, will be compensated.

Capizzano et al., 2003 WL 21432586, at *2.

On August 5, 2003, the court issued a decision memorializing its preliminary finding of medical plausibility in the case of "rechallenge" to the hepatitis B vaccine. As previously expressed, the decision stated,

> [h]ere the court finds the Maillefert study, the IOM criteria and the expert testimony persuasive evidence that the petitioners have met Prong 1 [of Stevens]. In essence, rechallenge cases are such strong proof of causality that it is unnecessary to determine the mechanism of cause – it is understood to be occurring.

Capizzano, Ashby, Analla, Ryman, and Manville v. HHS, Nos. 00-759V, 01-221V, 99-609V, 99-591V, 99-628V, WL 22425000, at *4 (Fed. Cl. Spec. Mstr. Aug. 5, 2003).

Subsequently, respondent filed documents requested by the court on July 24, 2003, and a post-hearing brief on August 27, 2003, addressing its position on the issues and facts presented at the June 2003 hearing. See Respondent's Notice of Filing Post Hearing Documents, filed July 24, 2003 (hereinafter Res. July 24 Filing); Respondent's Post-Hearing Brief, filed August 27, 2003 (hereinafter Res. Aug. 27 Brief). Likewise, petitioner filed her post-hearing documents on August 5, 2003 and a brief on September 10, 2003. See Notice of Filing for Post-Hearing Documents, filed August 5, 2004 (hereinafter Pet. Aug. 5 Filing); Petitioner's Posthearing Brief, filed September 10, 2003 (hereinafter Pet. Sept. 10 Brief).

Thereafter, in an unrelated matter, on September 30, 2003, Judge Susan Braden of the United States Court of Federal Claims issued a decision in Althen v. Secretary of HHS, 58 Fed. Cl. 270 (Fed. Cl. 2003), reversing the undersigned's finding of no causation in that case and rejecting the Stevens' criteria for resolving actual causation claims.[7] Recognizing that the results in Althen could affect dramatically the undersigned's analysis in the petitioner's case, on October 3, 2003, the undersigned ordered the parties to file simultaneous briefs discussing the causation issue by applying Judge Braden's legal analysis to the medical and factual information presented in the record. The parties complied. See Petitioner's Post Hearing Brief, filed December 8, 2003

[7]While not binding on the special masters, except in the reviewed case, (see Hanlon v. Secretary of HHS, 40 Fed. Cl. 625, 630 (Fed. Cl. 1998)) decisions of the Court of Federal Claims judges are obviously very persuasive and the reasoning is not to be taken lightly.

(hereinafter Pet. Dec. 8 Brief); Respondent's Brief in Response to the Chief Special Master's Order of October 3, 2003, filed December 2, 2003 (hereinafter Res. Dec. 2 Brief).

Before discussing the evidence presented to the court in this case, it is obviously critical to understand the causation-in-fact principles to be used in evaluating that evidence.

Causation-in-fact -- Basic Principles

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.[8]

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

To demonstrate entitlement to compensation in an off-Table case, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See, e.g., Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Secretary of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Secretary of HHS, 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, "[a petitioner must] show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Secretary of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Secretary of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Secretary HHS, 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by "[a] reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at

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

960.[9] See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. While petitioner need not show that the vaccine was the sole or even predominant cause of the injury, petitioner bears 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

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

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

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

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication "does *not* necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." Daubert, 509 U.S. at 594. However, the Supreme Court's only guidance to lower courts in determining the reliability of a novel proposition is that

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

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

1352-53. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Nor do petitioners satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating "inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation.")); Hodges, 9 F.3d at 960. Finally, a petitioner does 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.

The Stevens' Analytical Framework

The undersigned previously discussed in Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418, at *22 (Fed. Cl. Spec. Mstr. Mar. 30, 2001), the need for more specificity and clarification of the above-stated general principles of causation-in-fact. This concern arose after it became apparent that the application of the Federal Circuit's guidance to the evidence presented routinely before the special masters in this court was leading to disparate results among petitioners – even in cases where the same vaccine and injury were implicated.[10] This led the undersigned to publish an analytical framework for resolving off-Table cases, which reflected the undersigned's experience and thought process in evaluating and applying evidence presented in vaccine cases. This framework, which was presented in Stevens, was based on evidence that was routinely presented and relied on by expert witnesses in opining as to a petitioner's establishment of causation, evidence that other special masters in the court have consistently relied on in making causation-in-fact determinations, as well as the undersigned's interpretation of controlling Federal Circuit precedent.

In Stevens, the undersigned determined that epidemiology, while not a prerequisite for compensation under the Program, is the most desirable and probative direct evidence of causation-in-fact.[11] See Stevens, 2001 WL 387418, at *13. By presenting a reliable and relevant epidemiologic study indicating a relative risk greater than two and establishing that the vaccinee falls within the parameters of the group associated with the statistically significant relative risk, petitioners can successfully prove causation in a particular case more probably than not (assuming, of course, respondent fails to prove a factor unrelated). Id. (citing Daubert, 43 F.3d

[10]See Stevens, 2001 WL 387418, at *12-*20 (general discussion regarding inconsistent treatment of evidence).

[11]Other desirable evidence includes "dispositive clinical or pathological markers" or "vaccine footprints" evidencing a direct causal relationship between the alleged injury and the vaccine received. Stevens, 2001 WL 387418, at *14. This type of evidence is rarely available in vaccine cases.

at 1320).[12]

In the absence of such controlling epidemiological evidence, the undersigned, as well as the other special masters, has found that a petitioner can prove causation-in-fact with circumstantial evidence. After considering the types of evidence regularly submitted by petitioners, testified to by credible experts, and relied upon by the court, the undersigned posited a five-prong test that, if satisfied by a preponderance of evidence, would entitle petitioners to compensation. See Stevens, 2001 WL 387418, at *14.[13] In effect, this test codified the undersigned's thought process and, as was apparent from their decisions, some of the undersigned's colleagues' thought processes, in resolving causation-in-fact cases. This five-prong standard required that petitioner provide (1) proof of medical plausibility that the vaccine received can cause the injury alleged, (2) proof of confirmation of medical plausibility from the medical community and literature, that is, acceptance by the medical community that the vaccine causes the injury, (3) proof of an injury recognized by the medical plausibility evidence and literature, (4) proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and (5) proof that no reasonable evidence suggesting that an alternate etiology is a more probable cause of the injury. Stevens, 2001 WL 387418, at *23-*26 as clarified in Watson v. Secretary of HHS, No. 96-639V, 2001 WL 1682537, at *8 (Fed. Cl. Spec. Mstr. Dec. 18, 2001), White v. Secretary of HHS, No. 98-426V, 2002 WL 1488764, at *5 (Fed. Cl. Spec. Mstr. May 10, 2002). Id. at *23-*26; see also Althen, 2003 WL 21439669, at *9-*12. The five prongs must be supported by expert testimony with "appropriate validation," Daubert, 509 U.S. at 590, and proven by a preponderance of the evidence. See, e.g., Watson,

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[12]According to the IOM:

> A relative risk (or odds ratio) of 1.0 indicates no association between the vaccine and the adverse event. Relative risks of between 1.0 and 2.0 are generally regarded as indicating a weak association, whereas higher values indicate a moderate or strong association.

IOM Report on Causality, at 21.

[13]In formulating the five-prong test in Stevens, the undersigned recognized that there are other means available to a petitioner to prove causation-in-fact and pointed out that,

> [o]f course, where the prongs fail to adequately address the parties' proof, the special masters *may establish different or additional criteria*. In addition, *criteria are not limiting*; petitioners may present evidence outside of the five prongs. The court fully expects that future cases will result in refinements to the criteria, clarifying intentions and defining acceptable proofs.

Stevens, 2001 WL 387418, at *37 (emphasis supplied).

2001 WL 1682537, at *9,*19, *21, *22, *28; White, 2002 WL 1488764, at *12, *18. Acknowledging that the five criteria are not binding on other special masters in the Vaccine Program, petitioners were advised that Stevens would be controlling in subsequent cases before the undersigned. See Stevens, 2001 WL 387418, at *37.

Articulating the five-prong test in Stevens created quite an uproar in the Vaccine Bar; petitioners were very supportive while respondent was quite negative. The decision was seen as a "relaxation" of the causation-in-fact standard. This struck the undersigned as odd since the test merely reflected the reality of how the evidence available and proffered in vaccine cases was being organized, analyzed, and weighed by the special masters. Cases were decided prior to Stevens and continue to be decided after Stevens utilizing that very evidence. Stevens merely took the step of organizing the evidence into prongs. Even that was not original. See, e.g., Zimmer v. Secretary of HHS, No. 97-0861V, 1999 WL 1246937 (Fed. Cl. Spec. Mstr. Dec. 2, 1999).

The Althen Standard for Causation-in-fact

As noted above, on September 30, 2003, Judge Braden of the Court of Federal Claims issued a decision reversing the undersigned's decision in Althen v. Secretary of HHS, 58 Fed. Cl. 270 (Fed. Cl. 2003). In resolving Althen, the undersigned utilized the Stevens' analytical framework. The undersigned found that petitioner satisfied Prong One of the Stevens' analysis based on petitioner's expert witness testimony and an IOM report, both of which established biologic plausibility, that is, that the vaccine can cause the alleged injuries. With respect to Prong Two, however, the undersigned found that petitioner failed to establish that the relevant medical community is seeing, reporting, and discussing a potential relationship between the tetanus toxoid vaccine and petitioner's injury. Thus, the theoretical plausibility established under Prong One remained just that, theoretical, and was too speculative to support a causation-in-fact claim. Because petitioner failed to satisfy all prongs of the Stevens' analysis, the undersigned denied her entitlement claim.

Petitioner subsequently appealed the decision of non-entitlement to the Court of Federal Claims. On review, Judge Braden reversed and remanded the undersigned's decision. First, Judge Braden reviewed the "Stevens analytical framework," finding that "[i]n fact and in operation, three of the five Stevens' elements either significantly change the statutory burden of proof or directly contravene the language of the Vaccine Act and therefore are erroneous as a matter of law." Id. at 283.[14] "Based on petitioner's entire medical history and the record in [the]

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[14] The undersigned respectfully disagrees with the characterization of the Stevens' analytical framework in the Althen decision. As stated in Althen:

> Not a word in the Vaccine Act . . . authorizes the Chief Special Master to impose any particular 'analytical framework' in a causation-in-fact case; nor is the Chief Special Master charged with determining "the" framework. If a question of law arises

case," Judge Braden found that the petitioner carried her statutory burden of proving causation-in-fact. Id. at 286. She reasoned that because the petitioner had put forth 1) reliable medical records; 2) a reputable medical opinion; 3) a logical sequence of cause and effect; 4) a medical theory that causally linked the vaccination to the onset and development of petitioner's injury; 5) an appropriate temporal relationship; and 6) an absence of other causes, petitioner was entitled to compensation under the Act. Id.[15] In deciding the case at hand, the undersigned sought the parties' views on Judge Braden's reasoning and determination.

> regarding the interpretation or implementation of the Vaccine Act, that is a matter for the courts, not the special masters.

Althen, 58 Fed. Cl. at 282.

First, the Stevens' analytical framework was not binding on other special masters. As the undersigned pointed out in Stevens, "[t]he criteria *are not binding* on other program claims although the ***undersigned*** expects to follow this analysis in subsequent cases, absent compelling reasons otherwise." Stevens, 2001 WL 387418, at *38 (emphasis added). Moreover, as pointed out in Stevens, the undersigned stressed its "flexibility and pragmatism" anticipating that if the prongs failed to adequately address the parties' proof, "special masters may establish additional or different criteria." Id. at *37.

Furthermore, the undersigned attempted to meet Congress' challenge of resolving cases with dispatch, consistency and certainty. As explained in Stevens, 2001 WL 387418, at *37,

> most importantly, the proposed standard is derived from the universe of the evidence this special master has heard over a twelve year period and is routinely submitted in causation claims. That the evidence typically considered important by medical and scientific experts to demonstrate medical causality is similar to that seen on-Table is expected but hardly makes any criteria tantamount to a new Table of injuries. The fact is, the court is constantly faced with cases involving the same vaccines, injuries, symptoms, experts, literature, and arguments. The caption changes, but the evidence and the issues remain the same. Thus it is only logical that the court would formulate a means to deal more efficiently and equitably with such cases.

See also, Hines v. Secretary of HHS, 21 Cl. Ct. 634, 648 (Cl. Ct. 1990) (The Special Master is not required to be a "potted plant" at the hearing; the legislative history of the Act emphasizes that the proceedings are to be conducted in an inquisitorial format with the special master conducting discovery, cross-examination, and investigation as needed.).

[15] Althen remains an open case; the Decision on Remand was filed on June 1, 2004. Judgment has yet to be entered.

Positions of the Parties with Respect to Althen

The undersigned again acknowledges the disparate views as to the state of the law for the appropriate standard of causation-in-fact in vaccine cases, that is, how much and what type of evidence is sufficient to prove a causation-in-fact case. The extent of the divergence of opinion is reflected in both the petitioner's and respondent's briefs filed discussing Althen.

In her brief, petitioner argues that Judge Braden's decision in Althen requires a lower burden of proof in order for a petitioner to prevail in vaccine cases than does the Stevens' analysis. In petitioner's opinion, "a claimant must present 'evidence of a strong temporal relationship ***and either*** reliable medical opinion ***or*** scientific theory explaining a logical sequence of cause and effect . . .'" Pet. Dec. 8 Brief, at 32 (emphasis in original). Contrary to the Stevens' analysis, a lack of peer-reviewed scientific literature supporting a petitioner's theory "'does not preclude a petitioner from meeting a preponderance standard.'" Id. at 32 (citing Althen, 58 Fed. Cl. at 284). In fact, petitioner "strongly disagree[s] with the requirements of proof imposed by the Chief Special Master." See Pet. Sept. 10 Brief, at 12. Petitioner asserts that "the Federal Circuit's Golub standard, not the Stevens prongs, is the correct evidentiary standard in the Vaccine Program." Id. at 14.[16] Arguing that it is consistent with Golub, petitioner asserts that the undersigned should use the test enunciated by Judge Braden in Althen in lieu of Stevens in the case at bar.

Respondent, in its brief, agrees with petitioner that the Stevens' analysis is an improper standard for establishing causation-in-fact. Respondent also agrees with Judge Braden's assessment that the Stevens' analysis for causation "is contrary to law to the extent that it purported to set an analytical framework applicable in other cases," and because Prong One of

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[16] In Golub v. Secretary of HHS, 243 F.3d 561 (Fed. Cir. 2000) (unpublished opinion), the court stated that petitioner's requirements for proving causation-in-fact are "minimal." The court held:

> [E]vidence of a temporal association, with nothing more, would not suffice to establish a causal link. Should the petitioner advance claims substantiated by medical records and/or by medical opinion, along with evidence demonstrating a strong temporal relationship between the injury and the vaccination, however, such a showing may suffice to establish a causal link.

Id. at *6.

the standard relating to a showing of the "medical plausibility"[17] "'does not achieve the level of reliability expected in a medical record or medical opinion.'" Res. Dec. 2 Brief, at 3 (citing Althen, 58 Fed. Cl. at 283).

Respondent, however, strongly disagrees with several other positions articulated by Judge Braden in her Althen decision. First, respondent takes issue with the Judge's position that there is no need for certain medical propositions to be supported by published medical literature. Respondent asserts that it is a special master's responsibility for assuring that the medical evidence presented is reliable and probative, and that the availability of peer-reviewed literature is an indicator that the evidence is reliable and is gaining support in the relevant scientific community. Respondent asserts that it is up to a special master's discretion to determine whether or not the evidence is persuasive. See Res. Dec. 2 Brief, at 3.

Respondent also departs from the ultimate conclusion on causation in Ms. Althen's case – Judge Braden found that because there was a theoretical possibility that the vaccine may have caused Ms. Althen's disease, coupled with an appropriate temporal relationship and an absence of other possible causes, this was "sufficient as a matter of law to prove actual vaccine-causation in that case." Id. Relying on Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983) and Housand v. Secretary of HHS, No. 94-414V, 1996 WL 282882 (Fed. Cl. Spec. Mstr. May 13, 1996), aff'd per curium, 114 F.3d 1206 (Fed. Cir. 1997), respondent argues that the Judge's findings were "plainly wrong" because there is no "heavy lifting in a standard that requires petitioner to show nothing more than a plausible theory of causation and a correct temporal relationship. . . ." Res. Dec. 2 Brief, at 5, 6.

Boiled down, respondent stoutly disagrees with Judge Braden's standard for weighing evidence. Respondent argues that the analysis in Althen could be interpreted to

> show no more than (1) a theory of causation that is theoretically possible; (2) the onset of a disease within a time frame following vaccination which is appropriate and consistent with that theory; and (3) the absence of proof of another cause.

Res. Dec. 2 Brief, at 15.

In respondent's view "[e]vidence that vaccine causation is plausible and that the temporal relationship is correct is manifestly inadequate as a matter of law to prove actual causation." Moreover, "[t]he medical truism. . . that biologic plausibility and a temporal relationship do not constitute adequate 'proof' of causation – is the accepted legal standard for weighing evidence in traditional tort litigation and is therefore applicable to the Vaccine Program." Id. at 4. In

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[17] The IOM and testifying experts discuss medical plausibility as the first step in causation as "can the vaccine cause the injury alleged?" See IOM Report on Causality, at 20. There are legitimate disagreements as to how much and what type of proof is required to establish medical plausibility.

support for its position, respondent points to Huston v. Secretary of HHS, 39 Fed. Cl. 632, 636 (1997), which "announced" that

> contrary to what petitioner claims in his motion for review, a showing of biologic plausibility and temporal association is insufficient . . . [p]etitioner needed to prove a logical sequence of cause and effect showing that the [vaccination] *actually* caused his injury.

Id. at 636 (emphasis supplied). Respondent believes that the idea expressed in Huston "is so well established as to be axiomatic," because there are many other cases supporting this position. Res. Dec. 2 Brief, at 5.

While recognizing that Althen could be interpreted to require merely plausibility, timing, and absence of other causes, respondent contends that Judge Braden also required linking petitioner's medical records to an established medical theory to prove actual causation. [18]

Overall, in order to demonstrate entitlement, respondent asserts that a petitioner

> must show not only that the mechanism is a theoretical possibility, but also that it has been demonstrated to occur in the real world. Further, they must show that it occurred in *this case* (i.e., that it *did cause* the injury here. . .).

Res. Dec. 2 Brief, at 9 (emphasis in original).

The Undersigned's Viewpoint

Respondent urges the undersigned to "weigh the evidence in this case as directed by Federal Circuit case law. . . ." Res. Dec. 2 Brief, at 16. The critical question is "from whose viewpoint?" The undersigned believed the discussion in Stevens comported with the Circuit's teachings. Clearly, Judge Braden believes her decision in Althen follows the Circuit's decisions; petitioner concurs. Respondent disagrees with each. Therein lies the problem, in applying the medical evidence presented routinely in vaccine cases,[19] there is no accepted definition or

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[18] In Althen, Judge Braden found that petitioner's expert witness presented a reliable medical opinion linking the petitioner's medical records to an established medical theory of "degeneracy" and "epitope spreading." Pointing to a pathology report that appeared to support the medical theory, the Judge linked the disease to the petitioner. In the absence of other causes, the Judge found that petitioner had satisfied her burden of proof. See Althen, 58 Fed. Cl. at 285-86.

[19] In the context of available medical literature, the medical experts' testimony consistently discusses the plausibility of the vaccine causing the alleged injury (including the mechanisms for causing the injury), what injury was in fact suffered, whether the timing of onset

construct of "logical sequence of cause and effect."[20] The divergence of views can be seen further through the Althen decision and the parties' interpretations thereof.

Quoting from Althen, petitioner argues that Althen requires "evidence of a strong temporal relationship *and either* reliable medical opinion *or* scientific theory explaining a logical sequence of cause and effect. . . ." Pet. Dec. 8 Brief, at 35 (citing Althen, 58 Fed. Cl at 284 (emphasis in original). Respondent interprets the decision to require "(1) a theory of causation that is theoretically possible; (2) the onset of a disease within a time frame following vaccination which is appropriate and consistent with that theory; and (3) the absence of proof of another cause." Res. Dec. 2 Brief, at 17. In addition, respondent reads Althen to require a "link" between the theory of causation and the facts of the given case. Id. However, respondent argues that even the linkage found by Judge Braden would be insufficient to find causation in the case at hand, stating that "[a]dditional support in terms of clinical findings in each petitioner would be required to demonstrate, for example, that the binding occurred, that the T-cells were activated by the binding, that the T-cells traveled to the joints, and that production of the cytokine interferon gamma brought about synovial damage." Res. Dec. 2 Brief, at 19, n.10.[21] We are all citing and interpreting the same Federal Circuit cases, however, our interpretations as applied to the same types of evidence, presented case after case, varies routinely and widely.

One might argue that litigation is imperfect and no one formula can be devised for causation-in-fact. However, Congress expected a different "litigation" system for the Vaccine Program. As stated in the undersigned's opinion in Althen, 2003 WL 21439669,

Congress legislated the Office of Special Masters with the goal of creating 'experts'

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comports with medical knowledge, whether there are other known causes for the alleged injuries and why the vaccine is the cause of the injury in the individual case.

[20]Expressing some frustration on this point, petitioner wrote:

> In this regard, if the petitioner can be permitted some *dicta*, had the Court of Federal Claims or the Federal Circuit Court of Appeals properly exercised their authority by correctly instructing special masters about "dispositive issues of law," the construction of the Stevens Prongs by the Chief Special Master would not have been necessary.

Pet. Dec. 8 Brief, at 31, n.32.

[21]Respondent makes no effort to reconcile his position with the Federal Circuit's admonition in Knudsen that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen, 35 F.3d at 549.

> in resolving these disputes. These experts are an integral part of the Program's objective of "consistent and certain" justice. To meet that objective, the special masters must move beyond case-by-case decision-making towards instruction - what types of evidence are persuasive, how much evidence is necessary, what causal relationships are pure speculation, which relationships are proven - to ensure that similarly situated petitioners are treated alike and thus fairly.

Id. at *16.

It only makes sense that if the same type and quantity of evidence is sufficient to prove causation in one case, it ought to be sufficient in another. For example, if the petitioner in this case is correct that Althen's requirement of essentially proof of biologic plausibility, appropriate timing and absence of other causes is a correct formulation of causation, then the next case presenting a causation-in-fact question proving those same elements should be compensated as well. Unfortunately, that is not currently happening. That is because the next decision maker may agree with respondent that Althen is incorrect or apply another interpretation of "logical sequence of cause and effect" and rule against the petitioner. Same proof, different decision-makers, different interpretations of the Federal Circuit cases and disparate results. That may be how our civil system of justice operates, but clearly Congress expected something other than the replication of the tort system. See H.R. Rep. 99-908, at 1, 6-7, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344, 6347-48.

As Judge Braden recognized as well in expediting her decision in Althen "to facilitate any appellate review," Althen, 58 Fed. Cl. at 272, these are issues that the Federal Circuit will have to address to bring clarity and thus, consistency and certainty to this area of Vaccine Act practice. In the meantime, the undersigned must resolve this case. So the parties are clear as to what evidence the undersigned is looking for in determining whether a "logical sequence of cause and effect" is proven, an explanation follows.

The Undersigned's Interpretation

In considering the medical evidence in vaccine cases, the special masters face an "unenviable job." Hodges, 9 F.3d at 961. Many of the alleged injuries have not been studied in relation to the covered vaccines. As the IOM recognized, few epidemiological studies exist. See IOM Report on Causality, at 23, 30. Thus, in considering causation issues, the parties and the court are left to weigh the probative value of less meaningful case series and individual case reports. The court does benefit from expert testimony. However, one must be mindful of their appropriate role. While the experts are essential in elucidating pieces of the causation-in-fact puzzle, *e.g.*, mechanism of injury, appropriate timing for the injury, absence of other causes, etc., their opinions on the ultimate causation issue are problematic. That is because their own perspective of causation dictates how much and what type of proof is necessary. Scientists generally require epidemiological studies to prove causation, which even respondent concedes is

not legally required to prove causation-in-fact,[22] while clinicians require more of the circumstantial evidence discussed in Stevens. However, how much evidence is required to prove causation-in-fact is still debated. In fact, Stevens evolved from that dichotomy. See Stevens, 2001 WL 387418, at *16. The different approaches can be seen in the case at hand between respondent's own experts.[23]

Ultimately, the argument devolves to how much proof and what quality are sufficient to tip the scales in petitioner's favor. Central to the special master's task is rationalizing the Program's goals of speed, consistency, and certainty and the Federal Circuit's admonition in Knudsen[24] with respondent's seemingly fluid argument[25] that petitioner must establish with seeming certainty that the vaccine's mechanism of injury is actually occurring in the petitioner --

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[22]See White, 2002 WL 1488764, at *5, n.12 (citing Watson, 2001 WL 1682537, at *8).

[23]When asked by the court as to what proof he would look for to establish a causal relationship in a particular case, Dr. Zweiman responded that he would need an epidemiologic study to show causation "[t]o his level of reasonable certainty." Tr. at 205. Dr. Phillips, on the other hand, responded that "[he] definitely would be looking for a more direct temporal relationship. And you definitely would like to be sure any antecedent clinical events that were [RA] starting earlier than the vaccination." Tr. at 234. Furthermore, Dr. Phillips indicated that he would like to see more case reports to support a causal relationship between RA and the vaccine. For example, when asked whether reports of arthritis following hepatitis B infection would "indicate that [RA] would follow Hepatitis B vaccination," he responded, "[w]ell, it might. So as I think has been repetitively emphasized, again, by both the Plaintiffs and the defense." Tr. at 220. In addition, he "think[s] it is probably worth saying from a clinical point of view . . . going back to the question of why there aren't more cases of this association reported since there should be a lot more just based on coincidence." Id. at 224.

[24]"The Court of Federal Claims is . . . not to be seen as a vehicle for ascertaining precisely how and why DPT and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. The special masters are not 'diagnosing' vaccine-related injuries. The sole issues for the special master are, based on the record as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused a child's injury or that the child's injury is a Table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury." Knudsen, 35 F.3d at 549.

[25] The word "fluid" is used because respondent seems to raise the bar another notch, as petitioner produces more and more evidence, to maintain the causation bar just out of petitioner's grasp, while at all times never identifying that winning piece of evidence. See, e.g., Res. Dec. 2 Brief, at 19, n.10; see also Althen, 2003 WL 21439669, at *16.

that is, the mechanism must be linked with specificity to the injured party. Now, Althen, as interpreted by petitioner in this case, presents arguably a far more generous test for petitioners, requiring a supported theory of causation, appropriate timing of injury and an absence of other causes. In petitioner's view, Althen does not require the linkage advocated by respondent. Respondent argues to the contrary, and yet maintains that even with linkage, the Althen requirements are not enough. It is indeed, at times, an unenviable task!

Let us start with what we know. It has been established through expert testimony and resulting decisions that if an individual experiences a rechallenge event, or can demonstrate the presence of pathological markers indicating that the vaccine caused the injury, a petitioner has established causation-in-fact. As expressed *supra*, a rechallenge event occurs when a "disorder reappear[s] or worsen[s] when the [environmental] exposure was reintroduced." Pet. Ex. 26, at 17. A "pathological marker" is not defined, per se. However, we know that the word "pathological" is defined as "pertaining to pathology; pathologic," Dorland's Medical Dictionary, 27th Ed., at 1242 (1988), and that "pathology" has several different definitions in the medical community. In general, "pathology" is "that branch of medicine which treats of the essential nature of disease, especially of the structural and functional changes in tissues and organs of the body which cause or are caused by disease." Id. Going further, a "marker" is defined by the medical community as "something that identifies or that is used to identify," and more specifically, a "genetic marker" is "a genetic polymorphism with a simple mode of inheritance occurring with different frequencies in different populations, and therefore useful in family studies, studies of the distribution of genes in populations, and linkage analysis." Id. at 983. The experts have euphemistically referred to these markers as "footprints."

Moreover, if an epidemiological study finds a relative risk greater than two, that is legal probability. See Daubert, 43 F.3d at 1320; Liable v. Secretary of HHS, No. 98-120V, 2000 WL 1517672, at *15 (Fed. Cl. Spec. Mstr. Sept. 7, 2000). It is well settled that if a petitioner fits the profile of such a study, causation is proven. Unfortunately, as noted, the IOM recognizes and experience has taught that there are very few epidemiological studies concerning the vaccines covered by the Program. See IOM Report on Causality, at 23, 30. Interestingly, epidemiological studies do not make findings about individuals. Thus, in a case where an individual meets the profile of such a study finding a relative risk greater than two, the vaccine is deemed to be the causative agent, without proof of any linkage to the individual. Again, this is not an issue in dispute.

Now, what about cases which do not benefit from epidemiologic studies? We know that petitioners can prove their case without such studies. Respondent has stated consistently that epidemiological evidence is not required to prove causation-in-fact. See, e.g., White, 2002 WL 1488764, at *5, n.12. Respondent's expert, Dr. Moulton, see testimony *infra*, agreed that epidemiological evidence is not required to prove causation. Tr. at 129. Unfortunately, Dr. Moulton came up short with what proof would be satisfactory.

We do know from respondent's witnesses that causal relationships between vaccines and injuries reach a point of "acceptability" within the medical community with evidence short of

epidemiological data. Dr. Safran testified in Althen to that fact. Althen, 2003 WL 21439669, at *12. While not knowing what evidence is required for "acceptability," the undersigned surmises that reported cases of a potential causal link are of such quantity and quality that, even in the absence of direct proof, the medical community "accepts" the causal link.

Additional support for using case reports as evidence of causation comes from the IOM. The IOM has stated in its policies regarding causation that "[t]he sources of evidence for causality examined by the committee include demonstrated biologic plausibility, *reports of individual cases or series of cases*, and epidemiologic studies." IOM Report on Causality, at 27 (emphasis supplied). Furthermore, the IOM has used case reports to find a causal link between a vaccine and a particular injury, for instance, Guillain-Barré syndrome. The Committee found based on several case studies that "the evidence favors a causal relation between vaccines containing tetanus toxoid and GBS." Id. at 89. Thus, case reports and case series and other supportive medical literature can combine to convince the medical community that a vaccine is a probable causative agent.

The undersigned was first exposed to this notion in McCummings v. Secretary of HHS, No. 90-903V, 1992 WL 182190 (Cl. Ct. Spec. Mstr. July 10, 1992), aff'd, 27 Fed. Cl. 417 (Fed. Cl. 1992), aff'd, 14 F.3d 613 (Fed. Cir. 1993), cert. denied, 511 U.S. 1032 (1994). Therein, respondent's expert, Dr. Robertson, testified that even though there was "no scientific evidence to support the theory that transverse myelitis is caused by a virus," McCummings, 1992 WL 182190, at *7 (emphasis supplied), he concluded that based on her concurrent symptoms of a low grade fever and runny nose that a virus -- not the vaccine -- was the cause of petitioner's injury. Id. This was because "a viral infection *is frequently mentioned in the literature* with development of transverse myelitis." McCummings, 1992 WL 182190, at *7 (emphasis supplied). Moreover, "that because of the rareness of the condition, as well as the small number of reported cases. . . clinicians would be eager to report every case describing an association between transverse myelitis and vaccinations." Id. at *12.

Dr. Robertson's testimony in McCummings was, in fact, the genesis for Prong Two of Stevens; that is, the medical community's "acceptance," "frequent mentioning," or "thinking about" the causal relationship and thus elevating the theoretical or even established biologic mechanism to the level of probably occurring. The experts relied upon this evidence, when coupled with appropriate timing and absence of other causes, to establish causation. That quantity and type of evidence was sufficient for Dr. Robertson to testify to a virus as the cause of transverse myelitis to defeat petitioner's claim in McCummings -- it was recognized by Dr. Safran testifying for respondent in Althen and it was recognized by Dr. Phillips testifying in the case at hand. See, e.g., Tr. at 231. Likewise, credible experts testifying for petitioners have advanced the same contention innumerable times. From the undersigned's vantage point, it appears that the experts, in reviewing the evidence of a causal relationship, analyze the evidence of biologic plausibility, mechanisms, case reports and other literature and, in some instances, even without epidemiologic evidence, find that evidence of a causal relationship to be so strong that the medical community "accepts" the causal conclusion. If this analytical process is valid, as Dr. Robertson testifying for respondent testified to, it only follows that if a petitioner proves by a

preponderance of the evidence that the medical community "accepts" the causal relationship between a vaccine and injury (such an acceptance would logically subsume or be part of the discussion of biologic plausibility), the petitioner meets the profile of that acceptance (that would include the appropriate timing of onset), and there is an absence of other causes, petitioner would successfully prove a "logical sequence of cause and effect," and thus establish causation.

As with the epidemiological study, the general acceptance theory, as testified to by the above-noted experts, does not require proof of a mechanism occurring in the injured, but, again like the epidemiological proof, requires establishing the general acceptance and proof of meeting the parameters of that acceptance. While not knowing with certainty, the undersigned surmises that specific proof of the mechanism occurring in the individual is not required because, like with the epidemiological evidence that does not require linkage, the general acceptance by the medical community is based upon objective data of such quantity and quality that has risen to a level to overcome any speculation or conjecture - it is generally accepted. Thus, like with the epidemiological proof, meeting the profile of the accepted causal relationship and removing other potential causes is sufficient proof of probability -- not certainty -- but probability.

What if petitioner can produce no epidemiological study or proof of medical acceptance, is there a means of proving causation? To be frank, this is the main area of dispute involving the vast majority of cases. To be more precise, the primary dispute is over whether proof of linkage of the mechanism to the individual is required and how much proof. See Res. Dec. 2 Brief, at 19, n.10. Stated another way, to prove a logical sequence of cause and effect, is something more required than proving the vaccine can cause the injury -- biologic plausibility, and that it did by showing appropriate timing and absence of other causes? Petitioners say no; respondent says yes. Ultimately, the Federal Circuit will have to tell us. Until then, the undersigned agrees with respondent, to a point, that some linkage is necessary. Otherwise, a theoretical mechanism will be bootstrapped to a probable cause by the fact of a potential coincidental timing of injury coupled with the possible inability or lack of testing for an alternative cause. That would seem to be "speculative" or "conjectural" and thus not a legal probability. Snowbank Enter., 6 Cl. Ct. at 486. Thus in the undersigned's view, if petitioner proves by a preponderance of the evidence, which evidence includes "appropriate validation,"[26] that the proposed biologic mechanism is

[26]The undersigned acknowledges that this requirement for scientific and/or medical corroboration differs from that of Judge Braden in Althen. In Althen, Judge Braden found that a close temporal relationship combined with a reliable medical opinion *or* scientific theory explaining the causal link, in the absence of other causes, was sufficient for the petitioner to satisfy the burden of proof required for entitlement. Judge Braden noted that the lack of peer-reviewed literature "does not preclude a petitioner from meeting a preponderance standard, based on totality of the evidence in a particular case." Althen, 58 Fed. Cl. at 284.

The undersigned acknowledges that while it is legally correct that Daubert does not require a petitioner to present peer-reviewed literature to support his or her theory, Daubert does require that the testimony be supported by appropriate validation – i.e., "good grounds," based on

apparent or occurring in the injured, coupled with appropriate timing and reasonable absence of other causes, petitioner will establish a "logical sequence of cause and effect."

The undersigned recognizes that this is an extremely difficult task. In practice, requiring proof of the biologic mechanism occurring in the injured could "clash" with the admonition in Knudsen, 35 F.3d at 549. We will have to wait for the Federal Circuit to weigh in. In reality, the undersigned is aware of few successes in identifying a mechanism of injury and linking that mechanism to the injured.[27] However, to elevate the theory of mechanism for the vaccine causing an injury beyond speculation, it would seem that there must be some piece of evidence showing that the process testified to is occurring in the petitioner. The undersigned is unable to articulate what that proof is or what form it will take, but relies upon the experts' testimony on these issues.

Lastly, as stated in Stevens, see note 13, *supra,* and restated here, there may be other means of proving this linkage or of proving causation-in-fact. The undersigned welcomes that proof but is unaware of it. This is a difficult area of law. The special masters wrestle with it constantly, discuss it daily and look forward to further guidance from the courts above. The case at hand was resolved consistent with the above-stated thoughts.

Discussion

Petitioner asserts that under the standard posited by Judge Braden in Althen, that "the medical and factual evidence provided . . . is easily sufficient to warrant a judgment of entitlement. . ." Pet. Dec. 8 Brief, at 2. Petitioner bases this finding on several pieces of evidence including the testimony of an expert witness, VAERS data, as well as a number of scientific studies and journal articles that she asserts support her position. Respondent asserts that Dr. Bell's theory of causation, although theoretically possible does not "accomplish the 'heavy lifting' required in an actual causation case." Res. Dec. 2 Brief, at 20. As such, respondent argues that the mechanism presented "is not a lawful basis for a finding that Hepatitis B vaccine more likely than not can cause RA, or that it did cause RA" in this petitioner. Id.

In this case, the undersigned finds that the petitioner has established that the hepatitis B

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what is known. Daubert, 509 U.S. at 590.

To the undersigned and my colleges, this requirement is not new; it has been one facet of the special masters' evaluative criteria even before Daubert was issued by the Supreme Court. For example, in Aea v. Secretary of HHS, No. 90-568V, 1992 WL 121389 (Fed. Cl. Spec. Mstr. May 8, 1992), the undersigned required substantiation of a medical expert opinion based on "'reputable medical or scientific' support." Id. at *16 (citing Grant, 956 F.2d at 1148).

[27]The link was found in Althen, but it must be noted that the experts did not testify to that linkage.

vaccine *can* cause RA; however, she has failed to demonstrate that it *did* cause the injury. As discussed fully below and consistent with the discussion above on the undersigned's interpretation of the causation standards, there is no evidence of rechallenge, pathological markers or epidemiologic study in this case. In addition, there is insufficient proof of a general acceptance in the medical community that hepatitis B vaccine causes RA and petitioner's proof is woefully inadequate to support the plausible theories of causation, much less link them to the petitioner. Lastly, the undersigned reviewed petitioner's evidence for any other evidence of a "logical sequence of cause and effect" and found none. Each of these issues will be discussed in turn.

1. *Can* the Hepatitis B Vaccine Cause RA?

At the June 2003 hearing, petitioner presented Dr. Bell as her sole expert witness. Dr. Bell has a Royal College Fellowship in internal medicine.[28] Dr. Bell is a rheumatologist having treated patients with arthritis since "prior to taking up a faculty position at the University of Western Ontario in 1972," and continued to see patients with arthritic disorders at the University. Tr. at 8. Dr. Bell asserts that he does research and has published in the area of rheumatology. Dr. Bell testified that wild hepatitis B virus can cause RA. Dr. Bell also believes that it is medically plausible that the hepatitis B vaccine can cause RA, and in fact believes that the vaccine can cause the disease. Tr. at 10. The basis for Dr. Bell's opinion is his "own observations that have been published in the literature and the reports of others as well which support this relationship." Id. at 10-11.

Dr. Bell's main objective was to provide evidence supporting the hypothesis that the hepatitis B vaccine can cause RA. Specifically, Dr. Bell provided testimony regarding (1) a biologic mechanism for the occurrence of RA from the vaccine; (2) proof of medical plausibility from literature; and (3) his own studies supporting causation.

Dr. Bell testified that RA is a chronic, inflammatory form of joint disease that affects primarily middle-aged adults that are female. Tr. at 11. He does not know the cause of RA, but believes that "a prevalent theory" is that it is triggered by an agent, perhaps an environmental one, in a genetically-predisposed host. Tr. at 11.[29] In support of the notion that RA is potentially genetic in nature, Dr. Bell testified that there is a higher occurrence of the disease in identical twins than in non-identical twins, as well as a higher incidence in families. Tr. at 12.

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[28] This is equivalent in Canada to what is known as "Board Certification" in the United States. Tr. at 8.

[29] Dorland's Medical Dictionary, at 1460, defines "rheumatism" as follows: any of a variety of disorders marked by inflammation, degeneration, or metabolic derangement of the connective tissue structures of the body, especially the joints and related structures, including muscles, bursae, tendons, and fibrous tissue. It is attended by pain, stiffness, or limitation of motion of these parts. Rheumatism confined to the joints is classified as arthritis.

Based on these factors, Dr. Bell proposed to the court a medically/scientifically-based mechanism explaining how the hepatitis B vaccine can cause RA in potentially susceptible individuals. According to Dr. Bell:

> It is well established that [RA] is triggered in the early stages by activation of CD4 T cells which may traffic to the synovial tissue in joints. The analysis of the polypeptide components of the Hepatitis B Virus vaccine indicates the existence of several peptides which could bind MHC [histocompatibity complex] class II molecules, thereby, activating CD4 T cells. It is possible, although not known in this case, whether or not the patient had a genetic perpensity [sic] to develop [RA]. Individuals at risk of developing [RA] express the HLA antigen DR4 and have particular HLA DR4 alleles expressing a shared epitope. The binding groove of MHC class II molecules expressing the shared epitope, can accept a number of the polypeptides present in the hepatitis B vaccine used in this patient. In strains of mice transgenic for certain of these alleles (e.g. DR4 0401), immunization with several of the peptides present in the protein vaccine for this virus are able to bind to the DR4 0401 molecule and activate T-cells. This has been shown experimentally.

Pet. Ex. 15; see also Tr. at 12-17. Dr. Bell testified that this type of a response, occurs at the earliest "within a week," and at the latest "four to five weeks" after vaccination. Tr. at 21. Dr. Bell also testified that the putative mechanism is based on "fundamental scientific or medical concepts of immunology." Tr. at 21.

At the June 2003 hearing, the court heard extensive testimony from petitioner and respondent regarding biologic plausibility. Their presentations included a detailed discussion of a hypothesis that immunization by the hepatitis B vaccine can trigger onset of RA in patients who have a genetic predisposition for susceptibility. See Capizzano et al., 2003 WL 22425000, at *4. The court found it unnecessary to discuss in detail a mechanism of action for causation because respondent's Exhibit L, "Rheumatic Disorders Developed After Hepatitis B Vaccination," was found to be persuasive on the issue of biologic plausibility in rechallenge cases. In this paper, scientists linked four rechallenge cases of RA to the hepatitis B vaccination. See Resp. Ex. L., J.F. Maillefert et al., "Rheumatic Disorders Developed After Hepatitis B Vaccination," Rheumatology, 1999:38:978-983 at 979 (hereinafter Maillefert study).

The court has reviewed its previous analysis of biologic plausibility, see Capizzano et al., 2003 WL 22425000, at *4, and reaffirms this finding in the present Decision based on the following facts and analysis.

At the June 2003 hearing, Dr. Bell testified that the Maillefert study provided evidence of three rechallenge cases where a further vaccine injection caused worsening symptoms. Tr. at 38-

39. Two of respondent's expert witnesses, Dr. Zweiman[30] and Dr. Moulton[31] testified that evidence of rechallenge can be indicative of causality. In this respect, Dr. Zweiman conceded that the IOM has "made the point where if there is convincing evidence of recurrence of an adverse event with rechallenge it raises the level of suspicion higher of a possible causal relationship." Tr. at 201. Additionally, Dr. Moulton testified that:

> Positive Rechallenge for a rare event can . . . get you into the realm where you think. . . it's extremely unlikely to have happened by chance. So positive rechallenge for a rare event can be of interest to the medical community.

Tr. at 135.

In addition to the Maillefert study and testimony of the expert witnesses, the court found persuasive IOM findings regarding rechallenge and biologic plausibility. The IOM has on more than one occasion determined that rechallenge is strongly probative of a causal relationship. See Christopher P. Howson, et al., Institute of Medicine Adverse Effects of Pertussis and Rubella Vaccines, 48 (1991) (hereinafter IOM 1991 Report) ("increasing severity of the event with increasing dose number would tend to support a causal interpretation"); IOM Report on Causality, at 21("causality is strengthened by evidence that the risk of occurrence of an outcome increases with higher doses or frequencies of exposure"). In fact, in the instance of tetanus and Guillain-Barré Syndrome (GBS), the IOM found a causal relationship based upon evidence of rechallenge. IOM Report on Causality, at 88-89 (relying on Pollard and Selby). As stated in this court's June 20 Order,

> . . . tentatively, the undersigned finds the issue of medical plausibility (Prong 1) moot. That is because respondent's exhibit L, "Rheumatic Disorders Developed After Hepatitis B Vaccination" related four "rechallenge" cases to the Hepatitis B vaccine. R. Ex. L (J.F. Maillefert, J. Sibilia et al., Rheumatic Disorders Developed

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[30]Dr. Burton Zweiman is an immunologist. He has been a Professor of Medicine at the University of Pennsylvania since 1963, including a tenure of 24 years as the chief of the Allergy and Immunology division. Dr. Zweiman earned his Bachelor's degree and Medical degree from the University of Pennsylvania. Tr. at 158; Res. Ex. D.

[31]Dr. Lawrence Moulton is a biostatistician. He has been employed as an Associate Professor at the Johns Hopkins University Bloomberg School of Public Health since 1996. Prior to this appointment, Dr. Moulton had a series of professorships, including an appointment in France at the Institut National de la Santé et de la Recherche Médicale in Goustave-Roussy, and at the University of Michigan Department of Biostatistics.

Dr. Moulton earned a Bachelor of Arts degree in 1976 at the State University of New York at Buffalo in Statistics and Mathematics. He subsequently earned a Master's degree from the University of Texas School of Public Health in Biometry in 1978, and his Doctorate from Johns Hopkins in Biostatistics in 1987. See Res. Ex. B, at 1.

> After Hepatitis B Vaccination, Rheumatology, 1999:38:978-983 at 979). The Institute of Medicine (IOM) has stated that rechallenge is proof of causation. See Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines, 48, 53 (1991). The IOM has also stated that where causation is proven, biologic plausibility is a given. Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, 21 (1994). Therefore, if the court affirms this tentative determination, petitioners will have met Prong 1 of Stevens and any rechallenge rheumatoid arthritis case, if proven successfully to be a rechallenge case, will be compensated.

Capizzano et al., 2003 WL 21432586, at *2.

Analyzing this evidence of medical plausibility, this court found the Maillefert study, the expert testimony, as well as the IOM reports persuasive evidence that petitioner met the requirements for a biologically plausible mechanism by "'proffering a medically or scientifically supported means by which a vaccine component could cause the injury alleged.'" Capizzano et al., 2003 WL 22425000, at *3 (citing Stevens, 2001 WL 387418, at *23-*24). The rationale behind this finding was that "rechallenge cases are such strong proof of causality that it is unnecessary to determine the mechanism of cause – it is understood to be occurring." Id. at *4.

The court reaffirms its previous analysis in this decision. The court need not determine an exact mechanism for which hepatitis B occurs in rechallenge cases *or in any other cases* where a hepatitis B vaccination allegedly caused RA. The IOM's position, that rechallenge is tantamount to causation, ***logically includes the mechanistic event linking the vaccine to injury***. Dr. Moulton agreed, see Tr. at 135, and the undersigned is aware of no contrary argument to this position. See, e.g., Larive v. Secretary of HHS, No. 99-429V, slip. op. at 20 (Fed. Cl. Spec. Mstr. May 12, 2004) ("The [IOM] repeatedly positive rechallenge among its criteria for proving causation.").

Hence, the court finds that the Maillefert study, testimony by petitioner's and respondent's experts, and the IOM's position on rechallenge cases, support a logical sequence of events based on scientific and medical evidence that the hepatitis B vaccine *can* cause RA. Thus, petitioner has established biologic plausibility that the hepatitis B vaccine can cause RA.

2. *Did* the Hepatitis B Vaccine cause RA in this individual?

In order to determine whether or not the hepatitis B vaccine did cause RA in this particular individual, the undersigned relied heavily on the standards as articulated in the above discussion, which include the evaluation of evidence such as epidemiologic studies, rechallenge, presence of pathological markers or genetic predisposition, and general acceptance in the scientific and/or medical communities. The undersigned finds that petitioner has not proven by a preponderance of the evidence any of these means of establishing causation, ***or any other method proposed by petitioner***, and thus failed to prove that the hepatitis B vaccine caused her RA.

Epidemiologic Studies

As the undersigned has already described extensively, epidemiological evidence establishing a relative risk greater than two is sufficient to establish a causal link between a vaccine and a particular injury. However, petitioner concedes and respondent confirms that there are no epidemiologic studies at this time causally linking the hepatitis B vaccine to RA. See Tr. at 25, 113.

Rechallenge

As indicated by the undersigned above in this Decision as well as the August 5, 2003 Decision, rechallenge establishes biologic plausibility for the hepatitis B vaccine causing RA. Thus, if an individual can establish that a rechallenge event occurred in his or her case, in the absence of other potential causes, causality can be established.

In the undersigned's evaluation of the evidence in Ms. Capizzano's case, no evidence indicates that her injury is linked to a rechallenge event. Her affidavit does not indicate that she had any reaction to her first hepatitis B vaccination; only after the vaccination on May 3, 1998 does she indicate that there was a problem. In her words, "[b]efore May 1998 I was a normal mother working 40 plus hours per week and keeping up with three very active children." Dr. Bell testified that onset was within thirty days of administration of the vaccine. Tr. at 315. In addition, Dr. Bell testified that a third hepatitis B vaccine was never administered to petitioner. Id. at 321. Hence, the court is confident that petitioner did not experience a rechallenge event in developing her RA.

Pathological Markers

During the first day of the hearing, Dr. Bell indicated that a pathological marker is needed in order to determine if an individual has the capacity to develop RA from the hepatitis B vaccine. Tr. at 54-55. When asked by the undersigned if he had identified a genetic predisposition in any of the five cases, he answered "yes." Tr. at 83. But when probed further, Dr. Bell admitted that there is no current test to determine genetic susceptibility for RA in an individual. Tr. at 80, 83-84. Hence, petitioner has not provided any pathological marker proving that the hepatitis B vaccine is the cause of her RA.

General Acceptance in the Scientific and/or Medical Communities

Petitioner's proof of general acceptance of Dr. Bell's theory that hepatitis B vaccine causes RA consisted of Dr. Bell's testimony regarding causation, case reports, and the Vaccine Adverse Event Reporting System (VAERS) data.

First, petitioner relies on Dr. Bell's testimony as support for her proposition that the

medical community accepts that the hepatitis B vaccine can cause RA.[32] In his testimony at the June 2003 hearing, Dr. Bell represented to the court that he is aware of "peer review literature that reports that hepatitis B vaccine is associated in some sense with [RA]," and that the medical and scientific community has seen an association between Hepatitis B vaccine and [RA]. " Tr. at 24. In addition, he claims that he has discussed the relationship with other members of the scientific community," in that he and his colleagues have presented their work at meetings, as well as have published articles related to this topic. Tr. at 24. He "believes" that there is a general awareness in the scientific community about an association between hepatitis B vaccine and RA. Tr. at 25. Although Dr. Bell is aware of no epidemiologic studies that support the conclusion that hepatitis B vaccine causes RA, he believes that the scientific and medical community are reporting suspected or potential associations between the hepatitis B vaccine and RA. Tr. at 25. Unfortunately for petitioner, as discussed fully below, Dr. Bell's superficially supportive statements take on a dubious quality upon close scrutiny.

Petitioner alleges that case reports establish that the medical community is seeing a relationship between hepatitis B vaccine and RA. To that end, petitioner submitted articles that purportedly demonstrate that "[t]here exist a significant number of recent case reports of reactions to Hepatitis B vaccine." Pet. Aug. 5, 2003 Filing, at 2. During the hearing, Dr. Bell testified that "18 anecdotal reports of RA also support an association between hepatitis B vaccination and RA."[33] Pet. Sept. 10 Brief, at 6. According to Dr. Bell: (a) there were 18 published cases of RA-like disease following Hepatitis B vaccine by 1998 in Canada and Europe; (b) some patients developed transient and others persistent arthritis shortly after the second or third vaccination; (c) many were health care workers because they are a large group at risk due to mandatory vaccinations; (d) some of the cases were so severe as to require drug therapy; and (e) two different vaccine manufacturers' products were used, which consisted of multiple lots. Pet. Ex. 26, at 11.

During the hearing and in subsequent briefs, petitioner described several of these case reports in further detail. The oldest report offered by petitioner suggested an association between RA and the hepatitis B wild virus. Duffy, et al., "Polyarthritis, Polyarteritis, and Hepatitis B," Vol. 55, No. 1, Medicine, Jan. 1976, at 19-37; Pet. Ex.17, Tab A. However, respondent's witness Dr. Zweiman expressed serious concerns about equating RA developed from the wild hepatitis B virus to that purportedly developed from the vaccine. According to Dr. Zweiman:

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[32] Dr. Bell defines RA as "a chronic inflammatory polyarthritis of unknown etiology." See Pet. Exh. 17, Tab C, at 1687.

[33] It is not perfectly clear how Dr. Bell arrived at this number of case reports. At one point he did state that the 18 anecdotal cases are arrived at by including 11 patients from his own study and seven other anecdotal reports. Tr. at 42. Dr. Phillips' testimony confirms that the number of case reports in Dr. Bell's study is unclear, but is between 18 and 21. Tr. at 222. He stated that "I think the point is that this is a small number." Id. For purposes of this decision, the court assumes that a number between 18 and 21 is an accurate representation of the case reports that Dr. Bell examined to reach his conclusion that the hepatitis B vaccine can cause RA.

> . . . I've made it very clear that the Hepatitis virus infection is a very different thing than giving a purified protein immunization. That's been pointed out in a number of other settings because the virus infects and lives inside the cell, persist [sic] for a long period of time in many individuals and one cannot extrapolate from that to giving a recombinant protein. They didn't even extract it from the virus. It's made in yeast. And how one can extrapolate what is observe, even if it's a rare event that you did have RA occurring in some individuals with natural virus infection, to extrapolate that to giving a purified protein.

Tr. at 191-92. Dr. Zweiman concluded his testimony by pointing out that in the beginning, scientists obtained the protein from the virus. Today, however, it is purified protein of non-viral origin. Id. at 192.

The IOM Report on Causality confirms Dr. Zweiman's concerns:

> Since the arthritis that occurs in patients with acute hepatitis B [wild] virus infection appears to occur only during the period of antigen excess, it is most invariably self-limited and appears to subside as the level of antibody increases. It is therefore difficult to relate arthropathy following receipt of the hepatitis B vaccine to the same sort of serum-sickness like antigen-antibody reaction.

IOM Report on Causality, at 227. Dr. Bell offered no rebuttal or support for using literature related to the wild virus to support vaccine causation. The undersigned has heard consistent testimony over the years cautioning against extrapolating information concerning wild viruses to attenuated vaccines. Dr. Zweiman's testimony and the IOM's report are consistent with that prior testimony. Dr. Bell's testimony and petitioner's arguments to the contrary must be rejected.

In addition, petitioner offered multiple articles as examples of RA or RA-like diseases after hepatitis B vaccination. Petitioner offered as proof of individual case reports after hepatitis B vaccination a 1994 "Letter to the Editor" in the British Journal of Rheumatology entitled, "Acute Sero-positive Rheumatoid Arthritis Occurring after Hepatitis B Vaccination," by Vautier and Carty, Vol. 33, 991 (1994). See Pet. Ex. 16, Tab D; Pet. Dec. 8 Brief, at 9. This article relays the physicians' observations of four cases of acute reactive arthritis after hepatitis B vaccination. The paper focuses on a woman who developed oligoarthritis in her hands 24 hours after receiving her first vaccination, which rapidly developed into a symmetrical polyarthritis with signs of inflammation in the joints. The woman was later diagnosed as expressing the HLA antigen, which may have included the allele for the shared epitope. Dr. Bell testified that the woman "satisfied the accepted criteria for diagnosis of [RA]." Tr. at 34.

Dr. Bell described another "Letter to the Editor", published in the January 23, 1993 edition of the British journal, The Lancet, entitled "Hepatitis B vaccine side-effect," Vol. 341, at 250, by Carmeli and Oren. Petitioner offered this article as an example of individual case reports of polyarthritis after hepatitis B vaccination. See Pet. Dec. 8 Brief, at 9. Dr. Bell did not have many comments about this article – only that it was a case of acute glomerulonephritis as well as

polyarthritis, and that he "thinks" he included it in his table of 18 cases.[34] Tr. at 35. Another "Letter to the Editor," entitled "A new case of reactive arthritis after hepatitis B vaccination," published in 1993, by Biasi, et al., Journal of Clinical and Experimental Rheumatology, Vol. 11, at 215, was also described by Dr. Bell as causing a different type of arthritis, namely reactive arthritis, which is an arthritic reaction to a microbial agent. See Pet. Exh. 17, Tab E; Tr. at 36.

Dr. Bell also pointed to several anecdotal reports submitted by respondent that petitioner alleges support her position that the medical community is reporting a relationship between the hepatitis B vaccination and RA. Petitioner offers the article by Gross et al., published in 1995 in the Scandinavian Journal of Rheumatology, entitled "Arthritis after Hepatitis B vaccination," Vol. 24, at 50-52 to show a case report of RA being caused by the hepatitis B vaccination. See Pet. Dec. 8 Brief at 9; Res. Ex. K. Dr. Bell reported that the article described three cases of arthritis: one with RA and two demonstrating symptoms of reactive arthritis. In addition, Dr. Bell discussed the Maillefert study, which consisted of twenty-two patients who had recently had a hepatitis B vaccine. Six of these patients developed symptoms of RA, and four developed polyarthritis, totalling ten people with polyarthritis out of twenty-two. Petitioner also points out that the Maillefert study also presented three individuals that Dr. Bell claims exhibited rechallenge symptoms of RA after hepatitis B vaccination. See Pet. Dec. 8 Brief at 9.[35] Furthermore, petitioner asserts that an article by Sibilia and Maillefert entitled, "Vaccination and Rheumatoid Arthritis," Rheum. Dis., Vol. 61, 575-76 (2002), shows that hepatitis B vaccinations may exacerbate RA. See Pet. Dec. 8 Brief, at 9; Res. Ex. M.[36]

Lastly, Dr. Bell suggested that two articles involving studies of large populations submitted by respondent demonstrate a causal relationship between the hepatitis B vaccine and RA. The first article was a study of the "Frequency of adverse reactions of Hepatitis B Vaccine in 43,618 Persons," published in the March 1992 American Journal of Medicine, Vol. 92 at 254-56, by McManhon et al. See Res. Exh. N. A similar article presented by respondent was Exhibit O, "Assessment of a Universal, School-Based Hepatitis B Vaccination Program," by Dobson et al., published in the Journal of the American Medical Association in October 1995, vol. 274, No. 15 at 1209-12. This study examined 127,922 students after having a hepatitis B vaccination. Dr. Bell pointed out that "6 percent of the patients had arthritis within 20 days of receiving the vaccine." Tr. at 40. When questioned by the court as to whether the 6% figure supported his theory that hepatitis B vaccination causes RA, Dr. Bell stated "[y]es, I can use that to support that." Id.

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[34] When first asked by petitioner's counsel whether this case was a part of his 18, Dr. Bell responded , "No." However, after indicating that the patient developed polyarthritis, he said "he think[s]" he included it in the Table. Tr. at 35.

[35] The Maillefert study was the study that the court relied on to establish a plausible biologic mechanism in determining whether hepatitis B vaccination "can" cause RA.

[36]The article by Sibilia and Maillefert is a follow-up article to the Maillefert study.

As the finale to his testimony on case reports, Dr. Bell highlighted an article that he and several other scientists authored regarding the relationship between hepatitis B vaccine and RA seen in case reports. More specifically, Dr. Bell and several of his colleagues published an article in 1998 regarding eleven previously healthy adults, who after vaccination, exhibited "a persistent, and in some cases severe form of inflammatory polyarthritis, frequently fulfilling criteria for RA." Pope, et al., "The Development of [RA] After Recombinant Hepatitis B Vaccination," Journal of Rheumatology, Vol. 25, 1998, at 1687; see Pet. Ex. 17, Tab C. In this article, they examined the "clinical and laboratory features and HLA antigens" of five firefighters and six healthcare workers. Id. Dr. Bell and his colleagues pointed out that the vaccination was administered to a "group of previously healthy individuals" and the "persistent arthritis experienced by many of them was not predicted from any prior health problem or familial predilection to RA." Pet. Ex. 17, Tab C, at 1690. The study also points out that:

> [t]his *uncommonly reported outcome should alert others to look for this association*. *Further studies are required to confirm whether this association is other than coincidental*. Our studies suggest that genetic factors linked to MHC class II molecules *may* represent a risk factor for post vaccine arthritis but there are undoubtedly other determining factors, *given the frequency of these HLA class II molecules in the healthy population.*

Id. at 1692 (emphasis supplied).

When probed to discuss any other studies by scientists or medical doctors that are studying the purported relationship between hepatitis B vaccine and RA, Dr. Bell could not name any beyond the anecdotal studies, case reports, and surveys of arthritis following a vaccination. Dr. Bell also stated that of the eighteen individuals in his anecdotal study, eleven of which were his patients, he has not pursued a consistent follow-up study, although he notes that he has continued to monitor five of the patients that still retain symptoms. Tr. at 44. Moreover, he thinks that further studies would be "desirable if possible." Tr. at 54.

On cross examination, Dr. Bell's own testimony exposed several flaws in his hypothesis regarding RA and the vaccine. For example, Dr. Bell acknowledged that the textbook, Arthritis and Allied Conditions, is a highly reputable textbook in the medical community and could not explain to the court why its authors assert that "[t]he incidence of rheumatoid arthritis may be decreasing with time." Tr. at 52. In addition, Dr. Bell agreed that most of the limited number of reports about RA occurring after hepatitis B vaccine are case reports, and that case reports are considered to provide the least amount of evidence by which to prove a causal relationship. He also acknowledged that his study on the firefighters and healthcare workers was indeed a "case series" and acknowledged that his own article describing the case series posited that a connection between RA and the vaccine could be coincidental. Tr. at 51-53. More telling, however, was Dr. Bell's admission that he has "not seen anything in the last 12 months that [he] can recall that discusses this in the literature," although he and his colleagues "still discuss it amongst ourselves and we see cases where I work." Tr. at 246.

In response to Dr. Bell's testimony asserting that there is a causal relationship between hepatitis B vaccination and RA, respondent presented several expert witnesses to support respondent's position that medical evidence does not support such a relationship. Respondent's witness Dr. Phillips, a rheumatologist, testified that there are "very few cases" in general and no reported cases "since 1999." Tr. at 234-35. In addition, when asked whether the relevant medical community is seeing and reporting in peer review literature, and discussing a suspected or potential association between the vaccine Hepatitis B and rheumatoid arthritis, Dr. Phillips stated that

> [t]he relevant word is the first word "is," implying present. And as I've said, at present, the answer is no. We're not hearing about it. Dr. Bell may follow it more closely than I did, but I think when asked about recent reference, he didn't have any.

Dr. Phillips testified that it is more likely than not that hepatitis B vaccination does not cause RA. Tr. at 213. Dr. Phillips believes that there is no link between hepatitis B vaccine and RA because there are very few cases reported, and with that they are not "convincing associations." All of the data available is "old," and there have been no more case reports since 1999. Moreover, RA is a common disease and hepatitis B is a common event. He believes that "there are bound to be a large number of coincidental cases of rheumatoid arthritis in Hepatitis B vaccinees." Tr. at 213.

In addition, Dr. Zweiman's testimony confirms the Pope article's apparent recognition of a potential coincidental relationship between the hepatitis B vaccination and RA. In his words:

> A very large study [was] carried out by Priest et al., at Stanford in this country, and so it represents a U.S. population, showed 45 percent of their controls with [RA] expressed the [shared epitope]. Now, you can say, well, maybe that's true. Maybe there is another factor X not yet discovered that is needed to manifest [RA] in an individual who got hepatitis immunization. Well, I can see that except the fact is that about 1 percent of the population in the United States has [RA]. It is an uncommon, but not a rare disease. And that would mean about 1 percent of a group of individuals who got hepatitis immunization have the potential for developing [RA]. About two-thirds of those individuals, based on most studies would express this shared epitope, maybe three-quarters, 75 percent might express this shared epitope. About 5 million people get Hepatitis immunization a year. Now that contains 1 percent of that population who have the potential – that have all the equipment. They have [shared epitope]. They have factor X that makes them potential for having [RA]. One would expect 1 percent of that 5 million is 50,000. So there's a fair number of people who not only might express the [shared epitope], but have what is needed to have the potential to develop [RA], and ***we don't see that***. It's an extremely rare case reported event for the most part.

Tr. at 168 (emphasis added).

Making every effort to complete the record on whether the medical community is seeing a

causal relationship between the hepatitis B vaccine and RA, the court requested that petitioner and respondent file "additional medical evidence in the form of peer-reviewed literature that discusses whether or not there is a possible association between the Hepatitis B vaccine and rheumatoid arthritis or other evidence that assists the court in determining what the medical community is 'thinking' regarding the alleged [causal] association." Capizzano et al., 2003 WL 21432586, at *1. In her filing, petitioner reported that she "did not locate, after thorough research, any additional literature regarding Carpal Tunnel Syndrome and Rheumatoid Arthritis," nor could she "locate, after thorough research, any additional literature that discusses whether or not there is a possible association between the Hepatitis B vaccine and rheumatoid arthritis." Pet. Aug. 5 Filing, at 2. Petitioner notes that she will continue to search for more literature and will file with the court any documents that are found. Id. However, as of the date of this decision, no additional documents have been submitted to the court. Id.

Respondent's report seemingly confirmed petitioner's findings, or lack thereof. Respondent's Exhibit TT, a "Letter from Paul E. Phillips, M.D.," dated July 21, 2003, reported that Dr. Phillips had "engaged in an extensive literature search in an attempt to find additional case reports of RA following hepatitis B vaccination," Res. Ex. TT, at 1, and also to find additional literature concerning carpal tunnel syndrome as a not uncommon presentation in RA patients. Id. at 2. In his letter, Dr. Phillips states that he did a thorough inquiry and his search did not identify any additional cases of chronic arthritis following hepatitis B vaccination anywhere in the world subsequent to 1999, including none at all in North America. Even though he did identify three possible additional cases in Spain in 1999, as well as in Italy and France in 1997, it was "clear" to him that:

> 1) there have been no more reports of arthritis following HB vaccination in the last three years anywhere in the world in spite of continuing active HB vaccination program [sic] in many different countries.
>
> 2) the arthritis following hepatitis B virus infection, as well as that following natural rubella virus infection, are no longer even considered in review articles about viral arthritis, where 1-2 decades ago, they were two of the most common causes of viral arthritis. One suspects that it is entirely due to the effect of mass vaccination campaigns for both of these diseases.
>
> 3) this search identified many reports of both relatively common and rare arthritic and other reactions following various viral infections, including parvovirus B-19, herpes viruses, hepatitis C and multiple others. Thus, it seems unlikely that if arthritis, particularly chronic and persistent arthritis, is being seen following HB vaccination that it would not also be reported currently, as other reactions to other virus infections and immunizations are being.

Res. Ex. TT, at 2.

Dr. Phillips also noted that he could not find any additional literature with respect to RA patients

presenting with carpal tunnel syndrome.

Moreover, as respondent points out, there are other, more recent, studies in the literature that indicate that the medical community is *not* seeing a suspected relationship between RA and the hepatitis B vaccine. See Res. Aug. 27 Brief, at 14. Respondent proffered two studies demonstrating this point. For instance, the Sturkenboom study, which was published in abstract form in 2000, found that "[t]he risk for [RA] following hepatitis B vaccine did not seem to be elevated." Res. Aug. 27 Brief, at 10; Res. Ex. R, at S72.[37] Additionally, the Elkayam study, published in 2002, discusses a potential causal relationship between hepatitis B vaccine and RA, but ultimately rejects any such relationship. See Res. Aug. 27 Brief, at 13; Res. Ex. S, at 623, 625. In this study, twenty-two individuals already diagnosed with RA were given three doses each of hepatitis B vaccine. Their reactions were monitored against another group of RA diagnosed individuals who did not receive the vaccine. They found that "[t]he course of the seven months after vaccination was similar in both groups." Res. Aug. 27 Brief, at 14; Res. Ex. S, at 625; Res. Ex. C, at 2-3.

In further support of this court's observation that there are few recent case reports seeing a relationship between the hepatitis B vaccine and RA, the court finds the editorial written in 2002 by Sibilia and Maillefert highly probative. The editorial confirms that, as of the time it was written, the 1999 Maillefert study and the Pope, et al. study, of which Dr. Bell was a co-author, are the only case series of RA following hepatitis B vaccination. See Res. Ex. M, at 575. As respondent points out, the 2002 Maillefert article confirms that the only reports of more than one case of RA occurring after hepatitis B vaccination in peer-reviewed publications are those in the Pope, et al. article. There are other individual case reports of RA occurring after the administration of a hepatitis B vaccination, but these occurred prior to those reported by Pope and Maillefert, and there are only a few. See Res. Ex. at 2-3; see, e.g., Res. Ex. K; Res. Aug. 27 Brief, at 9. Moreover, the court finds highly probative the IOM's conclusion that "[t]he evidence is inadequate to accept or reject a causal relationship between the hepatitis B vaccine and either acute or chronic arthropathy." IOM Report on Causality, at 227.[38]

Petitioner attempted to buttress the case reports with data collected from VAERS, which lists "several hundred cases associating Hepatitis B vaccine with rheumatological reactions." Pet. Aug. 5 Filing, at 3. Petitioner also points out that approximately 153 of these cases are

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[37]Respondent indicated that he has been unable to obtain a full article relating to this abstract, and indicated that it is unclear as to whether a full article was ever actually published. See Res. Aug. 27 Brief, at 10, n.7

[38]According to the IOM, arthropathy is "[t]he general term for joint symptoms," and refers to any abnormality of the joint. The term "arthropathy" encompasses arthralgia (subjective pain in a joint or joints), stiffness (with arthralgia, commonly referred to as *rheumatism*), and arthritis (objective findings of swelling, redness, heat, and limitation of motion). IOM Report on Causality, at 222 (emphasis in original).

specific to [RA] and hepatitis B vaccine, and that these reports corroborate her position.[39] Petitioner argues that physicians are using the VAERS system as opposed to reporting "case reports" to medical journals. She argues that there are few case reports of hepatitis B causing RA because reported to medical journals because the reaction is no longer "newsworthy." Id; see Pet. Ex. 27.

In this regard, Dr. Bell testified that the VAERS database demonstrates a statistically significant increase in the incidence of chronic arthritis following hepatitis B vaccination. Tr. at 27. In making this assertion, Dr. Bell relied on an article written by Geier and Geier entitled, "A One Year follow-Up of Chronic Arthritis Following Rubella and Hepatitis B Vaccination Based upon Analysis of VAERS Database." Pet. Dec. 8 Brief, at 5, n.8.; Pet. Ex. 24. This report is a retrospective analysis looking for the occurrence of arthritis among patients who received the rubella vaccine from 1991 and 1999, or the hepatitis B vaccine from between 1997 and 1999. The authors[40] used this information to determine the relative risk of developing RA from the hepatitis B vaccine. Tr. at 27. However, Dr. Bell readily conceded that the report does not indicate whether the patients studied had RA. Id. Accordingly, it is of no evidentiary value.

The court also finds problematic petitioner's reliance on the 153 VAERS reports as indicating that the medical community is seeing and reporting a causal relationship. First, a VAERS report can be filed by *anyone*, including a healthcare provider, the vaccinee, or other individual. See Res. Ex. KK, at 191. Due to this factor, there are several problems using VAERS data to determine whether a causal relationship exists. First, the quantity and quality of the information obtained is often insufficient for assessment. Second, reports may be biased toward pre-existing or prevailing concepts of adverse events. Dr. Moulton, without a doubt the most qualified expert in this case on statistical matters, found it to "offer very little information regarding causality." Tr. at 118-19; Res. Aug. 27 Brief, at 12. As has been shown repeatedly in rebuttal to efforts to utilize VAERS data to prove causation, the data has extremely limited value due to the manner in which it is collected, the lack of confirmation of the reported information and the lack of any systematic analysis.

Most troubling, however, is that after giving petitioner additional time to supplement the record, she has come up with nothing substantive in over eleven months since the time that the court requested more information. The court finds this troubling because the evidence presented actually shows that the number of hepatitis B vaccinations per year is *growing*. Logically, it follows that if there is a causal connection between the vaccine and the injury, there should be an

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[39]The petitioner did not present any evidence regarding the 153 cases of RA at the hearing, but only first presented them in her Aug. 5 Filing. See Pet. Aug. 5 Filing, at 2-3; Pet. Ex. 27.

[40]The authors of this article are well known to the special masters. Dr. Mark Geier has been criticized frequently for reaching far beyond his expertise in offering testimony. See, e.g., Weiss v. Secretary of HHS, No. 03-190V, 2003 WL 22853059 (Fed. Cl. Spec. Mstr. Oct. 9, 2003).

increase rather than a *decrease* in the number of reported cases. Since the number of vaccinees is increasing, one would also expect to see more evidence of the medical community's interest as exhibited by more papers being published, more discussions about the relationship, as well as an experimental interest beyond that of just case studies and VAERS data. See Tr. at 153-54.

Petitioner's argument that she conducted an extensive search to "demonstrate that the lack of peer-reviewed case reports of vaccine reactions is not a reliable indicator as to whether the medical community is 'thinking' about an association, " is unavailing. Pet. Aug. 5 Filing, at 3. The fact that there are so few reports linking any vaccines to any injury indicates that there is a lack of support for the connection between the vaccine and the injury. See, e.g., Pet. Aug. 5 Filing, at 3.[41] This issue was also "puzzling" to Dr. Phillips because

> [h]epatitis B vaccine continues to be given and we're not seeing any cases. I don't think we're seeing it clinically. I mean, I don't hear my colleagues talking about it. We don't see these cases. So is something funny about what's been reported in the past or is, you know, there's something about the vaccine or whatever? I mean, I think we just don't know.

Tr. at 223.

As discussed, see pages 18-19, *supra*, the medical community has "accepted" a causal relationship where the objective proof is of such quantity and quality that the theoretical becomes probable. Clearly, the relationship between the hepatitis B vaccine and RA has not reached a level of "general acceptance" within the medical community. While the case reports and case series may raise questions about a relationship, respondent's experts effectively rebutted Dr. Bell's testimony with persuasive evidence of a ***lack*** of reporting despite millions of doses of the hepatitis B vaccine given. Dr. Bell provided no reasonable explanation for the lack of case reports since 1999, and in response to the court's request, was unable to provide a shred of evidence that this is a topic of discussion amongst rheumatologists. Dr. Bell's testimony on this issue of supportive case reports and literature was particularly ineffectual while respondent's experts provided cogent explanations as to why the literature should be read and interpreted to not support an accepted causal connection between the hepatitis B vaccine and RA.

Proof of Biologic Mechanism Linked to this Petitioner

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[41]Petitioner cannot argue that the issue is "novel" and therefore subject to the exception to the "peer review and publication" requirement of Daubert, 509 U.S. at 593. As indicated by petitioner's filings, a suspected relationship between the hepatitis B vaccine and RA goes back as far as 1993. See, e.g., Pet. Ex. 17, Tab E, F. In addition, petitioner's expert, Dr. Bell, has studied and continues to study the issue. See, e.g., Pet. Ex. 17, Tab C; Pet. Ex. 22 (notably filed one day prior to the hearing in this case). The more reasonable conclusion for the lack of current literature is that the medical community accepts the ***lack*** of any relationship between the hepatitis B vaccine and RA.

Lastly, the undersigned canvassed the record, including all of the information reviewed under the preceding section, to determine whether there was evidence linking the biologic mechanisms proposed by Dr. Bell to the occurrence of the injury in the petitioner as proof of a logical sequence of cause and effect.[42] Under this method, the court finds that petitioner has failed to satisfy the burden of proof because she has not established that the mechanism proposed by Dr. Bell is anything but a theoretical construct at this point in time. This is because, in the end, each element of Dr. Bell's "shared epitope" thesis[43] was either unsupported or effectively rebutted.

First, the court once again points out that Dr. Bell testified that he does not know the cause of RA. Tr. at 15. Respondent's experts also testified that they do not know its cause. See Tr. at 172, 233. Logically, at least to the undersigned, that would seem to eliminate, as well, the hepatitis B vaccine as a cause. However, petitioner presents the following process as her logical sequence of cause and effect for the hepatitis B vaccine causing her RA:

1) Patients likely to develop RA commonly express antigen presenting cells containing MHC Class II molecules which express "shared epitopes," with the hepatitis B vaccine. Tr. at 19-20; Pet. Sept. 10 Brief, at 4.

2) Peptides from the hepatitis B vaccine then bind to the shared epitope. Tr. at 19.

3) T-cells, which are responsible for participating in the immune response are stimulated by the binding of the peptide to the shared epitope. Tr. at 17, 28; Pet. Sept. 10 Brief, at 4.

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[42]Petitioner also points out that her various treating physicians attributed her illness to the hepatitis B vaccination that she received. See Pet. Dec. 8 Brief, at 18, 33. The court considered this evidence in its analysis and finds it unpersuasive. It appears that the diagnoses of RA in petitioner that were made by Drs. Himmel, Parker, Toma and West were based primarily on the temporal relationship of development of the RA after the hepatitis B vaccination. None of these physicians presented affidavits, nor were they presented at the hearing for questioning. Thus, the court can only speculate as to the basis of their statements concerning the vaccine's role in the development of RA, and thus cannot attribute much evidentiary weight to these medical records.

[43]Dr. Bell designed and conducted an experiment with transgenic mice that express the human MHC Class II molecules that are normally present in patients with RA. Immunization of the mice with portions of the Hepatitis B vaccine "should be able to induce an immune response to the vaccine peptide and eventually arthritis." Tr. at 28. The result obtained is that a high level of T-cells is created. The basis of Dr. Bell's opinion is that "the vaccine peptides are able to be recognized in those individuals who have the shared epitope, their MHC Class II molecules antigen-presenting cells, which could then in the context of that MHC trigger T-cells to start the cascade of activity leading to T-cell activation and eventually inflammatory response." Id. at 32.

4) The activation of the T-cells triggers a "cascade of events, eventually, leading to inflammation and arthritis in the joint." Tr. at 28.

The crux of her argument relies on the Pope, et al. article describing the proffered mechanism (as noted *supra*, Dr. Bell is a co-author), as well as Dr. Bell's transgenic mouse model. For the following reasons, the court has serious reservations regarding the validity of either Dr. Bell's proposed mechanism or the mouse studies.

Dr. Bell testified that the MHC Class II actually binds the hepatitis B antigens if it has the correct receptors. This component would then be presented to T-cells, which would be activated in an immune response reaction. Tr. at 15. However, later Dr. Bell testified that he didn't "know exactly why these T-cells in [RA] get into the joint, but that's where they work to produce inflammation." Tr. at 16-17. Indeed, Dr. Bell testified that the "accepted" biologic mechanism was indeed a "hypothesis." Tr. at 29. Respondent's witness Dr. Zweiman confirmed that there is no evidence that the mechanism proposed by Dr. Bell can happen in the joint. Tr. at 166. As expressed by Dr. Zweiman, this missing piece in the sequence of causation is critical because without a mechanism to get the T-cells to the synovial fluid in the joint, there can be no inflammatory response, and thus no RA. Tr. at 165-168; Res. Dec. 2 Brief, at 12.

Experimental results also confirmed that there is no evidence that Dr. Bell's theory actually occurs in the real world. Dr. Bell tested his hypothesis using genetically engineered mice that expressed human MHC Class II molecules that are commonly present in [RA] patients. According to Dr. Bell, immunization with the hepatitis B vaccine should induce an immune response to the vaccine peptide and eventually induce arthritis. The problem is that they "haven't seen arthritis yet. " Tr. at 79. Moreover, as pointed out by Dr. Zweiman, contrary to Dr. Bell's testimony, that the T-cells in the transgenic mice expressed high levels of the cytokine interferon gamma in the test tube, as seen in the Firestein article, Res. Ex. II, at 357, only very low levels of the interferon gamma were found in the synovial tissue of human RA patients. Tr. at 175-77. This further demonstrates that Dr. Bell's theory is just that – a theory.

In addition, as admitted by Dr. Bell and supported by Dr. Zweiman, the scientific community believes that it is problematic to apply experimental results obtained in animals to humans. Tr. at 79, 163-64.

The completely theoretical basis for Dr. Bell's "accepted" mechanism is also demonstrated by his testimony that a genetic marker for RA was present in nine individuals in his study with no other known risk factors for RA prior to the development of the disease. Tr. at 44, 54. Later, however, it was revealed that the only information that Dr. Bell had about these individuals was that "we have these patients that develop this reaction . . . and knowing what their genetic background is, we haven't any other information than that." Tr. at 80. To be sure, Dr. Bell testified that there are generic pre-disposing genetic factors, such as "that the disease occurs in more often . . . in identical twins than non-identical twins," and that it "occurs in families." Tr. at 12. However, Dr. Bell admitted later that there is no test available to determine precisely a person's genetic makeup. Tr. at 84.

In sum, the undersigned finds that Dr. Bell's testimony on mechanisms for development of RA is theory and conjecture heaped upon speculation. In fact, Dr. Bell and his co-authors actually describe the proposed mechanism as a "hypothesis," and mentioned that he and his co-authors were performing experiments on humans who had developed the disease post-vaccination and transgenic mice to "test the predictions of our hypothesis." See Res. Ex. JJ. Dr. Bell may prove to be correct in the future, but there is no proof to support his testimony today. Daubert requires substantiation to eliminate the very testimony offered in this case – well-presented, good-faith, but highly dubious conclusions. As stated, this is not a novel issue -- it has been studied and millions of doses of the vaccine have been given. Dr. Moulton commented that "if there was a relationship, they would have found it by now." Tr. at 114. Dr. Phillips testified similarly from a clinician's perspective that there are no case reports since 1999, see Tr. at 223, and the medical community is not even talking about such a causal link. See Tr. at 233. Dr. Bell was unable to provide any meaningful evidence that the hepatitis B vaccine is the first-known cause of RA. As succinctly stated by Dr. Zweiman, "the bottom line is that I think that there are many unanswered questions so that we cannot accept it as a proven hypothesis." Tr. at 180.

Other Methods Presented By Petitioner

As previously noted by the court, see page 20 and note 13, *supra*, petitioners are free to present other proof in order to demonstrate a logical sequence of cause and effect that the vaccine caused the alleged injury. The court is satisfied that all of petitioner's evidence has been analyzed thoroughly above in finding no causation.

CONCLUSION

Based on the foregoing discussion, the undersigned finds that petitioner has not demonstrated by a preponderance of the evidence that the hepatitis B vaccine caused her RA. To be sure, petitioner has established that the hepatitis B vaccine can cause RA by presenting rechallenge cases that establish the biologic plausibility that the vaccine can cause the disease. However, no persuasive evidence establishes that the vaccine did cause petitioner's RA.

The undersigned is cognizant that petitioner presented her case with one legal standard in mind – Stevens – and subsequently argued her evidence pursuant to another standard – Althen. The undersigned has viewed the totality of the evidence from every conceivable angle and finds it wanting. Dr. Bell's testimony certainly raises questions of some connection between the hepatitis B vaccine and RA. However, at every turn, Dr. Bell's efforts to raise the evidence a notch above theoretical simply failed. The proof is clear that Dr. Bell's theory is just that – a theory. There was no support for its occurrence, much less occurring in the petitioner. This is speculation in its purest form, and by all legal definitions fails the preponderance test.

Petitioner was unable to produce satisfactory proof of causation that the hepatitis B vaccine caused her RA in accordance with the standards and concepts expressed herein by the undersigned. Petitioner has not presented an epidemiologic study, nor has she presented evidence of general acceptance – i.e., that the medical community is currently "seeing" or "talking about" a

potential relationship between the vaccine and the injury. Furthermore, factually she has not established that she experienced a rechallenge event or that she possesses the genetic markers that her expert testified were necessary to link the development of the disease to the vaccine that she received on May 3, 1998. Finally, she has failed to show that the mechanism proposed by her expert is linked to the occurrence of her RA because evidence shows that the mechanism is more conceptual and theoretical than "actual."

Respondent's experts presented the stronger testimony, backed by logic, literature and medical reasoning.

The undersigned is fully aware that the petitioner suffers from a painful and chronic injury, and is very sympathetic to her plight. However, based on the foregoing analysis, the petitioner's entitlement claim must be *denied* based on the failure to satisfy her burden of proof.

In the absence of a motion for review filed pursuant to RCFC, Appendix B, the Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

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Gary J. Golkiewicz
Chief Special Master