In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 00-759V

Filed: November 8, 2006

To Be Published

ROSE CAPIZZANO, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	*	Hepatitis B vaccine causing rheumatoid arthritis; Rechallenge; Treating physicians; Logical sequence of cause and effect.

Ronald C. Homer, with whom was Sylvia Chin-Caplan and Kevin P. Conway, Conway, Homer, and Chin-Caplan, Boston, MA, for petitioner.

Vincent Matanoski, United States Department of Justice, Washington, D.C., for respondent.

RULING ON REMAND[1]

GOLKIEWICZ, Chief Special Master.

I. PROCEDURAL HISTORY

On December 15, 2000, petitioner filed a petition for compensation under the National Childhood Vaccine Injury Compensation Program [hereinafter "the Act" or "the Program"][2]

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

[2]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.

alleging that the hepatitis B vaccine that she received on May 3, 1998 caused-in-fact her rheumatoid arthritis [hereinafter "RA"]. On June 8, 2004, the undersigned issued an Entitlement Decision in the above-captioned case denying compensation because petitioner was unable to produce satisfactory proof that the hepatitis B vaccine in fact caused her RA. See Capizzano v. Secretary of Health and Human Services, No. 00-759V, 2004 WL 1399178 (Fed. Cl. Spec. Mstr. June 8, 2004) [hereinafter "Capizzano I"]. On July 8, 2004, petitioner filed a "Motion for Review" of the undersigned's Decision. Subsequently, on December 7, 2004, Judge James F. Merow of the United States Court of Federal Claims affirmed. 63 Fed. Cl. 227 (2004) [hereinafter "Capizzano II"]. Judgment was entered on December 7, 2004, and petitioner subsequently petitioned for review to the United States Court of Appeals for the Federal Circuit on February 7, 2005.

On March 9, 2006, the Federal Circuit issued a Decision vacating the Court of Federal Claims' Decision affirming the undersigned. The Circuit subsequently remanded the case "to the Court of Federal Claims to determine whether Ms. Capizzano has proven causation by a preponderance of the evidence based on the existing record." 440 F.3d 1317, 1328 (Fed. Cir. 2006) [hereinafter "Capizzano III"]. With respect to proving causation in an off-Table injury case such as the case *sub judice*, the Circuit instructed that:

> The proper inquiry is whether a petitioner in an off-Table injury case establishes a logical sequence of cause and effect, the second prong of Althen III, by a preponderance of the evidence. That approach has not yet been followed in this case because there has not yet been, in the first instance, an analysis of the evidence presented by Ms. Capizzano (i) under the teaching of Althen III and (ii) unencumbered by the constraints of the four-prong test formulated by the chief special master following Althen II.

Id. at 1327-28.[3] The Circuit left "it to the Court of Federal Claims, after receiving the views of the parties, to decide whether, in the first instance, the matter should be decided by the chief special master." Id. at 1328 n.8.

After accepting briefing from the parties, on June 14, 2006, Judge Merow remanded this case to the undersigned for a "'first instance'" decision in accordance with the Federal Circuit's instructions. Order, dated June 14, 2006 at 2. Pursuant to Judge Merow's remand, the undersigned convened a status conference call on June 22, 2006, to discuss with the parties the next course of action in this case. During the call, the parties agreed that the remand is limited to the existing record per instruction from the Federal Circuit. Moreover, although petitioner requested that the undersigned issue a Ruling on Remand in lieu of further briefing, the

[3]By the notation "Althen II," the Circuit is referring to the United States Court of Federal Claims Decision by Judge Susan G. Braden, 58 Fed. Cl. 270 (2003). Similarly, for "Althen III," the Circuit is referring to its Decision found at 418 F.3d 1274 (Fed. Cir. 2005). The undersigned will continue to use these notations hereinafter in this Ruling on Remand.

undersigned agreed with the respondent that given that the undersigned's Decision in Capizzano v. Secretary of Health and Human Services, 2004 WL 1399178, was issued before the Federal Circuit's decisions in Althen v. Secretary of Health and Human Services, 418 F.3d 1274 (Fed. Cir. 2005) and Pafford v. Secretary of Health and Human Services, 451 F.3d 1352 (Fed. Cir. 2006), further briefing would be beneficial. An Order was issued on June 23, 2006, requiring the parties to file simultaneous briefs and replies addressing several issues regarding the standard for causation-in-fact, as well as any other areas of interest the parties deemed appropriate.[4] The parties subsequently filed briefs required by the undersigned's Order.[5] The case is now ripe for resolution.

II. THE PARTIES' POSITIONS

A. Petitioner's Position

In her Brief, petitioner addressed the questions posed by the undersigned pursuant to the June 23, 2006 Order. First, with respect to the impact of Pafford on the resolution of the case *sub judice*, petitioner asserts that Pafford "provides strong support for her case." P. Brief at 2. Petitioner asserts that Pafford reaffirms the principles articulated in Althen III as well as Capizzano III. Petitioner points out that the Pafford decision "once again recognized that in a non-Table case, a petitioner 'must prove by preponderant evidence both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination.'" P. Brief at 7 (citing Pafford, 451 F.3d at 1355). Similarly, petitioner asserts that Pafford also affirmed the Circuit's three-part test articulated in Althen III and Capizzano III. Id. at 8 (citing Pafford, 451 F.3d at 1355). While Pafford "merely restates existing Federal Circuit precedent, with respect to proving causation in non-Table Program cases, the decision also highlights the significant probative value of two major elements of Rose's case." Id. Importantly, unlike the facts of Pafford, petitioner asserts that she has established the

[4] In the Order, the undersigned directed that the parties file briefs addressing the following areas of interest, as well as any issues the parties deemed appropriate: A. What impact does the Federal Circuit's decision in Pafford have on the resolution of the above-captioned case? B. In general, what evidence is required to prove logical sequence of cause and effect under the standard espoused by the Federal Circuit? C. Discuss the treating physicians' diagnoses of rheumatoid arthritis, see Capizzano III, 440 F.3d at 1326, in relation to prong 2 of Althen III regarding the logical sequence of cause and effect. See Althen III, 418 F.3d at 1278. D. Compare and address the Federal Circuit's discussion of probability of coincidence as possibly defeating a logical sequence of cause and effect, Capizzano III, 440 F.3d at 1327, with the rejection of Judge Merow's observation that the "immense number of people receiving the hepatitis B vaccine statistically results in instances where individuals suffer an initial onset of rheumatoid arthritis shortly after the vaccine, but not as the result of the vaccine." Id. at 1326 (citing Capizzano II, 63 Fed. Cl. at 230).

[5] Petitioner filed her "Response to the Chief Special Master's Order of June 23, 2006" on August 3, 2006 [hereinafter "P. Brief"] and a "Reply to Respondent's Response to the Chief Special Master's Order of June 23, 2006" on August 21, 2006 [hereinafter "P. Rep."]. Respondent filed his "Brief on Remand" on August 4, 2006 [hereinafter "R. Brief"] and a "Reply Brief on Remand" on August 18, 2006 [hereinafter "R. Rep."].

existence of an appropriate temporal relationship between the vaccine and her injury, as well as demonstrated that there are no other alternative causes for her disease. Id. at 8-9.

With respect to the undersigned's inquiry regarding evidence required for proving a "logical sequence of cause and effect" under Federal Circuit precedent, petitioner's view is that:

> [T]he only *required* evidence "to prove logical sequence of cause and effect" is a showing that a petitioner: (1) was healthy (or more healthy); (2) received a covered vaccine; (3) subsequently suffered an injury that, in theory, can be caused by the vaccine; and (4) the absence of a more likely cause of the injury. Unless she proved each of these elements, [petitioner] submits, her claim would be fatally defective.

Id. at 9 (emphasis in original). Petitioner takes the position that the phrase "logical sequence of cause and effect" is "mere *dicta,*" id., and that the "nature, quality, quantity, and sufficiency of the 'evidence' required by the statute for a petitioner to prevail will necessarily vary from individual case to individual case." Id. at 9-10. "[I]in the end," petitioner argues, in each individual case, "any determination of the sufficiency of evidence 'required' to prove 'a logical sequence of cause and effect' must be viewed in the precise words of the statute," more specifically, the wording of § 11 and § 13.

With respect to the type of evidence required to satisfy petitioner's burden, petitioner points out that the Act does not specify the nature, type, amount, quality, or quantity of evidence necessary, but asserts that it is the "job" of the special masters "'on the record as a whole'" to determine whether there is "preponderant evidence that a vaccine caused an injury." Id. at 10-11. Petitioner submits that in the case *sub judice*, the "expert testimony, vast literature, and written expert submissions are relevant," as they "provide a basis for a medical theory to support Rose's claim that the hepatitis B vaccine can cause RA." Id. at 11. Petitioner also states that the medical records are relevant to determining causation as they "establish Rose was healthy when she received her vaccine and subsequently suffered RA," and that the records, through her treating physicians, establish an appropriate temporal relationship, the absence of an alternate likely cause, as well as an association between the vaccine and RA. Id. at 11-12. Petitioner also asserts that all submitted evidence, including respondent's written submissions and VAERS data, constitutes evidence to be considered in evaluating the "record as a whole." Id. at 12. Petitioner submits that her interpretation of the phrase "logical sequence of cause and effect" is consistent with past Federal Circuit Decisions.[6] Id.

[6]Citing Grant v. Secretary of Health and Human Services, 956 F.2d 1144 (Fed. Cir. 1992); Jay v. Secretary of Health and Human Services, 998 F.2d 979 (Fed. Cir. 1993); Knudsen v. Secretary of Health and Human Services, 35 F.3d 543 (Fed. Cir. 1994). See P. Brief at 13-15.

Next, petitioner addresses the role of the treating physicians' diagnoses of RA in relation to prong 2 of Althen III.[7] Petitioner cites to numerous places in the medical records where petitioner's treating doctors discuss the potential role of the vaccine in causing her illness. Id. at 17-20. Relying on the notations of the treating physicians, petitioner argues that they establish that: 1) petitioner was healthy; 2) petitioner had an immediate reaction to the vaccine; 3) petitioner was advised against receiving another vaccination; 4) petitioner had an appropriate temporal relationship between the vaccine and her joint pain; 5) petitioner continues to suffer RA; 6) her treating doctors believed the hepatitis B vaccine was related to her RA; and 7) there was no likely alternative cause. Id. at 20. Petitioner submits that these records, along with the undersigned's finding that the hepatitis B vaccine can cause RA, "clearly demonstrate a logical sequence of cause and effect between her vaccine and her RA." Id.

Finally, with respect to the undersigned's question regarding the probability of a coincidence defeating a logical sequence of cause and effect, petitioner asserts that all cases of RA are "**caused by something**." Id. at 21 (emphasis in original). In this case, petitioner's doctors examined her recent past to identify potential triggers. Petitioner asserts that had they identified another trigger or triggers, the vaccine would be a less likely cause, which she asserts is in line with the Circuit's teachings regarding coincidence. Id. More specifically, she argues "when determining the likely cause of a petitioner's RA, it is essential to examine the competing potential triggers in each individual case to determine if the vaccine is the likely cause of the RA or if the vaccine is simply 'coincidental' (i.e. [,] due to the existence of a more compelling, more likely, trigger)." Id. at 23.

Petitioner then points out that the respondent may rely on Hasler v. United States, 718 F.2d 202 (6th Cir.1983) in support of his position regarding the role of "coincidence" in determining causation, as the Hasler court held that the "'inoculation is not the cause of every event that occurs within the ten day period . . . .[W]ithout more, this proximate temporal relationship will not support a finding of causation.'" P. Brief at 25 (citing Hasler, 718 F.2d at 205). Petitioner distinguishes the facts of Hasler in that the plaintiff in Hasler: 1) received the swine flu vaccine; 2) provided no additional evidence other than an appropriate temporal relationship; and 3) suffered from other symptoms that supported the existence of an alternative cause. Id. Petitioner also asserts that unlike the plaintiff in Hasler who did not present any theory linking the vaccine to the injury, petitioner's medical records with the statements, opinions, and conclusions of her treating physicians support a logical sequence of cause and effect. Id. at 26. Thus, because of the evidence supporting a logical sequence of cause and effect, in petitioner's view, the only "'coincidence'" that can defeat her claim is evidence of a more likely cause, which has not been shown by respondent. Id. at 26.

[7] Petitioner asserts that the treating physicians' opinions are relevant to all three prongs of the test in Althen III. P. Brief at 17.

B. Respondent's Position

With respect to the undersigned's inquiry regarding the impact of Pafford on this case, respondent asserts that Pafford is instructive in two areas of concern. First, respondent argues that Pafford "reiterated the requirement that a petitioner must show that the vaccine is the 'but for' cause of the injury alleged." Id. at 4 (citing Pafford, 451 F.3d at 1355). Second, respondent asserts that Pafford reiterated the long-standing implied proposition under the Program "that any temporal association must be a 'medically acceptable one.'" Id. Thus, the Pafford decision makes it clear that "it is not enough for Ms. Capizzano simply to demonstrate that hepatitis B vaccine can cause RA. She must also provide the evidentiary link between the theoretical concept and the facts of her case, and the evidentiary link must be reliable." Id. Respondent does not dispute that there is "a temporal association between Ms. Capizzano's receipt of hepatitis B vaccine and her development of symptoms." Id. at 5. Respondent, however, asserts that the temporal relationship is not enough to "strengthen petitioner's case," and posits that the temporal association must be evaluated in the context of what is a medically acceptable time frame given "the nature of the injury and the proposed causation sequence." Id. With respect to the case *sub judice*, respondent avers that after Pafford, the temporal association "should be critically evaluated to determine whether it is consistent with both the injury and with the causation theory pursued." Id.

With respect to the logical sequence of cause and effect requirement, respondent asserts that no hard and fast precepts govern the analysis with respect to the type of evidence that will satisfy the requirement. Id. at 5-6. Respondent asserts that the holdings in Althen III and Capizzano III caution against using set descriptions of qualifying types of evidence, as long as such evidence is reliable. Id. at 6. Respondent asserts that this required element of "logical sequence of cause and effect" serves two purposes. Id. at 3. First, respondent asserts that it

> provides further, specific development of the proffered medical causation theory. In this regard, the causation sequence is bound to and explains the medical theory espoused. For example, if the theory advanced is that the vaccine triggered an autoimmune response, the cause and effect sequence would explain the steps, in terms of the autoimmune response theory, leading to the effect (*i.e.*, the injury).

Id. Second, respondent believes that "the causation sequence provides the specific link between vaccination and the development of injury in the individual claimant by 'showing that the vaccination was the reason for the injury.'" Id. Respondent also notes that it is critical that "evidence bearing on the causation sequence must be scientifically or medically reliable." Id. (citing Grant v. Secretary of Health and Human Services, 956 F.2d at 1148). In essence, respondent avers that "Ms. Capizzano has not proven that her receipt of hepatitis B vaccine actually caused her RA because she has not provided a reputable medical theory of causation based on a logical sequence of cause and effect that links her development of RA to her receipt of hepatitis B vaccine." Id.

More specifically, respondent asserts that although the undersigned held that rechallenge established the biologic plausibility that hepatitis B vaccine can cause RA, this does not mean that "causation is established in every case alleging hepatitis B vaccine causing RA. If a medical theory establishes that a vaccine can cause an injury, a petitioner still must show that the vaccine did cause her injury." Id. at 8 (emphasis in original). Respondent points out that there is no dispute that petitioner did not experience a rechallenge. Id. at 9. Thus, respondent avers that she has not shown a logical sequence of cause and effect that the hepatitis B vaccine did cause her RA by rechallenge. Id. On the contrary, respondent asserts that petitioner's proffered medical theory, that being the "shared epitope theory," does not provide a logical sequence of cause and effect linking her RA to the hepatitis B vaccine because the undersigned has already determined that Dr. Bell's causal theory is unpersuasive. Id. Respondent points out that the Circuit did not direct the undersigned to revisit this factual finding. Id. at 10.

Upon respondent's review of the treating doctors' records, respondent asserts that "none provides the link that is missing: evidence that the hepatitis B vaccine did cause [petitioner's] RA." Id. Moreover, the doctors did not explain their own theories as to how the hepatitis B vaccine caused petitioner's RA. Id. As such, in respondent's view, the medical records do not provide evidence of "a logical sequence of cause and effect linking [petitioner's] RA to a persuasive theory of causation." Id. at 11.

Finally, as to the undersigned's query regarding the role of coincidence in determining causation, respondent interprets the Circuit's holding in Capizzano III to "mean that the possibility that an injury is coincidental is not enough in the face of competent causation evidence, but as the probability of coincidence increases, it may defeat such evidence." Id. at 6.

C. The Parties' Replies

Petitioner's Reply to Respondent's Brief

First, petitioner reasserts that Pafford provides "strong support," P. Rep. at 5, for petitioner's case, as Pafford "'bolsters a link between the injury and the vaccination,'" and respondent does not contest that petitioner's injury occurred within a medically appropriate time frame. Id. at 4. In addition, since respondent "offered no potential alternative causes for Rose's [RA]," this is also significant under Pafford. Id. at 5.

In response to respondent's position on what constitutes a logical sequence of cause and effect, petitioner asserts that she agrees that there are no "'hard and fast'" rules and that relevant evidence must be reliable. Id. at 6. Petitioner states further that the words "logical sequence of cause and effect" are not contained in the Act, and thus are "mere *dicta*." Id. Although the nature, quality, and quantity of evidence will vary from case to case, "any determination of the sufficiency of evidence 'required' to prove 'a logical sequence of cause and effect' must be viewed in the precise words of the statute," pointing specifically to § 11 and § 13. Id. at 7. Petitioner notes that since the Act does not delineate the "nature, type, amount, quality, or

quantity of evidence necessary" to satisfy a petitioner's burden of proof, this "chore" is left to the special masters. Id. Petitioner then points out that "*[r]equired* evidence . . . is different than *relevant* evidence," and that all "relevant evidence in the record is pertinent" to the determination of whether there is a "'logical sequence of cause and effect.'" Id. at 8 (emphasis in original). Petitioner asserts that the type of evidence relevant to her case is her expert's testimony, "vast literature," her medical records, as well as evidence presented by respondent, including respondent's experts' testimony. Id. at 8-9.

With respect to the role of the treating physicians' opinions, petitioner argues that respondent misses the point as to their probative value. Petitioner asserts that "[i]t is the role of a treating physician . . . to treat the illness, and to cure the patient," id. at 12, and that "[w]hen Rose's treating physicians associated her hepatitis B vaccine with her RA, they were simply attempting [to] identify the nature and cause of her symptoms so they could treat her and make her more healthy." Id. at 12-13. Petitioner contends that "in complete defiance of the Federal Circuit's clear language in Althen III and Capizzano III, the respondent assigns 'little evidentiary value' to these opinions," which in petitioner's view is "preposterous." Id. at 13. Petitioner again asserts that these opinions are relevant to all three prongs in the Althen III test, but in particular, prong 2. Id. Petitioner views the treating doctors' opinions as "virtually conclusive" because the hepatitis B vaccine can cause RA, as held by the undersigned in Capizzano I, as well as the respondent's "inability to identify a likely alternative cause." Id. at 14. In petitioner's view, "the treating physicians alone demonstrate a 'logical sequence of cause and effect'" between the vaccination and petitioner's RA. Id.

Petitioner then addresses why she believes that respondent dismisses these opinions. Petitioner believes that "[t]he respondent does so . . . solely because the treating physicians failed to provide in their records a 'reputable' medical theory or explanation as to how the vaccine caused the RA." Id. at 15. Petitioners point out that, in general, treating physicians do not elaborate on medical theories of causation in medical records because they "are not relevant to the clinician's agenda, which is to identify, treat, and heal." Id.

Lastly, with respect to respondent's argument regarding the role of "coincidence" in determining causation, petitioner asserts that "[t]he term 'coincidence' . . . is a misnomer. As used by the Federal Circuit in this case, it simply means 'unrelated' to a vaccine or 'caused by something other than a vaccine,'" and it "means nothing more." Id. at 17. Petitioner avers that respondent has not presented any evidence suggesting petitioner's injury was caused by anything but the vaccine. Thus, "coincidence" is not applicable to petitioner's case. Id. at 20.

Respondent's Reply to Petitioner's Brief

In reply to petitioner's brief, respondent asserts that petitioner's interpretation of the phrase "'logical sequence of cause and effect' is equivalent to presumptive causation," R. Rep. at 1, and that this reading of Circuit precedent is "patently incorrect." Id. at 2. Respondent points out that petitioner's proffered four required elements of proof are the "creation of a presumptive

causation claim anytime a special master finds that a vaccine 'can cause' a specific injury and there are no other more likely causes of that injury." Id. Respondent continues that "the only difference between a Table injury and [petitioner's] interpretation is that with a Table injury, the Secretary of Health and Human Services determines that a vaccine presumptively causes an injury, whereas in an actual causation case, the special master makes that finding." Id. at 2.

In respondent's view, the Circuit did not hold that "a showing of biologic plausibility, temporal proximity, and an absence of other causes is sufficient to prove a logical sequence of cause and effect that the vaccine is the reason for the injury." Id. at 3 (footnote omitted). If that were the case, respondent argues, there would be no need to remand the case for further findings of fact. Id. Respondent finds that there is a "glaring omission" in petitioner's analysis of the role of a "'logical sequence'" in proving causation. Id. Respondent avers that "this element of the causation analysis ties the 'biologic plausibility' (the 'can cause' determination) and the temporal relationship to the facts of the particular case." Id. Noting that the undersigned held that the hepatitis B vaccine can cause RA due to case reports indicating rechallenge events, respondent asserts that petitioner has presented no evidence of the "'logical sequence' that moves her case beyond the plausible 'can cause' realm to that of the actual 'did cause.'" Id. at 4.

Along this line of reasoning, respondent further argues that "[t]here is not a preponderance of 'reliable' evidence upon which to find that the hepatitis B vaccine caused [petitioner's] RA." Id. at 5. Respondent disagrees with petitioner's argument that all relevant evidence in the record is pertinent to the issue of "logical sequence of cause and effect." Id. Respondent argues that the correct inquiry involves "whether and to what degree the evidence is relevant to that issue," basically coming down to the amount of weight that is attributed to a piece of evidence. Id. Respondent also asserts that the evidence must be reliable. Id. Pointing out that the Act requires a special master to consider all relevant medical and scientific evidence contained in the record, he asserts that "[c]onsidering the evidence is not the same as finding that it proves causation." Id. at 7. Moreover, the Act requires that a finding of causation be substantiated with medical records or by medical opinion. It is the "sole province of the special master to weigh it for probative value," and the Act allows a special master to "reject the opinions or diagnoses of experts, including treating physicians." Id. Respondent also points out that the Supreme Court's decision in Daubert[8] "obligate[s] the [undersigned] to test [petitioner's] evidence under reasonable standards of scientific reliability." Id. at 8.

Respondent continues that the "issue before the Chief Special Master is to determine the probative value of [petitioner's] medical records, particularly those records that reference assessments of her condition by her treating physicians." Id. Although respondent acknowledges that there is "some" evidentiary value to petitioner's medical records, id., respondent points out that the medical records are deficient in that they "provide no medical explanation whatsoever that links [petitioner's] development of RA to her hepatitis B vaccination." Id. at 9. Moreover, "the lack of scientifically reliable evidence linking [petitioner's] receipt of hepatitis B vaccine to

[8] Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

the development of her RA is also the reason why the written assessments of her treating physicians do not establish a logical sequence of cause and effect." Id. Respondent asserts that the only evidence that the undersigned has not sufficiently considered is the treating doctors' opinions, and these, in respondent's view, do not "provide reliable, preponderant evidence curing the deficiency in causation proof." Id. at 10.

III. DISCUSSION

A. The Undersigned's Charge on Remand

Pursuant to the Federal Circuit's directive, the only remaining task for the undersigned in determining causation in this case is to evaluate the evidence in the record as it stands with respect to prong 2 of the Althen III three-prong test.[9] Accordingly, the undersigned must determine whether petitioner has demonstrated "a logical sequence of cause and effect showing that the vaccination was the reason for [her] injury." Althen III, 418 F.3d at 1278.

With respect to prong 2, the Circuit provided guidance as to what evidence should be considered in the determination of whether petitioner satisfied her burden to show a "logical sequence of cause and effect." Finding that the undersigned erred "in not considering the opinions of the treating physicians who concluded that the vaccine was the cause of Ms. Capizzano's injury," Capizzano III, 440 F.3d at 1326, because the doctors may have "relied in part on the temporal proximity of Ms. Capizzano's injuries to the administration of the vaccine," id., the Court held that this relationship is not disqualifying in considering the treating physicians' conclusions. The Circuit reasoned:

> We see no reason why evidence used to satisfy one of the Althen III prongs cannot overlap to satisfy another prong. In other words, if close temporal proximity, combined with the finding that the hepatitis B vaccine can cause RA, demonstrates that it is logical to conclude that the vaccine was the cause of the RA (the effect), then the medical opinions to this effect are quite probative. Moreover, Althen III explained that medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a "logical sequence of cause and effect show[s] that the vaccination was the reason for the injury."

Id. (citing Althen III, 418 F.3d at 1280).

[9] The Circuit stated that the "first prong of the Althen III test was satisfied by the finding that the hepatitis B vaccine can cause RA." Capizzano III, 440 F.3d at 1326 (citing Capizzano I, 2004 WL 1399178 at *16). The Circuit continued that "[t]he third prong was satisfied by the finding that Ms. Capizzano's RA appeared within days of receiving the vaccine." Id. (citing Capizzano I, 2004 WL 1399178 at *1).

The Circuit continued by explaining that "'[a] logical sequence of cause and effect' means what it sounds like – the claimant's theory of cause and effect must be logical." Capizzano III, 440 F.3d at 1326. The undersigned notes that the term "logical" means "[o]f, pertaining to, in accordance with, or of the nature of logic."[10] Stated another way, logical means "[s]howing consistency of reasoning," or "[r]easonable on the basis of earlier statements or events."[11] The evidence will be evaluated consistent with the Federal Circuit's standard.

B. Analysis of Evidence With Respect to Prong 2

The undersigned has considered thoroughly the excellent presentations made by the parties in their briefs. The parties' cogent arguments point out the continuing interpretive gulf that persists on the causation issues despite the Federal Circuit's three recent opinions on the issue.[12] In the final analysis, the undersigned agrees with petitioner's position and arguments as correctly interpreting and applying the Federal Circuit's precedent. The discussion follows.

The Federal Circuit's remand, as mentioned above, was quite focused: determine whether "petitioner in an off-Table injury case establishes a logical sequence of cause and effect, the second prong of Althen III, by a preponderance of the evidence." Capizzano III, 440 F.3d at 1327. The general foundation for this remand was a reaffirmance of the legal principles laid down in Althen III, including "'the purpose of the Vaccine's Act preponderance standard is to allow the finding of causation in a field *bereft of complete and direct proof of how vaccines affect the human body*.'" Id. at 1325 (citing Althen III, 418 F.3d at 1280) (emphasis in original). The Capizzano III Court, in rejecting the undersigned's requirement of some form of medical confirmation of the vaccine's role in the claimant's injury, reiterated the Althen III Court's admonition that "such an approach is inconsistent with allowing 'the use of circumstantial evidence envisioned by the preponderance standard.'" Id. at 1325 (citing Althen III, 418 F.3d at 1280). Specifically, the Federal Circuit instructed the undersigned to consider the opinions of the treating physicians in determining whether petitioner met prong 2 of the Althen III test as the "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Id. at 1326 (citing Althen III, 418 F.3d at 1280).

In determining whether Rose Capizzano established a logical sequence of cause and effect, the parties agree that all types of evidence will satisfy the requirement. R. Brief at 6; P. Brief at 11; P. Rep. at 6. As respondent stated, "no hard and fast precepts [] govern" and "the court should avoid set descriptions of qualifying types of evidence because of the impression created that the list is exclusive." R. Brief at 6. The parties also agree that in accordance with Grant, any evidence must be "reputable" or "reliable." R. Brief at 6; P. Rep. at 6. As petitioner

[10] The American Heritage Dictionary 740 (7th ed. 1985).

[11] Id.

[12] See Althen III, 418 F.3d 1274; Capizzano III, 440 F.3d 1317; and Pafford, 451 F.3d 1352.

correctly stated, "[u]nreliable evidence has no probative value, while reliable evidence has potentially strong probative value." P. Rep. at 6. The undersigned has reviewed fully the medical records, with special attention paid to the treating physicians. After that review, the undersigned concurs with petitioner's analysis, including the conclusion, that:

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

P. Brief at 20 (emphasis in original). [13]

First, it should be noted that respondent does not dispute that petitioner has RA. Tr. at 338. According to the medical records, petitioner received her second hepatitis B vaccination on May 3, 1998. Petitioner's Exhibit [hereinafter P. Ex. __] 1 at 5. On May 4, 1998, petitioner presented to the Westerly Hospital where she complained of a "rash over entire body," and "questioned [whether it was] from hep B shot." Id. at 6. Under "Diagnostic Impression," it was noted that petitioner had a "possible allergic reaction to Hep B vaccine" and she was subsequently instructed to take Benadryl. Id. at 7. It was also noted that petitioner should not have her third hepatitis B vaccination. Id.

On May 5, 1998, petitioner presented to the Westerly Hospital Emergency Room complaining of an "allergic reaction," id. at 8, reporting that she had taken Benadryl as prescribed the previous day, but had awoken "this A.M. with fever, headache post, stiff neck." Id. at 9. Upon examination, it was reported that petitioner's joints and muscles [were] achy and tender," id., and that she had "confluent hives [across] abd[omen], arms, neck." Id. Under "Diagnostic Impression," it was recorded that petitioner had a "severe reaction to hepatitis vaccination. Serum sickness." Id.

Petitioner again presented to the Westerly Hospital Emergency Room on May 6, 1998. Id. at 10. At that time, petitioner reported that she had arm and neck pain and was unable to lift

---

[13] Respondent "acknowledges that there is some evidentiary value to Ms. Capizzano's medical records." R. Rep. at 8. Respondent states that "[petitioner's] medical records indicate that she did not have symptoms of RA before receiving the hepatitis B vaccine; they show that she developed a rash and swelling within a few days after receiving [the] hepatitis B vaccine; they show that she was advised against receiving another hepatitis B vaccination; they establish that seven months after receiving her hepatitis B vaccination, a rheumatologist definitively diagnosed Ms. Capizzano with RA; and they do not discuss other likely etiologies of her RA." Id. at 8-9.

her left arm. Id. at 11. Under "Diagnostic Impression," it was recorded that petitioner suffered "serum sickness/allergic reaction [secondary] to hepatitis vaccination." Id.

Several months later, on October 1, 1998, petitioner was seen by Dr. J. Scott Toder, a rheumatologist. Dr. Toder indicated in his notes that in May of 1998, petitioner had a hepatitis B vaccination. P. Ex. 4 at 5. Twenty-four hours later, petitioner reported "rash, itchy – benadryl" and that these symptoms were secondary to her hepatitis B injection. Id. On October 6, 1998, after having an x-ray taken as advised by Dr. Toder, the diagnostic "Impression" was that petitioner had "mild periarticular osteoporosis which may be an early finding of erosive type arthritis." Id. at 3.

On January 19, 1999, petitioner filled out a patient questionnaire provided by Dr. Peter Himmel, a rheumatologist. On the questionnaire, she reported that her symptoms began in May of 1998 and that she was given a diagnosis of "Allergic reaction to hep B shot." P. Ex. 6 at 1. Dr. Himmel noted during a February 12, 1999 appointment that one of her hepatitis B injections led to her serum sickness and that he could "say with a reasonable degree of medical certainty that the serum sickness is related to the arthritis and tendonitis." Id. at 9.

Subsequently, on June 14, 1999, petitioner was seen by Dr. Virginia Parker for an "Independent Medical Examination" related to a worker's compensation claim. P. Ex. 7 at 1. Dr. Parker reported that petitioner "had no arthritis symptoms or disabilities prior to her hepatitis B vaccination." Id. at 3. On physical examination, Dr. Parker noted that petitioner had "active arthritis" and that [t]his problem does seem related to the vaccination. The sequella of the second vaccination does sound like serum sickness, although it could not be proven by the laboratory drawn." Id. Dr. Parker also noted that hepatitis B "[v]accination has been associated with the onset of an acute arthritis." Id.

Petitioner consulted with another rheumatologist, Dr. Wadie Toma, on July 26, 1999. P. Ex. 5 at 1. In her history, Dr. Toma noted that petitioner had a "history of joint pain and swelling which started after she had [a] hepatitis vaccine in May '98. After that[,] she developed an acute swelling of her joints and what was diagnosed as serum sickness but her joint pain and swelling continues with her and she started having stiffness in the morning." Id.

After having no improvements after several visits to Dr. Toma, petitioner saw another rheumatologist, Dr. Edmund West. Dr. West noted in petitioner's "History" that "two years ago she had a Hepatitis B vaccine injection as part of a series. . . . After the second hepatitis B injection[,] she needed to go to the emergency room . . . several times with a rash, high fever and inflammation of the joints." P. Ex. 12 at 6. Dr. West postulated that although "[s]he was initially thought to have had an episode of acute arthritis related to the Hepatitis B injections that would be self-limited," her "symptoms continued and she evolved into a chronic arthritic syndrome." Id. In Dr. West's opinion, his "Impression" of petitioner's condition was that she had "[i]nflammatory arthritis post vaccination." Id. at 8. Dr. West referred petitioner to the UCONN Medical Group of Rheumatology Associates, at which time she was examined by Dr.

Ann Parke. In her initial assessment, on October 3, 2000, Dr. Parke believed that petitioner suffered from "inflammatory arthritis status post hepatitis B vaccination, with features suggestive of [RA]." P. Ex. 20 at 43. Subsequently, in her report dated August 13, 2001, Dr. Parke noted that petitioner presented "with a history of polyarthritis, which developed following a hepatitis B vaccine." Id. at 33. Dr. Parke's "assessment" at that time was that petitioner had "polyarthritis of unknown etiology." Id. at 34. Dr. Parke's "diagnosis" ultimately was that petitioner had "polyarthritis, [] post vaccination arthritis." Id. at 35.

Applying the Federal Circuit's teachings, and based on the undersigned's complete and thorough review of petitioner's medical records, the undersigned finds that petitioner has satisfied her burden to show a "logical sequence of cause and effect showing that the vaccination was the reason for her injury." The Westerly Hospital ER doctors, along with Drs. Himmel, Parker, Toma, and Parke relate the initiation and further development of petitioner's RA to the hepatitis vaccine given on May 3, 1998. More specifically, their records establish that: 1) petitioner was a healthy person before her vaccination; 2) petitioner had an immediate reaction to the vaccine; 3) there were no other causes that the treating doctors believed more likely to be the cause of the RA; and 4) it was the doctors' diagnostic impression that the vaccine was the cause of petitioner's RA. Coupled with the Federal Circuit's finding that prongs 1 and 3 of the Althen III test were satisfied (meaning that the hepatitis B vaccine can cause RA and that there was a "showing of a proximate temporal relationship between vaccination and injury"), these additional pieces of circumstantial evidence, as established by the treating doctors' contemporaneous medical records, fulfill the "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Accordingly, the undersigned finds that petitioner has satisfied prong 2 of the Althen III test and is thus entitled to compensation.[14]

In making this finding, the undersigned has considered fully respondent's arguments. No effort is made here to repeat and address every argument, but fairly capturing the crux of respondent's arguments is that while the undersigned found and the Federal Circuit affirmed the finding that the Hepatitis B vaccine can cause RA (based upon the evidence of rechallenge), petitioner's evidence of a "logical sequence," "that moves her case beyond the plausible 'can cause' realm to that of the actual 'did cause'" is deficient. R. Rep. at 4. Respondent explains that the role of the "logical sequence" as an element of causation analysis is to "tie[]" the "biologic plausibility (the 'can cause' determination) and the temporal relationship to the facts of the particular case." Id. at 3.[15] Or, as respondent stated another way, "the causation sequence is

[14]In making this decision, the undersigned determined that there was insufficient evidence in the record to find that the probability of coincidence, that is that petitioner would have developed RA whether or not the vaccine was administered, outweighed the circumstantial evidence of the vaccine causing petitioner's RA in this case.

[15]Throughout his briefings in this case, respondent suggests that "the analysis of whether there is evidence of a temporal association appears to bear on what weight should be accorded the statements of the treating doctors." R. Brief at 5. Respondent supports this reasoning by asserting that Pafford "now instructs that the association should be critically evaluated to determine whether it is consistent with both the injury and with the causation theory pursued." Id. The undersigned declines to analyze whether there is an appropriate temporal relationship in this case

bound to and explains the medical theory espoused." R. Brief at 3. In any event, "the causation sequence provides the specific link between vaccination and the development of injury . . . by 'showing that the vaccination was the reason for the injury.'" Id.; see also R. Brief at 10 ("treating physician assessments reveal[] that none provides the link that is missing: evidence that the hepatitis B vaccine did cause Ms. Capizzano's RA"). While respondent eloquently sets forth his understanding of the Federal Circuit's precedent and how it applies to the facts of this case, the undersigned believes respondent is simply asking for too much proof.

In short, respondent is ignoring the Federal Circuit's latest teachings. The undersigned's Decision in Capizzano addressed the on-going argument between the parties of "whether proof of linkage of the mechanism to the individual is required and how much proof." 2004 WL 1399178 at *12. The undersigned sided with respondent, stating that until the Federal Circuit resolves the dispute, "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." Id. Citing its previous decisions in Knudsen and Althen, the Federal Circuit emphatically rejected requiring petitioners to provide the types of proof that would establish "linkage," stating that such a requirement "impermissably heightens the burden of proof placed upon a petitioner in an off-Table injury case." Capizzano III, 440 F.3d at 1327. The Circuit stated further that "such an approach is inconsistent with allowing 'the use of circumstantial evidence envisioned by the preponderance standard.'" Id. at 1325 (citing Althen III, 418 F.3d at 1280). Thus, it appears clear that respondent's argument for proof of "linkage" that requires evidence beyond circumstantial evidence is contrary to the Circuit's decisions.

The undersigned notes that respondent's discussion of the role of "logical sequence" as being "bound to and explain[ing] the medical theory espoused" has much merit. R. Brief at 3. However, unlike respondent, who is looking for "specific development of the proffered medical causation theory," and the "specific link between vaccination and the development of injury," the undersigned sees the explanation of the medical theory as a practical and consistent - and thus logical - completion of the injured's medical picture. Id. Thus, in this case, medical plausibility is established, appropriate timing was found, and there is an absence of other causes. What "ties" the case together, what binds the various pieces of circumstantial evidence into a coherent, consistent, medical package is the treating doctors. The treating doctors contemporaneously treated Rose, ran appropriate tests, analyzed the data, noted clinical factors, wrote their observations, and consistent with their role, determined the nature of the injury with an eye towards treating the illness and curing the patient. Based upon their medical analyses, the

---

as the Federal Circuit has determined that the third prong of the Althen III test, 418 F.3d at 1278, which requires a "showing of a proximate temporal relationship between vaccination and injury," "was satisfied by the finding that Ms. Capizzano's RA appeared within days of receiving the vaccine." Capizzano III, 440 F.3d at 1326 (citing Capizzano I, 2004 WL 1399178 at *1).

treating doctors considered the vaccine within their differential diagnoses.[16] The treating physicians' records can be critical evidence buttressing or negating the expert's testimony regarding a proposed medical theory - was the clinical course consistent with that theory, the timing of events, and with any other potential causes. This comports with the Circuit's admonition that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Capizzano III, 440 F.3d at 1324. In this case, as noted earlier, the treating physicians consistently considered the vaccine in their differential diagnoses as a potential cause of petitioner's RA. What that means to the undersigned is that all clinical indicators were consistent with the vaccine causing petitioner's RA. Coupled with the other circumstantial evidence – the plausibility of the vaccine causing RA, the timing, and absence of other causes – the totality of the evidence preponderates in petitioner's favor.

Respondent dismisses the probative value of the treating doctors. However, a close read of respondent's arguments shows that respondent's continued reliance upon an evidentiary standard that does not comport with the Federal Circuit's decisions is the reason for respondent's dismissal of the treating physician statements.[17] For example, respondent avers that "the treating physicians [do not] articulate and explain their own theory as to how the hepatitis B vaccine caused Ms. Capizzano's RA." R. Brief at 10. Further, respondent argues that the treating

---

[16] In Hocraffer v. Secretary of Health and Human Services, 63 Fed. Cl. 765 (2005), Judge Nancy B. Firestone explained the evidentiary value of the technique of differential diagnosis. She found that:

> Differential Diagnosis, or differential etiology, is "a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable is isolated." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999); see also, Federal Judicial Center, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, 470 n.12 (2d ed. 2000). The technique has "widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results." Westberry, 178 F.3d at 262 (quoting In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 758 (3d Cir. 1994)). Differential diagnosis or differential etiology has been accepted as reliable under the standards set forth in Daubert v. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579, 593-94 (1993) by virtually every United States Court of Appeals to consider the issue. See Heller v. Shaw Industries, Inc., 167 F.3d 146, 154-55 (3d Cir. 1999); Baker v. Dalkon Shield Claimants Trust, 156 F.3d 248, 252-53 (1st Cir. 1998); Zuchowicz v. United States, 140 F.3d 381, 385-87 (2d Cir. 1998); Kennedy v. Collagen Corp., 161 F.3d 1226, 1228-30 (9th Cir. 1998), cert. denied, 526 U.S. 1099 (1999); Ambrosini v. Labarraque, 101 F.3d 129, 140-41(D.C. Cir. 1996); and Glaser v. Thompson Medical Co., 32 F.3d 969, 978 (6th Cir. 1994).

Hocraffer, 63 Fed. Cl. at 777 n.15.

[17] Respondent asserts that scientific certainty is not necessary for a petitioner to prevail, but continued advocating throughout his briefs for some unidentified piece of evidence other than the circumstantial evidence presented in this case for petitioner to satisfy her burden of proof. This certainly strikes the undersigned as suggesting that respondent is looking for far more than a preponderance of evidence. See, e.g., R. Rep. at 9-10.

doctors' statements are subject to the reliability tests of Daubert, 509 U.S. 579,[18] "since those statements must provide a logical sequence of cause and effect that, in turn, must also be supported by a reputable or scientific explanation." R. Rep. at 8.

The defect in respondent's position is that he is assigning a greater evidentiary role to the treating physicians than is called for. The treating doctors are not providing the medical theory in this case. As petitioner correctly notes, that issue is moot as "[t]he Chief Special Master has already determined that the hepatitis B vaccine **can** cause RA." P. Rep. at 11 (emphasis in original). The treating doctors, at least in the vast majority of cases, are not through their records providing the causation evidence normally adduced through an expert, but are providing the medical "snapshot" through their contemporaneous notes, tests, and reports that allows medical experts and ultimately the decision-maker to tie the medical theory to the clinical course and determine whether the course of medical events is "logical." Treating doctors rarely, if ever, provide medical theories of causation; they do often provide critical circumstantial evidence. Petitioner's discussion of this issue is compelling and is in complete accord with the undersigned's experience.

> Why, then, does the respondent dismiss [the treating physicians'] evidence? The respondent does so, Rose submits, solely because the treating physicians failed to provide in their records a "reputable" medical theory or explanation as to how the vaccine caused the RA. However, as the Chief Special Master and the respondent are well aware, treating physicians rarely discuss "theories" in their notations. Theories are not relevant to the clinician's agenda, which is to identify, treat, and heal. If treating physicians needed to list their "theories" before their opinions became probative in the Vaccine Program, then no medical record would be probative. Clinicians simply don't have the time to indulge in theorizing.

P. Rep. at 15 (footnote omitted). As petitioner notes, again correctly, "the presentment and explanation of such theories is the role of experts, who are paid to study these issues and to present their opinions." Id. at n.10. Thus, if the treating physician is proffered as the sole evidentiary support for petitioner's case, that is, without the accompanying expert opinion, then the undersigned agrees completely with respondent, as it appears petitioner in this case does as well. In that scenario, petitioner's treating doctors would be subject to the reliability tests of Daubert and subject to inquiry on the question of what medical theory is being espoused, the bases for that medical theory, and what is the logical sequence of cause and effect. In this case, however, the treating physicians medical records are not substituting for the medical expert, but are providing critical clinical information which supports the timing of onset, the possibility of other causes than the vaccine, and the very important fact that the treaters considered the vaccine in their differential diagnoses. The fact that the vaccine was considered a possible cause shows

[18] In Terran v. Secretary of Health and Human Services, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit affirmed the special master's application of the reliability factors espoused by the Supreme Court in Daubert, 509 U.S. 579, in discounting testimony that the special master found to be scientifically unreliable.

that from the treaters' vantage point, the clinical sequence was logical. That information coupled with the other information provided by the experts, can provide the legal logical sequence of cause and effect, and did so in this case.

There may be instances when the treating doctors' records and information do not support the logical sequence of cause and effect. For example, as is frequently seen through the experts' testimony, from both petitioners' and respondent's experts, initial treaters' assessments are often based upon fragments of information.[19] Thus, as further testing is completed and additional pre-injury information is discerned from prior medical records and family interviews, the initial medical judgments are often proven wrong or are changed to reflect the more complete medical picture. Thus, the treating doctors' "snapshot" of medical information cannot be read in isolation, but must be viewed in the context of the total medical picture.[20] If, as in this case, the treating doctors provide a consistent clinical picture that comports with the experts' medical theory, the treating doctors' opinions are as the Federal Circuit determined, "quite probative." Capizzano III, 440 F.3d at 1326 (Stating that, "[i]n other words, if close temporal proximity, combined with the finding that hepatitis B vaccine can cause RA, demonstrates that it is logical to conclude that the vaccine was the cause of the RA (the effect), then medical opinions to this effect are quite probative.").

Respondent does raise a serious question of how the treating doctors' medical records "tie" or explain the medical theory to the facts of this case when the medical theory found by the undersigned and left undisturbed by the Federal Circuit is rechallenge, and Rose did not manifest a case of rechallenge. Moreover, the treating doctors mentioned various medical explanations, none of which were rechallenge. Stated another way, if, as stated above, the treating doctors provide critical clinical information which if consistent with the expert's medical theory establishes a logically consistent chain of events, how can one find a logically consistent chain of events where the treating doctors' clinical findings do not comport with the medical theory? The short answer from the undersigned is that one cannot. However, in this case, there is no inconsistency.

---

[19]Such factual information may come from petitioners, parents, or family members or gleaned from other physicians' notes. These contemporaneous notes only reflect what information is available at the time and are often an incomplete picture supporting the differential diagnosis.

[20]An example of this occurred at the June 2003 hearing regarding the link between serum sickness and the development of petitioner's RA. When questioned by the undersigned as to what the relationship between the serum sickness and RA was, petitioner's expert, Dr. Bell, stated that:

> One of the *earlier* theories about the cause of rheumatoid arthritis is that it might in fact represent a prolonged serum sickness reaction due to a persistent antigen. I don't think that most people would hold to that theory of [RA] anymore . . . .

Tr. at 333-34 (emphasis added). While this theory may not be the "accepted" theory in the medical community anymore, what is probative, in the undersigned's view, is that petitioner's treating physicians considered, at that time, that petitioner's clinical course was consistent with the hepatitis B vaccine causing petitioner's RA.

As found by the undersigned and affirmed by the Federal Circuit, the hepatitis B vaccine can cause RA based upon evidence in the medical literature of "rechallenge" in other vaccine recipients. Relying upon the Institute of Medicine's discussions of vaccine causality, the undersigned found 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." See Capizzano I, 2004 WL 1399178 at *2.[21] The question becomes how, if one does not know the underlying medical theory for how the vaccine causes the injury, can the treating doctors support that medical theory with their contemporaneous clinical information? The undersigned concedes that this is a close call, but considering the Federal Circuit's heavy emphasis on circumstantial evidence, the undersigned finds that the treating doctors' differential diagnoses, which include the vaccine, are the critical factors. The differential diagnoses establish that the treating doctors' clinical observations and findings are consistent with, and thus logical, that a vaccine caused the injury. The fact that those findings and observations cannot be measured against an unknown mechanism of cause where the mechanism is "understood to be occurring," is not determinative.[22]

IV. CONCLUSION

Based on the undersigned's review of the entire record and accordance with the Circuit's directive to determine whether petitioner has demonstrated a "logical sequence of cause and effect" that the hepatitis B vaccine was the cause of petitioner's RA, the undersigned finds that petitioner has satisfied prong 2 by preponderant evidence, as established by her treating physicians' opinions in the medical records. Having satisfied prong 2, petitioner has demonstrated that the hepatitis B vaccine caused her RA, and is thus *entitled to compensation*. An Order setting a damages schedule will follow.

IT IS SO ORDERED.

_____
Gary J. Golkiewicz
Chief Special Master

[21] Citing Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines, 48, 53 (1991) and Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, 23 (1994).

[22] However, if the treating doctors' clinical findings and observations were not consistent with the expert's medical theory of causation, clearly it would be illogical to conclude that the vaccine was the cause.