In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 99-594V

Filed: March 30, 2001

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

Ronald C. Homer, Boston, Massachusetts, for petitioner.

Joan E. Coleman, U.S. Department of Justice, Washington, D.C., for respondent.

RULING ON PETITIONER'S MOTION FOR SUMMARY JUDGMENT

GOLKIEWICZ, Chief Special Master.

I. INTRODUCTION AND PROCEDURAL BACKGROUND

On August 4, 1999, petitioner, Jane Stevens, filed a claim under the National Vaccine Injury Compensation Program. Petitioner alleged that she suffered permanent neurologic deficits, including transverse myelitis, as a result of the hepatitis B vaccines she received on November 29, 1994 and January 13, 1995. See Petition for Vaccine Compensation; Petitioner's Exhibit (hereinafter "P. Ex.") 1 at 1-3; P. Ex. 4 at 3-4, 10, 13; and P. Ex. 5 at 1-4. On March 8, 2000, respondent filed her Rule 4 Report recommending that compensation be denied. Respondent's Report (hereinafter "R. Report") at 10. Thereafter, on July 13, 2000, petitioner filed Petitioner's Motion for Summary Judgment (hereinafter "P. MSJ"), arguing, inter alia, that petitioner is entitled to summary judgment based upon her proposed standard of proof for a causation-in-fact claim which consists of a showing of scientific plausibility, absence of alternative causes, appropriate temporal relationship, and a

treating physician's clinical assessment of vaccine causation.[1] P. MSJ at 27-28. Respondent filed her opposition (hereinafter "R. Opp.") to petitioner's motion on August 31, 2000, contending, inter alia, that petitioner's proposed standard of proof is contrary to the law of the Federal Circuit and accepted scientific principles. R. Opp. at 1, 3. In response, petitioner filed a reply (hereinafter "P. Reply") on October 10, 2000, arguing that the elements of petitioner's proof are sufficient to support her Motion for Summary Judgment. P. Reply at 5-7. The court, after reviewing the arguments and for the reasons stated below, denies Petitioner's Motion for Summary Judgment. However, in so ruling, the court takes the opportunity to discuss in detail the appropriate standards for weighing a causation-in-fact claim.

II. FACTUAL BACKGROUND[2]

Petitioner, Jane Stevens, received a hepatitis B vaccination on November 29, 1994. Shortly thereafter, on December 10, 1994, petitioner saw Eric Klos, D.C., a chiropractor, for numbness, tingling, and difficulty writing. Subsequently, on December 13, 1994, petitioner saw Dr. Gerald Yorioka, a general practitioner, for an evaluation of her symptoms and was diagnosed with paresthesia of the arms and legs.

On January 13, 1995, petitioner received a second hepatitis B vaccination. Thereafter, on January 25, 1995, petitioner returned to Dr. Yorioka complaining of body fatigue and tingling in her arms and legs. Unable to find the cause of petitioner's symptoms, Dr. Yorioka referred her to a neurologist for a second opinion.

Petitioner saw Dr. Crispin Wilhelm, a neurologist, on February 8, 1995. Dr. Wilhelm found petitioner to have drift and curl in her right arm, impaired fine movements in her right hand and right foot, decreased strength in her right hand, mild impairment of vibration in her right foot, impairment of sensation over her right hand and forearm, and a minimally asymmetric gait. On February 10, 1995, an MRI scan of petitioner's cervical spine was performed. The scan found areas of increased signal in her cervical cord and a right herniated disc with mild cord impingement. Dr. Karen Rochelle, a radiologist, interpreted the findings of petitioner's MRI as being caused by multiple sclerosis.

Petitioner saw Dr. Wilhelm again on February 16, 1995. Dr. Wilhelm diagnosed petitioner with possible transverse myelitis and treated her with intravenous corticosteroids. Her symptoms

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[1]Transverse myelitis is not a Table injury for hepatitis B. Thus, petitioner must prove that the vaccine in-fact caused her injury.

[2]Petitioner stated in her Motion for Summary Judgment that for purposes of her motion she accepts the facts as stated by the respondent in Respondent's Rule 4 Report. P. MSJ at 4. Therefore, the following facts are taken directly from Respondent's Rule 4 Report at pages 1-4. Obviously, if and when the case proceeds to trial, petitioner will have the right to support and contest any and all factual issues.

subsided over the next month. For the remainder of 1995, petitioner's symptoms fluctuated with some improvement in her condition.

Petitioner continued to see Dr. Wilhelm for symptoms of back pressure and tingling, gait disturbance, and fatigue. Dr. Wilhelm's impression of petitioner's condition was that she had stable transverse myelitis caused by her hepatitis B vaccinations. Petitioner continues to have some right leg weakness, numbness in her right thigh, and back discomfort.

III. PETITIONER'S PROPOSED STANDARD AND ARGUMENTS AND RESPONDENT'S COUNTER-ARGUMENTS

A. PETITIONER'S PROPOSED STANDARD AND ARGUMENTS[3]

Petitioner argues that she is entitled to summary judgment in this matter for the following reasons: (1) she has transverse myelitis; (2) it is scientifically plausible that the hepatitis B vaccine can cause transverse myelitis; (3) there is an appropriate temporal relationship between the administration of the vaccines and petitioner's symptoms; (4) there is no likely alternative cause for her injury; (5) petitioner's treating doctors believe her transverse myelitis was caused by the hepatitis B vaccines; and (6) there are no material issues of fact. P. MSJ at 27-28. Based on the above, as well as petitioner's contention that she does not have to prove her case with scientific certainty, petitioner concludes that she is entitled to summary judgment because the evidence demonstrates by a preponderance of the evidence that the hepatitis B vaccines caused her transverse myelitis. Id. at 27; P. Reply at 12-13. Petitioner's points are discussed more fully below.

First, petitioner posits that it is scientifically plausible that the hepatitis B vaccine can cause transverse myelitis. P. MSJ at 9. To support this notion, petitioner offers the following: a study[4] where four cases of transverse myelitis were reported following hepatitis B vaccinations, the Institute of Medicine's (hereinafter "IOM") report[5] which found several cases of transverse myelitis following

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[3]The following summary is taken from both Petitioner's Motion for Summary Judgment and Petitioner's Reply.

[4]Frederic Elijah Shaw et al., Postmarketing Surveillance for Neurologic Adverse Events Reported After Hepatitis B Vaccination, 127 Am. J. Epidemiology 337, 337-352 (1988).

[5]Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality 84-85 (1994) (hereinafter "IOM 1994 Report").

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 in 1994 in the report cited above. Considering the IOM's statutory charge, the

vaccines, including the hepatitis B vaccine, and the package inserts from the manufacturers of the vaccine which list transverse myelitis as a possible adverse reaction. Id. at 10, 11. Moreover, petitioner argues that the IOM has determined that it is "biologically plausible" that the hepatitis B vaccine can cause demyelinating diseases such as transverse myelitis and has suggested a possible mechanism of injury. Id. As a result, petitioner maintains that "plausibility," while not the same as "causation," has probative value and is an essential building block of her case. P. Reply at 8.

Second, petitioner argues that the temporal relationship between the vaccines and her transverse myelitis is supportive of a causal relationship.[6] Petitioner supports this by indicating that the timing of the onset of her symptoms following the hepatitis B vaccines was appropriate for such a demyelinating disorder. P. MSJ at 11. In addition, petitioner highlights that she had similar reactions to two separate vaccinations, with her first symptoms beginning approximately eight days after the first shot and increasing approximately nine days after the second shot. Id. While petitioner agrees that a temporal relationship alone is insufficient to prove causation, she posits that it is strong evidence that such a causal relationship exists. P. Reply at 9.

Third, petitioner, relying in part on her medical records, argues that there is no likely alternative cause for her injury. P. MSJ at 13-14. According to petitioner, while absence of a likely alternative cause is not proof of causation, it is an essential aspect of her theory and has significant probative value. P. Reply at 11. As with a proper temporal relationship, petitioner argues that absence of alternative causes is strong evidence that a causal relationship exists. Id.

Fourth, petitioner argues that her treating neurologist's opinion that the hepatitis B vaccines caused her transverse myelitis supports a probable causal link between the two. P. MSJ at 14-15. Relying on Rogers v. Secretary of HHS, No. 94-89V, 2000 WL 1337185 (Fed. Cl. Spec. Mstr. June 6, 2000) (holding that the evidence submitted, including the treating physicians' opinions, supported a determination that petitioner's tetanus toxoid vaccination caused her injury), petitioner asserts that

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scope of its review, and the cross-section of experts making up the committee, the court has consistently accorded great weight to the IOM's findings.

[6]The term "temporal relationship" has two possible meanings as used in litigation under the Vaccine Act: (1) the literal meaning, in other words, that the injury occurred subsequent to and close in time to the administration of the vaccine, or (2) the scientific meaning, in other words, that there is an accepted time frame supported by scientific evidence within which the injury should manifest itself following vaccination. The difference can be critical. For example, a literal temporal relationship of an adverse reaction to a mumps vaccine could be hours; however, a scientific temporal relationship would be no sooner than five days. See 60 Fed. Reg. 7678, 7692 (Feb. 8, 1995) (codified at 42 C.F.R § 100.3); 57 Fed. Reg. 36878, 36880-36881 (Aug. 14, 1992) (codified at 42 C.F.R. § 100.3). Appropriately so, petitioner relies on the scientific meaning to advance her arguments: "It is generally understood that neurologic symptoms of demyelinating diseases, such as transverse myelitis, generally occur 'within a few days' [of vaccination]." P. MSJ at 12 (citing Raymond D. Adams & Maurice Victor, Principles of Neurology 624 (2nd ed. 1981)).

the opinions of treating physicians should be given "considerable weight." P. MSJ at 15. Petitioner urges the court to credit her treating physician's diagnosis of vaccine causation in the present case and find that she is entitled to compensation. Id. at 15-16.

As a final point, petitioner asserts that her proposed standard is in accordance with the tests and principles outlined in Grant, Shyface, Hines, and Daubert.[7] Id. at 16. Specifically, petitioner posits that her evidence satisfies Grant by showing a medical theory casually connecting the vaccine and the injury, as well as a logical sequence of cause and effect, fulfills Shyface's "substantial factor" and "but for" tests because there is no other explanation or competing cause for her illness, and, when considered as a whole, meets Hines' two-step analysis by proving that the hepatitis B vaccine can cause transverse myelitis and that it did so in this case. Id. at 16-19. Furthermore, petitioner opines that the principles of Daubert permit her to prevail in this matter even without an epidemiologic study or an expert report because, inter alia, her physician's clinical diagnosis falls within the "range of accepted standards governing how scientists . . . reach their conclusions." Id. at 21 (quoting Daubert, 43 F.3d at 1317).

B. RESPONDENT'S COUNTER-ARGUMENTS

Respondent contends that petitioner's Motion for Summary Judgment must be rejected for the following reasons: (1) traditional tort standards of causation apply to off-Table vaccine cases; (2) petitioner's proposed standard of proof is contrary to accepted scientific principles; (3) petitioner's proposed method of proof is contrary to the law; (4) petitioner failed to meet her proposed standard of proof; and (5) substantial disputes of fact exist. See R. Opp. at 1-14, 16, 18. Respondent's points are discussed more fully below.

Respondent argues that traditional standards of tort litigation apply to cases litigated under the Vaccine Act. Id. at 2. This standard, respondent notes, which amounts to "heavy lifting," has been applied in numerous special masters' decisions under the Program. Id. As a result, respondent contends that petitioner's claim that principles of "generosity" apply in determining the burden of proof in off-Table cases must be rejected. Id. at 3.

Next, respondent posits that petitioner's proposed standard of proof, which consists of a showing of biologic plausibility, proper temporal relationship, a clinician's judgment of vaccine causation, and absence of alternate causes, is contrary to accepted scientific principles. Id. at 3-4. Respondent further explains her position.

First, respondent argues that biologic plausibility has no probative value in this case regarding the existence of a causal relationship between transverse myelitis and the hepatitis B vaccine. Id. at 6. The IOM describes two types of biologic plausibility: theoretical biologic

[7] See Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992); Shyface v. Secretary of HHS, 165 F.3d 1344 (Fed. Cir. 1999); Hines v. Secretary of HHS, 940 F.2d 1518 (Fed. Cir. 1991); Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311 (9th Cir. 1995).

plausibility, which exists for all vaccine-adverse event associations; and demonstrated biologic plausibility, which was the only type considered by the IOM committee in reaching its causality judgments. R. Opp. at 4-5. In the present case, respondent argues that petitioner failed to show that biologic plausibility reached the level of demonstrated biologic plausibility described and utilized by the IOM. Id. at 6. Moreover, respondent notes that even demonstrated biologic plausibility was considered by the IOM committee as insufficient to "shift the balance" between a finding to accept or reject a causal relationship. Id. at 5.

Second, respondent argues that a temporal relationship is insufficient to prove causation.[8] Id. at 6 (citing Grant, 956 F.2d 1148; Thibaudeau v. Secretary of HHS, 24 Cl. Ct. 400 (1991); Lunn v. Secretary of HHS, No. 97-436V, 2000 WL 246237 (Fed. Cl. Spec. Mstr. Feb. 17, 2000)). According to respondent, the Federal Circuit has adopted the principle that "inferring causation solely on the basis of a proper temporal sequence is the logical fallacy of *post hoc ergo propter hoc* (literally, "after this, therefore because of this")." Id. at 7 (quoting the IOM 1994 Report at 23). This logical fallacy, respondent notes, exists whether or not there is evidence of biologic plausibility, alleged absence of alternate causes, and/or a clinical judgment of vaccine-causation. Id.

Third, respondent maintains that petitioner's treating physician's clinical diagnosis of vaccine causation is not probative because it is clinically impossible to distinguish between cases in which the hepatitis B vaccine caused transverse myelitis and cases in which the vaccine is only coincidentally related. R. Opp. at 7. Furthermore, respondent contends that unless petitioner can establish a legitimate clinical way to distinguish between the two, such clinical judgments do not comport with threshold standards of scientific reliability set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Id. at 11-12.

Fourth, respondent argues that petitioner's proposed method of proof is contrary to law. Id. at 13. According to respondent, a showing of biologic plausibility, temporal relationship, and absence of alternative causes does not constitute adequate legal proof of causation. Id. To support this contention, respondent cites the following cases: Huston v. Secretary of HHS, 39 Fed. Cl. 632, 636 (1997), for the proposition that a showing of biologic plausibility and temporal association is insufficient to prove actual causation; Grant, 956 F.2d at 1149, for the proposition that evidence showing the absence of other causes does not meet petitioner's affirmative duty to show actual causation; and Hasler v. United States, 718 F.2d 202, 204-205 (6th Cir. 1983), for the propositions that a proximate temporal relationship alone will not support a finding of causation and that evidence supporting the notion that "A" can cause "B" does not show that "A" actually did cause "B." Id. at 13-14, 16. Finally, respondent, relying on Lampe v. Secretary of HHS, 219 F.3d 1357 (Fed. Cir. 2000), contends that petitioner's method of proving causation would create a new Table injury

[8]Respondent notes that the term "proper temporal sequence" reflects the IOM's "recognition that biological plausibility exists sufficient to determine the proper temporal bounds of such a [temporal] sequence (e.g., 5 days to 6 weeks for an immune-mediated event)." R. Opp. at 7, n. 4; see also supra n. 6, at 4.

because it would establish a presumption of vaccine causation for every case of transverse myelitis within a certain time frame after vaccination. Id. at 17.

Lastly, respondent argues that petitioner failed to satisfy her own proposed standard of proof because she has not proven an absence of alternative causes. R. Opp. at 9, 18. In off-Table cases, respondent contends, petitioner carries the burden of proving that subclinical factors do not exist or, at least, are less likely than the vaccine to have caused the injury. Id. at 18. Transverse myelitis, respondent opines, occurs spontaneously without any prior antecedent event. Id. at 9. Thus, respondent argues, to the extent cases of transverse myelitis after vaccination are not clinically different from cases which occur spontaneously, it is impossible to tell from the clinical presentation whether the vaccine caused petitioner's injury or was due to unapparent factors. Id. at 10. In the present case, respondent contends that petitioner failed to provide any evidence which would allow the special master to assess the relative likelihood that petitioner's condition was caused by such unapparent factors and, thus, has not carried her burden of proof. Id. at 9-10, 18.

IV. DISCUSSION

The court did not request and the parties did not ask for oral arguments on their briefs, but the undersigned thoroughly studied their submissions and issues two rulings in this case. The first resolves Petitioner's Motion for Summary Judgment and follows immediately at Section "A." The second, the lengthier of the two discussions, proposes a five-prong test for analyzing actual causation claims under the Program. This second ruling can be found specifically at Section "C" and is preceded by Section "B" which offers a history of the treatment of causation-in-fact claims under the Act and explains why the proposing of the five-prong criteria is so critical. Due to the combined rulings' length and for the reader's convenience, the undersigned has attached "Appendix I" at the end of this decision; the appendix provides an index of the stated discussions.

A. RULING ON PETITIONER'S MOTION FOR SUMMARY JUDGMENT

The court's primary task is to rule on petitioner's Motion for Summary Judgment. In vaccine claims, the special master may decide a case on summary judgment pursuant to Vaccine Rule 8(d) and Rule 56 of the United States Court of Federal Claims' rules. In this case, the undersigned invited the parties to brief their understanding of the applicable causation-in-fact standards in the context of a summary judgment motion. According to the Federal Circuit in Jay v. Secretary of HHS, 998 F.2d 979, 982 (Fed. Cir. 1993), "[s]ummary judgment is appropriate when 'there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law.'" The special master may not make credibility determinations, weigh the evidence, or draw legitimate inferences from the facts when ruling on a motion for summary judgment. Id. at 982-983 (citations omitted). Rather, the moving party "bears the burden of demonstrating [the] absence of all genuine issues of material fact" and "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Id. at 982 (citations omitted). As the Circuit further explained, "[t]he summary judgment inquiry in essence is whether the evidence presents a

sufficient disagreement of fact to require submission to the factfinder or whether it is 'so one-sided that one party must prevail as a matter of law.'" Id. (citations omitted).

After a complete review of the present record and considering the above principles, the court finds that the factual record as it now stands is sufficiently controverted, as it relates to the issues of medical plausibility, temporal relationship, and the absence of alternate causes, that petitioner's motion must be denied. As respondent correctly points out, significant questions remain regarding the treating doctor's determination that petitioner's transverse myelitis was not caused by some unrelated factor. In addition, the court believes the medical issues presented in this case are sufficiently complex to warrant the opinions and testimony of appropriate medical experts. In the end, the averments of counsel regarding the proofs may bear out. However, the court is not convinced that the underlying factual and medical issues are established at this point in the proceedings. Exercising its broad discretion in ruling on a summary judgment motion,[9] the court believes ventilation at trial is the appropriate means of resolving these issues. Therefore, the existence of genuine issues as to material facts precludes the court from ruling in petitioner's favor at this time. Petitioner's Motion for Summary Judgment is, therefore, denied.

B. DISCUSSION OF THE CRITERIA CURRENTLY GOVERNING ACTUAL CAUSATION CLAIMS UNDER THE PROGRAM

1. Introductory Comments and Background

Having denied petitioner's motion, the court could conclude the decision at this point. However, the parties' respective briefs raise legitimate legal issues which the court and the parties wrestle with on a daily basis in their attempts to resolve fairly these vaccine cases. The overarching issue is what is the appropriate analytical framework for evaluating off-Table, so-called causation-in-fact, claims? In an attempt to answer this question, the court invited the parties to brief the issue in the context of a summary judgment motion. The court will now set about giving its answer. Before doing so, however, some background information may be helpful.

As has been discussed in numerous opinions over the years and will be further explained infra, the Vaccine Program was created to reduce tort litigation against manufacturers and administrators and to provide compensation to injured parties without requiring the difficult proofs of individual causation, negligence, and product defectiveness. Hence, the Program was designed as "no fault," with a goal to render expeditious, certain, and generous determinations. To that end, the cornerstone of the Program **was** a Table of injuries.[10] Meeting the Table's requirements relieves

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[9] See Vaccine Rule 8(d). See also Miller v. Secretary of HHS, No. 90-50V, 1991 WL 44302, at *4-*5 (Cl. Ct. Spec. Mstr. Mar. 14, 1991) (stating that under the Program, the special masters have broad discretion to determine whether a hearing is necessary).

[10] As discussed infra at page 10, the relevance of the Vaccine Injury Table has greatly diminished.

the proponent of proving that the vaccine in-fact caused the injury. Proof of a Table injury requires evidence that the person received a listed vaccine and suffered an injury listed on the Table within a prescribed time frame. Unless there is demonstrated proof of another cause of the injury, proof of a Table injury constitutes proof of entitlement.

If petitioner is unable to meet the Table's requirements, petitioner may still qualify for compensation. However, the proof is more arduous as petitioner must show that the vaccine actually caused the alleged injury. Unfortunately, Congress imparted little guidance as to what proof would be necessary to show causation. The little bit of legislative history reads as follows:

> [T]he petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner. . . . The Committee does not intend, however, to susgest [sic] that variance from the Table should act as a presumption against the petitioner but rather only that such a petitioner is not to be deemed to be eligible for compensation without further showings of causation.

H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N 6344. Nevertheless, Congress clearly intended that its goal to render expeditious, certain, and generous determinations apply equally to off-Table claims.

The court's efforts to fulfill the Act's purpose have resulted in a large body of interpretive case law, which will be discussed fully infra. For purposes of this discussion, it is noted that litigating Table cases has met Congress's programmatic desire; that is, the special masters handle the cases relatively quickly and render decisions with certainty. This is mostly because the straightforward requirements of the Table foster limited factual issues and medical testimony and rather speedy decisions. Unfortunately, litigating actual causation cases clearly fails in this regard. While the factual issues are similar to those raised in Table claims, the medical testimony is extensive. Frequently two or three experts per side grapple with questions of epidemiology, neurology, immunology and virtually every other medical discipline. Extensive legal arguments concerning the sufficiency of the evidence follow the medical testimony. The cases take longer to prepare, longer to present, and longer to decide. Even though the same vaccines and injuries are represented in the cases, clear answers have proven elusive to the numerous causation-in-fact issues presented over the twelve year history of the Program. Decisional law has not, as of yet, provided the answers. In short, litigating causation cases has proven the antithesis of Congress's desire for the Program. Instead of speed, certainty, and fairness, costly lengthy case presentations, inconsistent outcomes, and disparate treatment of similarly-situated litigants has resulted. In its Report accompanying the 1989 amendments, the courts and the parties drew ire from Congress because the Program was not functioning as a quick, flexible, and streamlined alternate system, as intended. See H.R. Rep. No. 101-247, at 509 (1989), reprinted in 1989 U.S.C.C.A.N. 1906, 2235. Congress aggressively called upon the participants of the Program to re-dedicate themselves to the original

goals of the Act for the benefit of all. Twelve years later, we continue to struggle to achieve the goals Congress unequivocally and repeatedly articulated. If this problem has existed for so long, why is the issue more acute today?

With the enactment of the administrative Table amendments, effective March 10, 1995, there was a dramatic shift in the percentage of cases decided pursuant to the Table versus those decided under an actual causation theory. While possessing no empirical data, experience and anecdotal evidence suggest that the percentages flip-flopped; prior to the amendments 90% of cases were Table cases, while after the amendments 90% of cases were actual causation cases. In fact, the undersigned has yet to adjudicate a case involving the interpretation of the amended Table; all litigated claims have been causation cases. The acuteness of the problem is seen with newly added vaccines, such as the hepatitis B vaccine which was added to the Program in August of 1997. These vaccines are being added without the benefit of a multi-injury Table.[11] Thus, practice has shown that virtually all of the cases proceed as causation-in-fact disputes. In fact, all 267 pending hepatitis B cases are causation claims. In the absence of clear guidance as to what proof is sufficient to establish a causation case, each case proceeds as a traditionally litigated case – that is, full blown litigation. Clearly, that is not what Congress intended when it designed the Program as an *alternative* to tort litigation.

Given that causation entails showing that the vaccine actually caused the injury, as opposed to the presumed causation available in Table cases, can one avoid the lengthy, costly litigation outlined above? The undersigned believes the answer is yes. Twelve years of experience has shown that while the vaccines and injuries differ from case to case, the nature of the evidence is essentially the same. Experts agree, with few undisputed exceptions, that vaccines do not leave "footprints," or pathological markers, on the body that prove causation. The next best evidence, epidemiologic studies, is rarely available. Where it is available it is utilized. Thus, unless one is prepared to argue, as respondent appears to do, that in the absence of either of these two types of evidence petitioner loses, the court is left to evaluate several pieces of clinically supportive, but not definitive, circumstantial evidence in ruling on the causation claim. Neither the special masters nor the reviewing courts have accepted respondent's narrow interpretation of what constitutes sufficient causation-in-fact evidence. Thus, each case proceeds with circumstantial clinical evidence weighed against uncertain, ill-defined, and often times differing evidentiary standards. It is the inconsistent weighing of this clinical evidence that results in disparate treatment of petitioners.

The undersigned believes the establishment of an evidentiary standard for weighing this circumstantial clinical evidence will bring fair, expeditious, and certain decision-making to causation

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[11]Indeed, the only injury specified for hepatitis B, the vaccine at issue in this case, is anaphylactic shock. Some newer vaccines have no specific Table injury listed at this time, for example, rotavirus, pneumococcal conjugate, *Haemophilus influenza* type B (polysaccharide conjugate), and varicella (chicken pox), and therefore all claims involving them must be pursued under an actual causation theory.

cases. Congress mandated such decision-making, the litigants deserve such decision-making, and the court has the knowledge and experience to provide such decision-making.

In the following sections, the court will analyze the law governing causation-in-fact claims. This discussion will show the reader the various interpretations of causation principles as well as provide a foundation for this court's evidentiary proposal.

2. Historical Discussion of Causation-in-Fact Standards in Vaccine Claims

For the most part, with few notable exceptions,[12] the courts have held petitioners pursuing off-Table claims to the same causation standards governing civil tort litigation.[13] The special masters and appellate judges employing these standards have historically demanded "heavy lifting" on petitioner's part.[14] To that end, they have precluded claimants from benefitting from the relaxed standards of proof and principles of generosity generally available to those claiming Table injuries. The following discussions describe the Circuit's legal construct and the lower courts' efforts to apply that framework to vaccine claims.

a. Actual causation standards under the Federal Circuit's direction

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[12]See, e.g., Sharpnack v. Secretary of HHS, 27 Fed. Cl. 457, 462 (1993) ("There is nothing in the statute that requires application of traditional tort litigation standards of proof. Such a concept would be an anomaly in this Program that seeks to provide a substitute system of compensation for vaccine injury in lieu of traditional tort litigation. It is in keeping with the objectives of the Program to conclude that a showing that the injury more likely than not was caused by the vaccine is adequate to establish causation in fact."), aff'd by unpublished opinion, 17 F.3d 1442 (1994); Knudsen v. Secretary of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994) ("[T]o 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.").

[13]See, e.g., Shyface, 165 F.3d at 1351; Candelas v. Secretary of HHS, No. 90-759V, 1991 WL 187316, at *4 (Cl. Ct. Spec. Mstr. Sept. 5, 1991); Terran v. Secretary of HHS, No. 95-451V, 1998 WL 55290, at *6, *7 (Fed. Cl. Spec. Mstr. Jan. 23, 1998), aff'd, 41 Fed. Cl. 330 (1998), aff'd, 195 F.3d 1302 (Fed. Cir. 1999), cert. denied, 121 S. Ct. 45 (2000).

[14]See, e.g., Grant, 956 F.2d at 1148; McClendon v. Secretary of HHS, 24 Cl. Ct. 329, 333 (1991), aff'd by unpublished opinion, 41 F.3d 1521 (1994); McCummings v. Secretary of HHS, No. 90-903V, 1992 WL 182190, at *7 (Cl. Ct. Spec. Mstr. July 10, 1992), aff'd, 27 Fed. Cl. 417 (1992), aff'd by unpublished opinion, 14 F.3d 613 (1993), cert. denied sub nom., 511 U.S. 1032 (1994); Hodges v. Secretary of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993); Terran, 1998 WL 55290, at *6; Brice v. Secretary of HHS, 240 F.3d 1367, 1368 (Fed. Cir. 2001).

The Federal Circuit has provided legal causation guidelines which the lower courts have attempted to understand and faithfully apply. First, the Federal Circuit has confirmed that 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.[15] A preponderance of the evidence requires that the trier of fact "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." Hodges, 9 F.3d at 963 (Newman, J., dissenting) (citing Concrete Pipe and Products of California, Inc. v. Construction Laborers Pension Trust for Southern California, 508 U.S. 602 (1993), quoting In re Winship, 397 U.S. 358, 371-372 (1970) (Harlan, J., concurring)).

Second, 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, 165 F.3d at 1353.[16] 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, 998 F.2d at 984; Hodges, 9 F.3d at 961; Knudsen, 35 F.3d at 548.[17] Furthermore, the logical sequence of cause and effect must be supported by "[a] reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960.[18] Finally, according to the Federal Circuit, 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

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[15]See, e.g., Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991); Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1146, 1148; Munn v. Secretary of HHS, 970 F.2d 863, 865 (Fed. Cir. 1992); Hodges, 9 F.3d at 962-963 (Newman, J., dissenting); Knudsen, 35 F.3d at 549. See also Wilson v. Secretary of HHS, No. 90-795V, 1992 WL 118955, at *4 (Cl. Ct. Spec. Mstr. May 15, 1992); McCummings, 1992 WL 182190, at *7; Johnson v. Secretary of HHS, 33 Fed. Cl. 712, 721 (1995), aff'd by unpublished opinion, 99 F.3d 1160 (1996).

[16]See also Shaw v. Secretary of HHS, 18 Cl. Ct. 646, 651 (1989); Strother v. Secretary of HHS, 21 Cl. Ct. 365, 370 (1990), aff'd by unpublished opinion, 950 F.2d 731 (Fed. Cir. 1991); Wilson, 1992 WL 118955, at *7; Guy v. Secretary of HHS, No. 92-779V, 1995 WL 103348, at *1-*2 (Fed. Cl. Spec. Mstr. Feb. 21, 1995).

[17]See also Shaw, 18 Cl. Ct. at 651; Sumrall v. Secretary of HHS, No. 90-135V, 1991 WL 20074, at *2 (Cl. Ct. Spec. Mstr. Jan. 10, 1991), aff'd, 23 Cl. Ct 1 (1991); Marlow v. Secretary of HHS, No. 90-701V, 1991 WL 202226, at *6 (Cl. Ct. Spec. Mstr. Sept. 20, 1991); Wilson, 1992 WL 118955, at *7.

[18]See also Knudsen, 35 F.3d at 548; Shaw, 18 Cl. Ct. at 651; Strother v. Secretary of HHS, 18 Cl. Ct. 816, 823 (1989), aff'd, 21 Cl. Ct. 365, 370 (1990); Wilson, 1992 WL 118955, at *7; Sharpnack, 27 Fed. Cl. at 462; Bosch v. Secretary of HHS, No. 95-313V, 1997 WL 254218, at *5 (Fed. Cl. Spec. Mstr. Apr. 25, 1997). See also H.R. Rep. No. 99-908, at 15 (1986).

the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-1353.

The Federal Circuit has also articulated certain constraints on petitioner's proof. For instance, a petitioner does not meet this affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods.[19] Nor does petitioner satisfy his burden by merely showing a proximate temporal association between the vaccination and the injury.[20] Finally, a petitioner does not demonstrate actual causation by solely eliminating other potential causes of the injury.[21]

Despite the Federal Circuit's aforementioned legal construct, its standard of review has limited the development of more precise criteria in the causation arena. As Special Master Hastings explained in Liable v. Secretary of HHS, No. 98-120V, 2000 WL 1517672, at *9 (Fed. Cl. Spec. Mstr. Sept. 7, 2000):

> rulings with respect to "actual causation" are factual findings, and factual conclusions of special masters are to be upheld upon review unless found to be "arbitrary or capricious." § 300aa-12(e)(2)(B); see also Hines v. Secretary of HHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991); Henkel v. Secretary of HHS, 42 Fed. Cl. 528 (1998); Lankford v. Secretary of HHS, 37 Fed. Cl. 723 (1996). Thus, under this deferential standard of review, the differences in analysis among the special masters . . . have not been resolved by the courts reviewing such decisions. Instead, the various factual

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[19]See, e.g., Grant, 956 F.2d at 1148. See also Shaw, 18 Cl. Ct. at 651; Sumrall, 1991 WL 20074, at *2. See also H.R. Rep. No. 99-908, at 15.

[20]See, e.g., 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. See also Borchardt v. Secretary of HHS, No. 89-82V, 1990 WL 293875, at *1 (Cl. Ct. Spec. Mstr. July 16, 1990); Sumrall v. Secretary of HHS, 23 Cl. Ct. at 5; Thibaudeau v. Secretary of HHS, 24 Cl. Ct. 400, 403 (1991); Parks v. Secretary of HHS, No. 90-268V, 1991 WL 33233, at *3 (Cl. Ct. Spec. Mstr. Feb. 21, 1991); Boehmer v. Secretary of HHS, No. 90-317V, 1991 WL 242995, at *6 (Cl. Ct. Spec. Mstr. Oct. 31, 1991), remanded by Order (Jan. 10, 1992); McCummings, 1992 WL 182190, at *7; Schuler v. Secretary of HHS, No. 92-140V, 1995 WL 634391, at *1, *4-*5 (Fed. Cl. Spec. Mstr. Oct. 13, 1995); Housand v. Secretary of HHS, No. 94-441V, 1996 WL 282882, at *4 (Fed. Cl. Spec. Mstr. May 13, 1996), aff'd by unpublished opinion, 114 F.3d 1206 (Fed. Cir. 1997); McCarren v. Secretary of HHS, No. 92-764V, 1997 WL 341694, at *11 (Fed. Cl. Spec. Mstr. June 6, 1997), aff'd, 40 Fed. Cl. 142 (1997); Terran, 1998 WL 55290, at *7.

[21]See, e.g., Grant, 956 F.2d at 1149-1150; Hodges, 9 F.3d at 960.

> decisions, though some may have been somewhat contradictory of others, have been affirmed as constituting factual decisions which were not "arbitrary and capricious."

Thus, by rightfully deferring to the special masters on factual findings, the Federal Circuit by and large has "*not* attempted to impose any particular analysis" in actual causation claims. Id. at *11 (emphasis in original). However, the Federal Circuit's limited development of causation law can also be attributed to the appellate courts' affirmation of special masters' decisions as "credibility calls" or "the battle of the experts." Similar to factual rulings, such credibility calls are subject to great deference on review. But are they really credibility calls?

A closer look will show that the characterization of special masters' decisions as credibility-based is questionable in many cases. For the most part, case outcome is determined by the weighing of the substantive evidence presented against the *particular* evidentiary standard employed – *this standard frequently varies between the individual special masters and even between decisions by the same special master*. The outcome in these instances should not be imputed to the "battle of the experts," but more correctly should be characterized and analyzed as disputes over the appropriateness of the evidentiary standard. As further illustration of this point, consider these scenarios involving the same experts: Decision maker "A" applies a *less* stringent causation standard, accepts the expert testimony that comports with that standard, and, in doing so, finds the accepted expert testimony "more credible" than the competing expert. However, in a factually and medically similar case, decision maker "B" opts to apply a *more* stringent standard and ergo finds as "more credible" the testimony of the competing expert who testified accordingly. In fact, the same experts have testified similarly on identical medical issues resulting in different outcomes before different special masters. While the opposite findings may be cloaked in determinations based upon the credibility of the experts' testimony, in actuality it is the particular evidentiary standard employed that determines each outcome. The experts play a secondary role in affirming or contesting the individual elements of the particular standard applied. The special master's characterization of the decision as a credibility call sets in motion at the appellate level the deference given to the decision. The consequence is affirmance of different outcomes in similar cases using varying evidentiary standards because of the deferential standards of review applied to credibility calls. Judge Plager incisively discerned the problem in his recent Lampe dissent:

> In actual causation cases such as this one, the ultimate decision often turns on the outcome of the "battle of the experts," and the present case is no exception. Both sides presented expert medical witnesses in support of their respective positions. The Special Master viewed Rachael's witnesses as failing to provide "detailed credible testimony," and "unpersuasive." The Court of Federal Claims couched it in terms of determining the "credibility" of these competing witnesses. It is often said that, on appeal, evaluations of credibility are "virtually unreviewable." See, e.g., Bradley, 991 F.2d at 1575. *On closer examination, however, it becomes apparent that credibility is not really the issue in this case*.
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> . . . .

> *The majority attempts to dismiss these realities by characterizing the dissent's quarrel as "really with the special master's evaluation of the evidence, which is a 'matter[] within the purview of the fact finder.'"* Maj. Op. at 1364 (citation omitted). *Indeed, my quarrel is with the special master's evaluation of the evidence. He evaluated it using an incorrect analytical approach . . .*
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> *The majority tells us that the evaluation of evidence by a special master is "within the purview of the fact finder."* Id. *That reflects the fundamental error in the majority's approach to this case.* Yes, determining who among conflicting live witnesses is more credible is a determination that is rarely possible on a cold record, thus giving the trial official substantial freedom in making that determination; and yes, a fact-finder is entitled to substantial deference in resolving disputed questions of fact. *But an appellate court is not a potted plant when the question is whether the trial official correctly evaluated the facts found, and whether he arrived at correct conclusions of fact and law based on the evidence*. Indeed, Congress specifically provided for review by this court, under a proper standard of review, of precisely those questions. *In many cases it is only disputed facts that are at issue, and our standard of review dictates that we withhold our hand; this is not one of them, and it does not do to try to make it one*.

Lampe, 219 F.3d at 1373-1375 (Plager, J., dissenting) (emphasis added).

Thus, while the Federal Circuit's opinions supply the broad principles of causation, precise guidance has not developed. The lack of uniform and precise criteria means the principal question presented and litigated over and over again is what type and amount of evidence is legally sufficient to meet these general evidentiary requirements? For instance, what medical or scientific proof must, at a minimum, support petitioner's expert's medical theory? Is there evidence without which petitioner cannot prevail? Is an expert theory grounded in a treater's clinical perspective sufficient? Can a single case report support petitioner's medical theory of causation? What minimal amount or type of evidence meets the Shyface requirement that the vaccine be a substantial factor in the occurrence of the alleged injury?[22] Twelve years of litigation under the Vaccine Program has not

[22]For instance, in Shyface, the Federal Circuit concluded that petitioners successfully met their burden based on the special master's finding "that Cheyenne would not have died but for the DPT vaccination, and that the DPT vaccine *contributed to* Cheyenne's death by causing him to experience an exceptionally high fever." Shyface, 165 F.3d at 1353 (emphasis added). Are the special masters to infer that a finding that the vaccine "contributed to" the injury successfully meets the substantial factor burden? Or should the special masters take direction from Judge Plager's dissenting opinion in Lampe, 219 F.3d at 1374, wherein he chastised this special master for rejecting petitioners' expert's testimony that the vaccine was "instrumental" in producing the injuries alleged. The special master concluded the testimony did not rise to the level of actual causation, but Judge Plager considered this finding contrary to Shyface which requires only that the vaccine be a substantial factor. Id. Need the vaccine only be *instrumental* then to meet the Shyface requirement?

provided answers to these questions. In turn, inconsistent decision-making results even for similarly-situated litigants. The following section exposes these disparities.

b. Actual causation standards under the special masters and the U.S. Court of Federal Claims: the application and development of the Federal Circuit's analytical framework and the resulting inconsistent findings and disparate treatment of petitioners

The special masters have undertaken efforts to apply the broad principles of causation articulated by the Federal Circuit. To that end, the court routinely evaluates causation claims through a two-prong approach, assessing first whether the vaccine can cause the injury alleged (whether it is medically possible for the vaccine to cause the alleged injury), and, if so, then whether it did in the particular case.[23] Not infrequently, the special masters' efforts result in inconsistent findings and disparate treatment of similarly-situated petitioners. While factual differences in each case partly account for this, the more appreciable factor is the various legal standards that the special masters employ. The resulting disparity involves not only what type or combination of evidence supports petitioner's claims, but the scope of petitioner's burden as well.

(1) The court's evaluation of the type and combination of evidence supporting petitioner's claims

For the most part, petitioners submit the same type of evidence in almost every vaccine claim. Generally, experts testify to the petitioner's pre-vaccination medical history, the timing and characteristics of the symptoms suffered subsequent to the vaccination, the extent of any permanent damage, the support from the medical community or literature for opining that the vaccine caused the acute and chronic injuries alleged, and the treating physician's efforts to eliminate alternate causes. In rebuttal, respondent usually offers expert testimony that petitioner's evidence is scientifically deficient since no epidemiological or pathological evidence exists. It would seem logical and equitable then, that in cases where the vaccinee received the same vaccine, suffered the same or similar injury, and supported her claim with the same type and/or amount of evidence, including the same expert testimony, the court would render uniform results. Unfortunately, this has not always been the case, as shall be seen, regardless of whether the court is evaluating direct or circumstantial evidence.

(a) The court's evaluation of "direct evidence"

[23] See, e.g., Alberding v. Secretary of HHS, No. 90-3177V, 1994 WL 110736, at *6 (Fed. Cl. Spec. Mstr. Mar. 18, 1994); Guy, 1995 WL 103348, at *1; Schuler, 1995 WL 634391, at *1, *3, *5; Housand, 1996 WL 282882, at *5; McCarren, 1997 WL 341694, at *11.

When evaluating petitioner's causation evidence, the special masters initially look for direct evidence linking the vaccine to the alleged injury. Vaccine and traditional tort case law is replete with references to "direct evidence," "hard science," and "circumstantial evidence." In this court's discussion, "direct evidence" refers to that evidence which experts on both sides routinely accept as sufficient medical proof of causation. In the twelve years the undersigned has listened to expert testimony, numerous highly-credentialed experts have accepted that the vaccine directly caused the alleged injury when the proof is based on an epidemiologic study demonstrating a relative risk greater than two (assuming the vaccinee meets the study's parameters) or dispositive clinical or pathological markers evidencing a direct causal relationship (for example, the presence of anterior horn cells on autopsy as evidence of polio contracted from the oral polio vaccine or the presence of the rubella virus in synovial fluid taken from the joints as evidence of a rubella-related arthropathy). Stated another way, direct evidence is that which moves the physician or the factfinder closer to a "scientifically certain" determination of vaccine causation.[24]

In vaccine claims, the most desirable direct evidence is epidemiology. Where it is available, the special masters find it highly probative. While supportive epidemiology is not a prerequisite to compensation,[25] evidence indicating a relative risk greater than two suffices to prove causation in a particular case more probable than not.[26] Thus, a petitioner may successfully demonstrate actual

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[24]Evidence other than the two types of direct evidence referenced is otherwise deemed herein as "circumstantial evidence." Circumstantial evidence may include a wide range of evidence, as well as epidemiologic studies with a relative risk less than two and clinical symptoms which are compatible with, but not dispositive of, a vaccine-induced injury.

[25]See, e.g., Carter v. Secretary of HHS, No. 89-80V, 1990 WL 293453, at *4, *5 (Cl. Ct. Spec. Mstr. June 27, 1990), aff'd, 21 Cl. Ct. 651 (1990); Robinson v. Secretary of HHS, No. 91-1V, 1991 WL 268650, at *6 (Cl. Ct. Spec. Mstr. Nov. 27, 1991); McCummings, 1992 WL 182190, at *11; Gall v. Secretary of HHS, No. 91-1642V, 1999 WL 1179611, at *8 (Fed. Cl. Spec. Mstr. Oct. 31, 1996). See also Daubert, 43 F.3d 1311 (9th Cir. 1995); IOM 1994 Report at 22 ("[I]f one or more cases have clearly been shown to be caused by a vaccine (i.e., *Did it?* can be answered strongly in the affirmative), then *Can it?* is also answered, even in the absence of epidemiologic data.").

[26]The Daubert court explained:

> California tort law requires plaintiffs to show not merely that Bendectin increased the likelihood of injury, but that it more likely than not caused *their* injuries. In terms of statistical proof, this means that plaintiffs must establish not just that their mothers' ingestion of Bendectin increased somewhat the likelihood of birth defects, but that it more than doubled it – only then can it be said that Bendectin is more likely than not the source of their injury.

Daubert, 43 F.3d at 1320. See also Maiorana v. United States Mineral Products Company, 52 F.3d 1124, 1128 (2nd Cir. 1995).

causation by providing a reliable and relevant epidemiologic study and establishing that she falls within the parameters of the group associated with the statistically significant relative risk (assuming, of course, respondent fails to prove a factor unrelated). The successful use of epidemiology is most apparent in the context of DPT-related injuries where petitioners may rely on the National Childhood Encephalopathy Study (NCES). Although the NCES has faced criticism over the years, petitioners and the special masters use it regularly as a gauge for determining causation in DPT cases. Indeed, Special Master Hastings decided recently in Liable that a petitioner claiming a DPT-related injury meets her causation burden by demonstrating that "a neurologically-intact vaccinee (1) suffers, within seven days after a pertussis vaccination, a neurologic episode that would have qualified as a 'serious acute neurologic illness' under the NCES; (2) goes on to experience chronic neurologic dysfunction of the type described in the NCES; and (3) no other cause for that dysfunction can be identified." Liable, 2000 WL 1517672, at *12.

Despite the value of epidemiology, however, the special masters have not always consistently applied such evidence to similarly-situated vaccinees. Special Master Hastings acutely observed the following in Liable with respect to the NCES:

> In cases in which the first significant symptoms of neurologic damage occurred *more than three days but no more than seven days* after vaccination, on the other hand, the results were mixed. A number of decisions, issued by a wide variety of special masters, found that "actual causation" had, in fact, been demonstrated in such instances.
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> In a number of other Program cases, in which the onset of symptoms occurred between four and seven days post-vaccination, however, special masters found that the available evidence was *insufficient* to justify a finding of actual causation.

Id. at *6 (citations omitted) (emphasis in original). To be sure, treating similar cases differently is not new. Judge Margolis noticed this years ago in Estep v. Secretary of HHS, 28 Fed. Cl. 664 (1993), wherein he affirmed Special Master Baird's finding of entitlement, but not before commenting on the special master's contrary finding in a similar case:

> The court is aware that in previous decisions, special masters have reached varying conclusions as to the probative value of the IOM Report and the NCES. See Sharpnack v. Secretary of Health and Human Servs., 27 Fed. Cl. 457, 459 (1993); Cucuras v. Secretary of Health and Human Servs., 26 Cl. Ct. 537, 543 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993); Sumrall v. Secretary of Health and Human Servs., 23 Cl. Ct. 1, 6 (1991). Indeed, in Cucuras, the same special master as in this case, Special Master Baird, was presented with a conflict of evidence very similar to that in this case. The respondent offered the IOM Report, and the petitioner offered the NCES plus the testimony of Dr. Geier. 26 Cl. Ct. at 543. In Cucuras, Special Master Baird came to the opposite conclusion from our case; he concluded that the IOM Report was more persuasive, and Dr. Geier's testimony less persuasive. Id. at 543,

> 545-46. It appears, however, that the variety of conclusions reflects the complexities of fact finding in vaccine cases, factual differences, and differences in proof offered in each case. On the record in this case, however, the court finds no basis for disturbing the special master's decision.

Estep, 28 Fed. Cl. at 668-669. Thus, factual differences aside, even in the face of seemingly supportive epidemiological evidence – *the evidence most desired in a vaccine claim* – not infrequently a petitioner's prospect of prevailing may depend heavily on which special master decides the case. The undersigned submits this inequity stems more often than not from the various legal interpretations the special masters employ *in the absence of clear causation criteria*.

The other desirable direct evidence is dispositive clinical or pathological markers evidencing a direct causal relationship. The presence of such "vaccine footprints" leaves little doubt in the mind of the experts and the factfinder that the vaccination is the likely cause of the injury. Unfortunately, most petitioners cannot benefit from the introduction of such evidence because it is unavailable. On this point, the competing experts agree. Its absence may be due to certain tests not being conducted in the particular case or simply science's failure to identify or even accept certain markers. Where petitioners have relied on credible footprint evidence, the government usually and rightfully concedes the claims. For example, in some OPV and rubella cases, post-vaccinal testing confirms the vaccine reaction. However, the availability of footprint evidence is simply *very limited* in vaccine litigation.

In sum, in most instances a petitioner may successfully prosecute her claim by relying on dispositive epidemiology or vaccine footprints which scientifically and legally demonstrate that the vaccine is the more likely cause of the injury alleged. Unfortunately, few petitioners are afforded this evidentiary luxury since epidemiology and footprints are rarely available – such is the nature of science. This lack of direct evidence leaves petitioners no other recourse than to corroborate their causation claim with circumstantial evidence. Such proof presents evidentiary quandaries, as the following explains.

(b) The court's evaluation of "circumstantial evidence"

In the absence of epidemiology or direct clinical or pathological evidence linking the vaccine to the alleged injury, the court faces an even more perplexing causation analysis. *With few exceptions, the special masters encounter the absence of dispositive epidemiology or vaccine footprints in the vast majority of causation-in-fact cases under the Program.* The reasons for this are several. First, relevant research regarding causation is often extremely limited. A number of factors restrict the medical community's efforts to conduct such studies including the costliness of the research and the rarity of the illnesses studied.[27] Second, most vaccines simply leave no unique

[27]Experts frequently testify, and the literature confirms, that the rarity of certain reactions makes it logistically impossible to create a reliable study because of the need for an inordinately large population. Ethical concerns, such as giving a placebo to a child, may also prevent statistical

markers, footprints, or clinical and/or pathological patterns of injury which would enable one to specifically identify the vaccine as the causative agent or otherwise distinguish the injury from one caused by another factor, such as a viral or bacterial infection or other illness. Physicians have accepted this medical fact in a number of cases.[28] In the absence of supportive literature and clinical markers then, petitioners typically rely on "circumstantial evidence." This circumstantial evidence includes: epidemiology (evidencing a relative risk less than two), animal studies, case reports/case series studies, anecdotal reports, manufacturing disclosures, Physician Desk Reference citations, journal articles, institutional findings (such as those reported by the Institute of Medicine), novel medical theories, treating physician testimony, and non-dispositive but inferential clinical and laboratory findings. Not surprisingly, the petitioners' use of this evidence is met with varying success depending on the particular evaluative standard the special master utilizes.

For instance, some special masters remain largely skeptical of whether animal studies can be extrapolated to humans.[29] Similarly, the special masters have debated the utility of case reports. In 1991, Special Master French deemed case reports and a condition consistent with a vaccine-related injury insufficient proof of actual causation.[30] Yet, in the same year, she concluded that a single persuasive case report and a petitioner whose symptoms matched the case report's facts adequately supported petitioner's actual causation claim for a tetanus toxoid caused GBS.[31] Later,

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research.

[28]See, e.g., Loe v. Secretary of HHS, No. 89-83V, 1990 WL 292877, at *4 (Cl. Ct. Spec. Mstr. Aug. 1, 1990), aff'd, 22 Cl. Ct. 430 (1991); Robinson, 1991 WL 268650, at *5, *6; Misenko v. Secretary of HHS, No. 92-13V, 1995 WL 761436, at *12 (Fed. Cl. Spec. Mstr. Dec. 7, 1995); DeFazio v. Secretary of HHS, No. 90-3174V, 1997 WL 383142, at *11 (Fed. Cl. Spec. Mstr. June 25, 1997), aff'd, 40 Fed. Cl. 462 (1998); Shyface v. Secretary of HHS, No. 95-272V, 1997 WL 829404, at *5 (Fed. Cl. Spec. Mstr. Nov. 13, 1997); Williams v. Secretary of HHS, No. 94-1005V, 1997 WL 803112, at *10 (Fed. Cl. Spec. Mstr. Dec. 10, 1997); Almeida v. Secretary of HHS, No. 96-412V, 1999 WL 1277566, at *8, *10 (Fed. Cl. Spec. Mstr. Dec. 20, 1999). See also Kathleen R. Stratton et al., Institute of Medicine, DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis 1 (1994) ("There [are] no special characteristics associated with the acute or chronic nervous system illnesses linked to DPT exposure.").

[29]See, e.g., Parks, 1991 WL 33233, at *4; Braccio v. Secretary of HHS, No. 90-1318V, 1993 WL 59266, at *9 (Fed. Cl. Spec. Mstr. Feb. 19, 1993); Haim v. Secretary of HHS, No. 90-1031V, 1993 WL 346392, at *15 (Fed. Cl. Spec. Mstr. Aug. 27, 1993).

[30]See Muchnick v. Secretary of HHS, No. 90-703V, 1991 WL 217673, at *4 (Cl. Ct. Spec. Mstr. Oct. 10, 1991).

[31]See Robinson,1991 WL 268650, at *3, n. 12, *5, *6, n. 17 (noting petitioners relied on a single case report describing the temporal onset of GBS in an Australian man following each of his three tetanus vaccines).

in O'Leary v. Secretary of HHS, No. 90-1729V, 1997 WL 254217, at *3 (Fed. Cl. Spec. Mstr. Apr. 4, 1997), Special Master French opined that a single case report may support the possibility that a vaccine can cause a certain injury "[i]f sound medical and scientific principles have been applied in that one case, and the matter has been published for peer review."[32] Still others argue that published and peer-reviewed evidence, case reports or otherwise, is not required.[33] The undersigned references these opinions only to illustrate the inconsistencies which may arise when evaluating circumstantial evidence in the absence of uniform causation criteria.

To be sure, the special masters have articulated a number of general approaches to evaluating circumstantial evidence. In Schell v. Secretary of HHS, No. 90-3243V, 1994 WL 71254, at * 5 (Fed. Cl. Spec. Mstr. Feb. 22, 1994), Special Master Baird ruled that in instances where there are no biological or symptomatic ways to distinguish a vaccine-related injury from one caused by an alternate factor,

> there must be a continuum of symptomatology which commenced during the Table period following the vaccination – or at least within a few hours thereafter – and continued essentially uninterrupted until the first seizure or diagnostic symptom of encephalopathy occurred.

He concluded that "[i]n the absence of such a nexus, one can only speculate as to causation."[34] Id. In McCummings, the undersigned resolved that where petitioner presents a novel causation issue lacking support from epidemiological or other hard medical evidence, "[t]he court will decide the case looking at the expert's reasoning, how the limited medical information supports that reasoning,

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[32]Incidentally, science supports the special masters' reliance on case reports, even one, in finding that a vaccine can cause an alleged injury. In its 1994 report entitled Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, the IOM acknowledged that while general causation is usually demonstrated by epidemiological evidence, it can be proven on the basis of individual case reports in the absence of epidemiologic studies. IOM 1994 Report at 22. In fact, the committee favored acceptance of a causal relation in several instances where there existed only one or more convincing case reports. Id. The IOM relied on these individual case reports as long as the nature and timing of the adverse event and the absence of other likely causes "were such that a reasonable certainty of causality could be inferred . . . from one or more case reports." Id. at 30-31. The committee also outlined numerous questions which one might ask to assess the utility of case reports for ascertaining causality. Id. at 23-24.

[33]See, e.g., Gall, 1999 WL 1179611, at *8 (citing Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 593 (1993)).

[34]See also Williams, 1997 WL 803112, at *10 ("[S]ince there are no medical markers for a DPT caused injury, it would appear that a clinical scenario – beginning shortly after vaccination and continuing unabated to the severe neurologic event – might be necessary to establish causation more probably than not.").

and whether the reasoning is logically sound and in accordance with generally accepted medical practice." McCummings, 1992 WL 182190, at *10. In essence, the court considers whether the methodology used to formulate the minority opinion, rather than the expert's opinion itself, is generally accepted. The undersigned clarified the approach: "[I]n novel areas of medical questions, the requirements of evidence are changed from the preferred epidemiological studies to lesser circumstantial evidence *that is generally relied upon by the profession.*" Id. at *11 (emphasis added). The undersigned held similarly in Cruz v. Secretary of HHS, No. 96-820V, 1998 WL 928418, at *6 (Fed. Cl. Spec. Mstr. Dec. 21, 1998):

> Because the case cannot be resolved on the significance of petitioner's symptoms alone [since the symptoms were compatible with both poliomyelitis and GBS], the court must look to other factors such as the experience of the experts, the deference, if any, to be afforded the treating physicians, the support of petitioner's case through the literature, and the strength of respondent's arguments.

But, the consequence of these and other analyses is that special masters have been both reluctant[35] and conversely willing[36] to award compensation in cases where the vaccine cannot be positively identified or otherwise distinguished from competing causes. As Special Master French noted, the struggle is to weigh the scientific certainty of the evidence against the court's obligation to find the evidence only legally sufficient:

> "Attribution of a cause in individual cases must be speculative." So cautions one of the authors of the NCES. That statement is true of course. No identifiable markers or other means exist for proving causation at the level of scientific certainty. The possibility of some other, unknown, unidentifiable [cause] exists in every vaccine case. Scientific certainty, however, is not required. The requisite standard requires a reasonable degree of medical certainty.

Almeida, 1999 WL 1277566, at *21 (footnote omitted).

In addition to the evaluative inconsistencies already mentioned, the special masters must grapple with the frequently presented question of how much weight to accord a *treating physician's*

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[35] See, e.g., Williams, 1997 WL 803112, at *10 (Chief Special Master Golkiewicz); Crockett v. Secretary of HHS, No. 94-15V, 1997 WL 702559, at *12 (Fed. Cl. Spec. Mstr. Sept. 30, 1997) (Special Master Wright); McCarren, 1997 WL 341694, at *16 (Chief Special Master Golkiewicz); Wilson, 1992 WL 118955, at *8 (Special Master Wright).

[36] See, e.g., Almeida, 1999 WL 1277566, at *8 (Special Master French); Robinson, 1991 WL 268650, at *6 (Special Master French); Loe, 1990 WL 292877, at *4 (Special Master Wright).

opinion when it is based on clinical medicine rather than hard science. Express statutory language[37] accords no special weight to a treater's opinions or diagnoses and early case law[38] concludes that the "treating physician" rule[39] does not apply to Program cases. But, a treater's assessments of the cause of the injury, just as any other expert's in the case, may be probative if the opinions expressed are relevant, rational, cogent, and well-supported.[40] In vaccine cases, just as in civil tort cases, petitioners present contemporaneous medical records and reports from treating physicians. The treating physicians may also testify at a hearing and the records and testimony often offer a mechanism for injury or identify the vaccination as the cause of the injury alleged. The opinions are generally grounded in the *clinical* perspective and arrived at following a process of differential diagnosis which involves patient examination and laboratory testing to exclude alternate causes. The causal relationship may be identified numerous times throughout the medical records and even accepted by a number of interdisciplinaried treating physicians. When the claim proceeds to trial, however, this evidence is then pitted against opinions from respondent's experts hired in the course of litigation who most often neither examined the patient nor talked with the treating physicians. Instead, the hired experts rely on the medical records as their source of information about petitioner's medical condition. Respondent's experts then combine their knowledge of the case with their views of causation, gleaned from relevant medical or scientific literature (or the lack thereof), to render an opinion that is most often grounded in the *scientific* perspective. Based on the lack of epidemiological support and vaccine footprints, respondent's experts usually contest not only that the vaccine caused the injury in the particular case, but more basically, based on the available scientific information, that the vaccine can even cause the injury alleged generally. The court's duty then is to weigh the scientifically-based opinions against those clinically-grounded in the context of an Act meant to compensate vaccine-injured persons, but without concrete criteria explaining how to achieve this. It is a constant and confounding balancing problem illustrated well by the following cases.

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[37] See 42 U.S.C.A. § 300aa-13(b)(1) (1991) ("Any such diagnosis, conclusion, judgment, test result, report, or summary [contained in the record and 'regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death'] shall not be binding on the special master or court."). Hereinafter, references to the statute will be by section only, without citation to "42 U.S.C.A. § 300aa."

[38] See, e.g., Fricano v. Secretary of HHS, 22 Cl. Ct. 796, 803-804 (1991); Knudsen v. Secretary of HHS, No. 90-2067V, 1992 WL 395631, at *6-*7 (Fed. Cl. Spec. Mstr. Dec. 17, 1992).

[39] According to Black's Law Dictionary, this rule is "[t]he principle that a treating physician's diagnoses and findings about the degree of a . . . claimant's impairment are binding on [the tribunal] in the absence of substantial contrary evidence." Black's Law Dictionary 1507 (7th ed. 1999).

[40] See Cruz, 1998 WL 928418, at *6, n. 28.

In Heyman v. United States, 506 F. Supp. 1145, 1149 (S.D. Fla. 1981), a swine flu case, the Government submitted deposition testimony from an epidemiologist which the court paraphrased as follows:

> [A] clinician generally can not make a prediction as to whether a relationship exists between an illness and a preceding event such as a vaccination. A mere temporal relation between an event and an illness does not demonstrate any causal connection between the two events. To demonstrate such a connection, statistical studies must be conducted; otherwise the temporal relationship may be simply the result of chance.

Id. The court concluded that "[g]iven the general inability of a physician to make accurate predictions of causation without at least some reference to epidemiological studies, plaintiff's position that her illness was caused by the swine flu shot amounts to nothing more than speculation." Id. Special Master French encountered similar competing perspectives in Robinson but reached a different conclusion:

> [T]he court concludes that in formulating his professional opinion, [respondent's expert] Dr. Wiederholt, an epidemiologist, requires a very high standard of proof of cause and effect, one much higher than required under the Vaccine Act. Dr. Wiederholt would have the court reject the opinions of the treating physicians and consultants as well as statements contained in the medical literature because of the lack of epidemiological studies such as those he personally performed relative to the swine flu controversy. Following his study, Dr. Wiederholt was able to conclude that the swine flu vaccine was a causal factor in GBS. Epidemiological studies are, indeed, relevant, but they are not necessarily the standard by which this court is required to render its decision in vaccine cases. If so, it would be virtually impossible for claimants to prove off-Table cases.

Robinson, 1991 WL 268650, at *6. Of course, clinically-based testimony can also be unpersuasive, as Special Master French found in O'Leary:

> For purposes of clinical diagnosis, care, and treatment, a treating physician is expected to proceed according to his or her assumptions. Such assumptions, however, may not be legally sufficient to prove the accuracy of those assumptions. The court finds [the expert's] assumptions [regarding the possible mechanisms for injuries and alternative causes] insufficient in this case. Too many unknowns exist, and as Dr. Jablecki admits, other causes are possible. As the evidence stands, the court considers it to be in equipoise. Something more is needed in an off-Table case to tip the scales. The court is ill equipped to identify the type of evidence that might establish petitioner's case.

O'Leary, 1997 WL 254217, at *3.

In evaluating this clinical testimony, the application of Daubert, 509 U.S. 579, and its successors has added confusion just as much as it has been considered "helpful in providing a framework for evaluating the reliability of scientific evidence." Housand, 1996 WL 282882, at *4.[41] Daubert states, among other precepts, that 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, 509 U.S. at 594. In addition, Daubert submits that scientific knowledge "connotes more than subjective belief or unsupported speculation." Id. at 590. Rather, some application of the scientific method must have been employed to validate the expert's opinion. Id. Under Daubert, 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, 43 F.3d at 1316 (Kozinski, J.), on remand from 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-594.

Despite these clearly stated principles, Daubert's application to non-scientific evidence remains at issue. In Rogers v. Secretary of HHS, No. 94-89V, 2000 WL 1337185, at *4 (Fed. Cl. Spec. Mstr. June 6, 2000), Special Master French examined the disagreement in federal courts over whether a treating physician's testimony on causation, in other words, the clinical perspective, must satisfy Daubert. Special Master French observed that the Third and Fourth Circuits held "that a physician's testimony is admissible under the Daubert test even if it is not supported by scientific studies" and other courts have held that the Daubert factors are flexible and not applicable in every case. Id. at *4 (citing Heller v. Shaw Industries, Inc., 167 F.3d 146, 152 (3rd Cir. 1999); In re Breast Implant Litigation, 11 F. Supp. 2d 1217 (D. Colo. 1998)). But the Fifth Circuit held otherwise in Moore v. Ashland Chemical Inc., 151 F.3d 269, 290 (5th Cir. 1998), although the dissent "warned . . . that it made no sense to lock the gate on such causation evidence that has been derived through [valid] principles of clinical medicine, [for example, differential diagnosis – a common tool used by clinicians – a method for determining diagnosis and treatment of patients.]" Rogers, 2000 WL 1337185, at *4 (alterations in original). Special Master French endorsed the Moore dissent as "consistent with the requirements of the Vaccine Act" in that "[e]vidence may be in the form of scientific studies or expert medical testimony [including that from treating physicians] to demonstrate causation in fact." Id. (emphasis in original). The special master elaborated:

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[41] See also Terran, 41 Fed. Cl. at 336 (citing Leary v. Secretary of HHS, No. 90-1456V, 1994 WL 43395, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 1994)), aff'd, 195 F.3d at 1316 (stating that per Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137 (1999), Daubert's general principles apply broadly to scientific, technical *or* other specialized knowledge and the trial judge is bound by the rules of evidence to determine "whether the testimony has 'a reliable basis in the knowledge and experience of [the relevant] discipline'").

> The opinions of treating physicians, working in the trenches, take a practical view of clinical implications, and this court gives them considerable weight. . . . [T]reating physicians use differential diagnosis as a method of applying their expertise in every day practice of clinical medicine to determine what caused their patient's illness and how to treat it.

Id. at *13. Special Master French continued:

> The 3rd Circuit found that a differential diagnosis is a physician's "tool of the trade" and that even in the absence of scientific research or supporting studies, when a doctor has 'good grounds' for his or her conclusions, that testimony is admissible . . . and if used to testify to a novel conclusion, is not alone sufficient grounds to exclude the testimony.

Id. at *13, n. 19. Special Master French reaffirmed her position in a subsequent Order:

> Helen Rogers' treating physicians assessed their patient by their own standards using the honored tools of their trade – differential diagnosis, informed intuition based on experience and learning, and on the clinical course of the injured individual – that is, "hands on" expertise, a respectable and practical approach. As stated earlier, causation need not be proved at the level of the laboratorian; a "preponderance" of the evidence means "more likely than not."

Order Denying Respondent's Motion for Reconsideration and Order Denying Petitioner's Motion to Strike, No. 94-89V, 2000 WL 1517675, at *4 (Fed. Cl. Spec. Mstr. Sept. 8, 2000).[42] [43] Of course,

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[42] See also Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1535-1536 (D.C.Cir. 1984) (permitting in cases of novel medical theories where evidence such as epidemiology is lacking, that the court look to the soundness of the basic methodology employed by the expert to reach his conclusion or theory), cert. denied, 469 U.S. 1062 (1984).

[43] The U.S. District Court in Globetti v. Sandoz Pharmaceuticals, Corporation, 111 F. Supp. 2d 1174, 1177 (N.D. Ala. 2000), recently noted the value of a treating physician's differential diagnosis:

> In the case of at least Drs. Finney, Cox, and Waller, the methodology used to lead them to this conclusion is the differential diagnosis, a well-recognized and widely-used technique relied upon by medical clinicians worldwide to identify and isolate the causes of disease so that they may be treated. The differential diagnosis calls for the physician to list the known possible causes of a disease or condition, usually from most likely to least likely. Then, utilizing diagnostic tests, the physician attempts to eliminate causes from the list until he is left with the most likely cause. These diagnostic tests may include physical examination, medical history, testing of blood

it is not uncommon for special masters to find treater testimony or records unpersuasive or unhelpful. Whatever guidance can be garnered from Daubert, without some additional direction on how to evaluate petitioner's clinical evidence from a legal perspective and weigh that evidence against the scientific evidence routinely offered by respondent, the special masters are left to their own devices.

Incidentally and much to the concern of this court, respondent not infrequently objects to the value of the treating physician's contemporaneous examination and diagnosis. In Cruz, the undersigned rejected respondent's subsequent efforts to "re-diagnose" petitioner's original poliomyelitis diagnosis (as contracted from her daughter's OPV) as GBS. The court admonished respondent's tactic:

> In numerous cases before this court, respondent has deferred, without exception in this court's memory, to the treating physician's diagnosis. In this case, petitioner presented respondent with extensive medical records which documented two treating physicians' opinions that petitioner had poliomyelitis. This case is unlike many others where the petitioner's injury claimed is neither supported by, nor even mentioned in, the medical records. In those instances, respondent will meticulously examine the records to determine if petitioner's claims are supported. Respondent will closely scrutinize an expert witness claiming an injury that is not substantiated by the medical records, and in such cases, will seek her own independent expert to either confirm or reject petitioner's expert's opinion. This is the nature of litigation under the Program, and the court makes no criticism of the process in such cases. However, where, as here, the records are substantial, detailed, and replete with notations of the treaters' thought-processes and conclusions, the court questions respondent's, in essence, re-diagnosing petitioner.

Cruz, 1998 WL 928418, at *8.[44]

> and other bodily fluids, X-rays, CT scans, MRIs, and any of a host of generally accepted techniques for eliminating or "falsifying" a hypothesis that the disease arose from a particular listed cause. In Mrs. Globetti's case these testing techniques included physical examination, family and medical history, . . . Ultimately, following the protocol of a different diagnosis, her physicians were able to eliminate every possible cause for the AMI except for spasm. The court has no difficulty finding that that conclusion – the AMI was caused by an arterial spasm – to be well-supported and on good grounds.

[44]See also McMurry v. Secretary of HHS, No. 95-682V, 1997 WL 402407, at *9 (Fed. Cl. Spec. Mstr. June 27, 1997) (considering it egregious to reject a DPT claim when every contemporaneous medical record identified the vaccine as the cause of the initial seizures suffered). Incidentally, it has not eluded this court that treating physicians' opinions and diagnoses are typically contemporaneous to the onset of the injury and administration of the vaccination. The Federal Circuit has instructed the court to accord greater weight to the contemporaneous histories as it is

The special masters' efforts to create standards for evaluating circumstantial evidence have not faired well. The difficulties stem largely from the less scientific, more clinical, nature of the evidence submitted. The special masters want petitioners to present a claim rooted in scientific or medical principles, as Daubert commands, but the court is not wholly convinced of how that is successfully effected when petitioners can only rely on circumstantial evidence. There simply exists no consensus about what circumstantial evidence, if any, sufficiently supports petitioner's claim. The result is confusing and inconsistent standards. Not surprisingly, the special masters' inconsistent evaluations also extend to whether circumstantial evidence alone or in combination with direct evidence sufficiently demonstrates actual causation, as the following briefly explains.

(c) Inconsistent findings involving the combination of evidence supporting petitioner's claims

Whether the parties present direct or circumstantial evidence, conflict also surrounds what *amount or combination* of evidence sufficiently demonstrates causation generally and in the particular case. Some cases consider the combination of a demonstrated mechanism or medical plausibility and a temporal relationship insufficient.[45] But, the special master in Borchardt, 1990 WL 293875, at *2-*3, disagreed by concluding that a temporal relationship with "controlled studies, a description of an etiology linking the two events that is propounded and accepted by a notable medical expert, specific test results linking the two events or some other significant probative evidence" may satisfy causation. Others consider the combination of medical plausibility (an accepted or plausible medical theory) and the elimination of alternate causes satisfactory.[46] Some cases suggest plausibility, a medically appropriate temporal relationship, and the elimination of

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well-established that medical records, particularly contemporaneous ones, should be considered "trustworthy evidence." Such "records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." Cucuras v. Secretary of HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

[45]See, e.g., Yergert v. Secretary of HHS, No. 90-2228V, 1995 WL 108673, at *7 (Fed. Cl. Spec. Mstr. Feb. 24, 1995) (Special Master French); Housand, 1996 WL 282882, at *7 (Special Master French).

[46]See, e.g., Robbins v. Secretary of HHS, No. 89-118V, 1990 WL 293867, at *4 (Cl. Ct. Spec. Mstr. Nov. 5, 1990) (Chief Special Master Golkiewicz); Wilson, 1992 WL 118955, at *8 (Special Master Wright); Bobbitt v. Secretary of HHS, No. 90-1156V, 1992 WL 159524, at *3-*4 (Cl. Ct. Spec. Mstr. June 10, 1992) (Special Master French).

alternate causes suffices to prove causation.[47] Still others disagree.[48] A temporal relationship and symptoms consistent with a vaccine-related injury (a recognized injury) has also been found deficient.[49]

As if weighing direct or circumstantial evidence did not present enough confusion, the special masters must also contend with differing opinions involving the scope of petitioner's burden in off-Table claims. The competing interpretations further thwart the court's decision-making process, as illustrated by the succeeding discussions.

(2) The court's evaluation of the scope of petitioner's burden

While there exists any number of disputes involving petitioner's burden in off-Table claims, two significantly impact the evaluation process. These two disputes involve whether petitioner must prove the absence of alternate causes or a mechanism for injury.

(a) The debate surrounding whether petitioner bears the burden of proving the elimination of alternate causes

Generally, the parties agree that demonstrating solely the elimination of possible alternative causes is insufficient to prove causation[50] and that evidence demonstrating the absence of alternative causes contributes to a finding of actual causation.[51] But, some cases assign the burden of showing no competing etiologies to petitioner[52] under a traditional tort theory and even collapse the "factor

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[47]See, e.g., Carter, 1990 WL 293453, at *5; Grant v. Secretary of HHS, No. 88-70V, 1990 WL 293410, at *10 (Cl. Ct. Spec. Mstr. July 13, 1990), aff'd, 956 F.2d 1144 (Fed. Cir. 1992); Borchardt, 1990 WL 293875, at *2-*4; Sumrall, 1991 WL 20074, at *5. See also infra at pages 49-51, discussing cases arguably supporting the five-prong analysis proposed herein.

[48]See, e.g., Schell, 1994 WL 71254, at *5; Kern v. Secretary of HHS, No. 92-545V, 1996 WL 477074, at *9 (Fed. Cl. Spec. Mstr. Aug. 8, 1996) (stating that the acceptance of this combination of evidence is tantamount to creating a new Table which the special master declined to do).

[49]See, e.g., Muchnick, 1991 WL 217673, at *4 (Special Master French).

[50]See, e.g., Grant, 1990 WL 293410, at *5; Robbins, 1990 WL 293867, at *4; Grant, 956 F.2d at 1149; Guy, 1995 WL 103348, at *1; Schuler, 1995 WL 634391, at *1; McCarren, 1997 WL 341694, at *11.

[51]See, e.g., Strother, 21 Cl. Ct. at 375-376; Carter, 1990 WL 293453, at *5; Robbins, 1990 WL 293867, at *4; Bobbitt, 1992 WL 159524, at *4.

[52]See, e.g., Grant, 1990 WL 293410, at *5; Schuler, 1995 WL 634391, at *1; McCarren, 1997 WL 341694, at *11; Terran, 1998 WL 55290, at *6; Almeida, 1999 WL 1277566, at *5; Lampe, 219

unrelated" analysis under § 13(a)(1)(B) into petitioner's alternate causes discussion.[53] Still others believe the special master must affirmatively and separately conduct the analyses under §§13(a)(1)(A) and (B), although it is still petitioner's burden to prove the elimination of alternate causes.[54] Conversely, other cases assign the burden wholly to *respondent* under the statute's factor unrelated provision at § 13(a)(1)(B).[55]

These competing interpretations are most evident in two decisions rendered in Wagner v. Secretary of HHS. In Wagner v. Secretary of HHS, 37 Fed. Cl. 134, 139 (1997), Judge Bruggink reversed and remanded a decision denying compensation for a rubella-related arthropathy, holding that the special master erred in placing the affirmative burden on petitioner to "disprov[e] every alleged alternative cause" or, in essence, to show that there is not an unrelated cause which could be blamed for the injuries alleged. The court expressed that:

> [p]lacing that burden on the petitioner would require the petitioner to affirmatively prove that an infinite number of potential causes were not at work causing the injuries suffered. There is no foreseeable end to the burden that would be placed on the petitioners under such a statutory interpretation. The statutory language and the purpose of the Vaccine Act do not anticipate or support such a construction.

Id. at 139. Thus, in the court's view, "[u]nder the terms of the Vaccine Act, such alternative factors of causation should be both offered and proven by the Government."[56] Id. On remand, Special

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F.3d at 1371 (Plager, J., dissenting).

[53]See, e.g., Johnson, 33 Fed. Cl. at 721 (citing Munn v. Secretary of HHS, 970 F.2d 863, 865 (Fed. Cir. 1992)).

[54]See, e.g., Strother, 18 Cl. Ct. at 823-824; Strother, 21 Cl. Ct. at 375; Grant, 1990 WL 293410, at *5, *12-*20; Wagner v. Secretary of HHS, No. 90-2208V, 1997 WL 617035, at *9 (Fed. Cl. Spec. Mstr. Sept. 22, 1997) (ruling on remand).

[55]Incidentally, the cases also differ in terms of *which* alternate causes petitioner must exclude; the list ranges from all possible, unknown or asymptomatic causes (see, e.g., Strother, 21 Cl. Ct. at 375-376; Carter, 1990 WL 293453, at *5; Silva v. Secretary of HHS, No. 90-1098V, 1992 WL 700265, at *6 (Cl. Ct. Spec. Mstr. May 22, 1992); McCummings, 1992 WL 182190, at *14.) to those only considered plausible, likely or reasonable (see, e.g., Grant, 1990 WL 293410, at *5, *9-*10; Candelas, 1991 WL 187316, at *5.).

[56]Judge Bruggink relied on O'Connor v. Secretary of HHS, 24 Cl. Ct. 428, 429-430, n. 2 (1991), aff'd, 975 F.2d 868 (Fed. Cir. 1992), and McClendon, 24 Cl. Ct. at 333, in support of his opinion. See also Shifflett v. Secretary of HHS, 30 Fed. Cl. 341, 347 (1994) (finding that Special Master Abell demanded a higher standard than required by the Act when he expected petitioner to rule out other enteroviruses to prove the logical sequence of cause and effect in the absence of a

Master Hastings conceded the reasonableness of Judge Bruggink's interpretation of petitioner's actual causation burden, agreed the statute requires a two-part analysis under §§ 13(a)(1)(A) and (B), but emphatically affirmed in *dicta* his belief that petitioner bears the burden to prove that the vaccine is the more likely cause than any other agent. See Wagner v. Secretary of HHS, No. 90-2208V, 1997 WL 617035, at *10 (Fed. Cl. Spec. Mstr. Sept. 22, 1997). The special master also posited that Judge Bruggink's interpretation actually *reduced* petitioner's burden in actual causation cases to one far different from that advanced in traditional tort cases, such that petitioner need only prove plausibility (that the vaccine can cause the injury) and a temporal relationship before the burden shifts to respondent under § 13(a)(1)(B). Id. at *11-*12. Finally, Special Master Hastings averred that petitioner could sufficiently prove the elimination of competing etiologies if her expert stated a familiarity with other potential causes and opined that none explained petitioner's condition; petitioner would not have to "affirmatively prove that an infinite number of potential causes were not at work," as Judge Bruggink feared. Id. at *17. Only further evidence or discussion would be necessary if respondent specifically pointed to a factor unrelated in the case.[57] Id. The higher courts have not directly addressed this conflict of assigned burdens.[58]

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contemporaneous diagnosis); Vant Erve v. Secretary of HHS, 39 Fed. Cl. 607, 615, n. 19 (1997) (Bruggink, J.).

[57]Other cases supporting Special Master Hastings' opinion include Almeida, 1999 WL 1277566, at * 5; Williams v. Secretary of HHS, No. 90-3091V, 1998 WL 156967, at *11 (Fed. Cl. Spec. Mstr. Mar. 18, 1998); and Crockett, 1997 WL 702559, at *10.

[58]The undersigned referred to the competing interpretations in Gherardi v. Secretary of HHS, No. 90-1466V, 1997 WL 53449, at *8, n. 16 (Fed. Cl. Spec. Mstr. Jan. 24, 1997), aff'd by unpublished opinion, 230 F.3d 1382 (Fed. Cir. 2000):

> Under traditional tort standards, petitioner must prove the vaccine causative ***more likely than not***. Implicit in this standard, is that petitioner must prove that the vaccine is more likely the cause of the injury than ***some other possibility***. Accord Munn v. Secretary of DHHS, 970 F.2d 863, 865 ("The claimant must prove by a preponderance of the evidence that the vaccine, ***and not some other agent***, was the actual cause of the injury.") (emphasis added). An apparent conflict thus arises in cases brought under the Act pursuant to a causation in fact theory. On one hand, ***petitioner*** must address the issue of other likely causative agents in proving that the vaccine is the more likely cause of the subsequent injury. See, e.g., Johnson v. Secretary of DHHS, 33 Fed. Cl. 712, 720 (1995), aff'd, 99 F.3d 1160 (Fed. Cir. 1996). On the other hand, once petitioner makes a prima facie case under 300aa-13(a)(1)(A), the court assigns the burden of proving alternative etiologies, i.e., "factors unrelated" to ***respondent***. See 300aa-13(a)(1)(B); see, e.g., McClendon v. Secretary of DHHS, 24 Cl. Ct. 329, 333 (1991), aff'd, 41 F.3d 1521 (1994); see also Wagner v. Secretary of DHHS, No. 90-2208V, slip op. at 6 (Fed. Cl. January 6, 1997). Thus, with regard to causation in fact cases, case law appears to assign the

(b) The debate surrounding whether petitioner bears the burden of proving a mechanism for injury

The case law also offers confusing opinions about whether petitioner bears the burden of introducing a mechanism for injury. Early on in Borchardt, 1990 WL 293875, at *4, the special master recognized the importance of a proffered mechanism for injury:

> It may well be that . . . proof [that the vaccine caused the illness] in a case of this type is impossible to come by. The medical literature is itself quite vague on the mechanisms that lead to this illness. If medicine cannot explain *how* the illness arises, it is difficult to see how anyone could, at this point, establish some specific cause in a specific case.

(Emphasis added.) But, two years later in Silva, the court ruled that petitioner need not specifically identify the biological or immunological mechanism: "The fact that petitioners cannot identify the precise biological or immunological mechanism by which the vaccine produces an injury is not necessarily fatal to their claim." Silva, 1992 WL 700265, at *7 (citation omitted). This approach was followed by the U.S. Court of Federal Claims in Sharpnack,[59] the Federal Circuit in Knudsen,[60]

> burden of showing no competing etiologies to petitioner under traditional tort theories, see, e.g., Johnson, 33 Fed. Cl. at 721, while other cases assign the burden to respondent under the statute's factor unrelated provision. See 300aa-13(a)(1)(B); see also Wagner, slip op. at 7, n. 5 (recognizing the conflict with Johnson, and respectfully disagreeing with that decision.) This conflict is an issue that has not been directly addressed by the higher courts.

(Emphasis in original.)

[59] "Respondent would require proof of the mechanics of how specific pertussis toxins that were contained in the shot administered to the petitioner on February 19, 1988, worked to cause the injury experienced by this particular petitioner. There is nothing in the statute that requires application of traditional tort litigation standards of proof." Sharpnack, 27 Fed. Cl. at 462.

[60] "[C]ausation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child *without detailed medical and scientific exposition on the biological mechanisms*. Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." Knudsen, 35 F.3d at 549 (citation omitted) (emphasis added).

and subsequent special master decisions.[61] But other special masters have ruled differently or otherwise
found the nature of the evidence probative in the causation analysis, if not requisite.[62]

Unfortunately, the nature of the evidence routinely submitted in vaccine claims necessarily compels the special masters to look for a described mechanism for injury, Knudsen notwithstanding.[63] This is so because under Grant the petitioners must demonstrate a "logical sequence of cause and effect." To that end, the court has looked to two types of evidence to explain the nexus of cause and effect, one being the mechanism of injury and another being direct evidence in the form of epidemiology and vaccine footprints. Since epidemiology and footprints are rarely available, petitioners are forced to rely on a mechanism of injury. Abiding by Grant and Knudsen is thus a struggle, albeit one handled delicately by Special Master French in Almeida. Under her

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[61]See e.g., O'Connell v. Secretary of HHS, No. 96-63V, 1998 WL 64185, at *12 (Fed. Cl. Spec. Mstr. Feb. 2, 1998) (Special Master Millman rejecting respondent's demand for precise proof of a causative mechanism as contrary to law (Knudsen) and medicine (IOM) and observing that the IOM's 1994 committee concluded that the DPT can cause a serious, acute neurological illness which is followed by chronic nervous system dysfunction although the IOM did not describe an exact mechanism underlying its conclusion), aff'd, 40 Fed. Cl. 891 (1998), aff'd by unpublished opinion, 217 F.3d 857 (1999), cert. denied, 121 S. Ct. 45 (2000); Johnson v. Secretary of HHS, No. 99-219V, 2000 WL 1141582, at *11 (Fed. Cl. Spec. Mstr. July 27, 2000) (Special Master Millman accepting that the tetanus-diphtheria (Td) vaccine was a substantial factor in causing petitioner's ADEM without understanding the mechanism or homology to explain it).

[62]See, e.g., Sepulveda v. Secretary of HHS, No. 92-349V, 1995 WL 502887, at *4 (Fed. Cl. Spec. Mstr. Aug. 10, 1995) (the undersigned stating that a petitioner cannot prove a logical sequence of cause and effect without identifying which illness he suffered and the mechanism for injury); Roy v. Secretary of HHS, No. 90-2929V, 1996 WL 445383, at *7 (Fed. Cl. Spec. Mstr. July 24, 1996) (Special Master Hastings noting that petitioner's expert only speculates versus states "how" the rubella vaccine causes FMS); Bosch, 1997 WL 254218, at *7 (Special Master Millman concluding petitioner needed, to prevail, proof of an illness sufficient to cause-in-fact death and medical expertise explaining a logical and reliable way on *how* the vaccine caused the death).

[63]See, e.g., Yergert, 1995 WL 108673, at *5 (Special Master French concluding Dr. Kinsbourne's mechanism theory of an immune reaction had a logical sequence to it and was accepted among some in the medical community even though petitioner did not ultimately meet his causation burden); Awad v. Secretary of HHS, No. 92-79V, 1995 WL 366013, at *5, *8 (Fed. Cl. Spec. Mstr. June 5, 1995) (Special Master Hastings rejecting petitioner's claim based on a number of factors and noting that she did not propose a mechanism for injury nor explain whether the mechanism for a rubella-related arthropathy is the same for an alleged rubella-related FMS); Kern, 1996 WL 477074, at *6 (Special Master French noting that the literature submitted offering a logical mechanism for injury, systemic capillary leak syndrome, failed to link the injury to MMR although it neither ruled the vaccine out).

discussion of "The Mechanism for Injury," Special Master French first articulated petitioner's burden under the Federal Circuit's decisions in Grant and Knudsen to demonstrate a "logical sequence of cause and effect [backed] with [a] sound and reliable medical or scientific explanation." Almeida, 1999 WL 1277566, at *12 (citing Grant, 956 F.2d at 1148; Knudsen, 35 F.3d at 548). The special master then detailed petitioner's expert's causation opinion and his proposed mechanism of injury: "[the] antigens in the vaccine breach[ed] the blood-brain barrier, attack[ed] brain cells, and affect[ed] neuronal metabolism." Id. Dr. Kinsbourne opined:

> [B]ecause it is consensual that DPT can cause seizures, logically, there has to be a way by which it can do that. There is not yet a general agreement as to the particular way or mechanism that causes seizures. . . . Regardless of the details of its mechanism, the biological plausibility of acute brain damage caused by pertussis vaccine is beyond doubt.

Id. (citations omitted). Dr. Kinsbourne also admitted the minority acceptance of his blood-brain barrier breach theory. Id. at *13. Special Master French then explained her reliance on this proposed mechanism in the context of petitioner's burden:

> The court presents this information, not for proof of Dr. Kinsbourne's proposed mechanism of injury, but to suggest that the proposed sequence of cause and effect meets the requirements of Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994), citing Jay v. Secretary of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993). It is logical and based on a "sound and reliable medical or scientific explanation." The court's analysis of the basis for Dr. Kinsbourne's opinion, leads the court to the opinion that it falls within the range of accepted standards governing medical or scientific research required by Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995), and should not be cavalierly dismissed. His theory of the mechanism of injury neither persuaded me nor dissuaded me from my ultimate decision. The Federal Circuit has held in Knudsen that the precise details of the mechanics of injury are not needed for Petitioner's case to succeed. According to Knudsen, a "detailed medical and scientific exposition on the biological mechanisms," of an injury, is not necessary. Knudsen, at 548. The Federal Circuit held further: ["]The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain. See Bunting v. Secretary of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991) (Scientific certainty is not the standard of proof); (citing Hodges v. Secretary of HHS, 9 F.3d 958, 966-68 (Fed. Cir. 1993) (Newman, J., dissenting). . . . [C]ausation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms. E.g., Jay, 998 F.2d at 984. Furthermore, 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.["]

Id. at *13-*14 (citing Knudsen, 35 F.3d at 549). Special Master French's discussion illustrates the difficulties in evaluating the types of evidence routinely presented in vaccine cases against the requirements of Grant – "logical sequence of cause and effect" – but in a manner that does not contravene Knudsen – "without a detailed medical and scientific exposition on the biological mechanisms."

The preceding, exhaustive historical recitation exemplifies the difficulties the special masters encounter when weighing evidence against the general principles of causation. As stated earlier, the undersigned submits that similar evidence is being adjudged differently in vaccine cases because of the application of various evidentiary standards. In turn, the differing results are being affirmed on the basis of deference given to credibility determinations. Unfortunately, the critical issue of the correctness of the evidentiary standard is evading examination. The undersigned hopes the historical review exposes the critical need for such an examination.

C. RULING ON THE STANDARD GOVERNING ACTUAL CAUSATION CLAIMS: THE COURT'S PROPOSED FIVE-PRONG CRITERIA

1. Introductory Comments

The statute provides that to award compensation the court must find petitioner demonstrated by a preponderance of the evidence that the vaccine caused the injury alleged. Unfortunately, the vaccine case law, as shown above, has been somewhat inconsistent and has not established what type and amount of evidence sufficiently meets this preponderance standard.[64] After studying Program jurisprudence and case law in other courts and having considered from experience the types of evidence submitted in causation-in-fact cases over the past twelve years and the goals and purposes of the Program, the court finds that the following five-prong test, if met, meets the preponderance test.[65]

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[64]Thus, petitioner's proposed standard is not contrary to vaccine precedent. See R. Opp. at 19 ("Petitioner seeks to relax Vaccine Program standards of proof because she cannot meet the one currently mandated by the Federal Circuit.").

[65]The special masters are uniquely qualified to formulate a more precise and legally tenable means of reviewing causation-in-fact claims under the Act. In Hodges, the Federal Circuit stated:

> Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters[']fact-intensive conclusions; the standard of

2. The Court's Five-Prong Evidentiary Standard

The court finds that petitioners satisfy their *prima facie* burden to demonstrate by a preponderance of the evidence that the vaccine caused the injury alleged by meeting *all five prongs* outlined below.

PRONG ONE: Proof of medical plausibility

This prong is one of two parts of the "*can cause*" inquiry. It requires that petitioner demonstrate it is medically plausible for the vaccine received to cause the injury alleged. This is done by proffering a theory of biologic mechanism by which a *component* of the vaccine can cause the type of injury suffered. If a component of the vaccine is not capable of causing the alleged injury by some feasible mechanism, it follows logically that the vaccine did not cause the injury in a given case.[66] The focus of the inquiry is not on the vaccine but on the components that make up the vaccine and whether those components can cause the alleged injury. This is not a rigorous burden. Experts routinely rely on fundamental scientific or medical concepts rooted in the literature on immunology, neurology, toxicology, and other disciplines to show that a component of the vaccine is capable of causing the alleged injury. For example, petitioners have shown that the live virus in the oral polio vaccine can cause the recipient to develop polio, just as it would with wild polio. Likewise DPT recipients frequently argue that since the toxins contained in the "wild" pertussis organism can cause a toxin-induced reaction, or more specifically, neurological injuries, identical toxins contained in the pertussis inoculation can as well.[67] These are just two ways in which

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> review is uniquely deferential for what is essentially a judicial process. See Munn, 970 F.2d at 870. Our cases make clear that, on our review of the judgment of the Court of Federal Claims, we remain equally deferential. Id.; see also Phillips v. Secretary of Dep't of Health & Human Servs., 988 F.2d 111, 112 (Fed. Cir. 1993). That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Hodges, 9 F.3d at 961.

[66]See, e.g., Gherardi, 1997 WL 53449, at *2, n. 7; McCarren, 1997 WL 341694, at *11, n. 12. Of course, there may be those rare instances in which science accepts the vaccine can cause an injury based on evidence first derived through the *Did it?* analysis. For instance, in the case of tetanus toxoid and GBS, the IOM concluded: "[B]ecause the case by Pollard and Selby (1978) demonstrates that tetanus toxoid *did* cause GBS, in the committee's judgment tetanus toxoid *can* cause GBS." IOM 1994 Report at 89 (emphasis in original).

[67]As another example, the IOM suggested mechanisms for injury with respect to demyelinating diseases:

> Thus, it is biologically plausible that injection of an inactivated virus, bacterium, or

petitioner might support the first prong.[68] While demonstrating a biologic mechanism requires support from science or medicine for implicating a component of the vaccine, petitioners need not prove here that the literature associates *the vaccine itself* with the alleged injury (which is instead the inquiry in Prong Two). To be sure, petitioners are not required to present a "detailed medical and scientific exposition on the biological mechanisms" in violation of Knudsen (see supra at pages 32-34), nor demonstrate with scientific certainty that the vaccine can cause the injury alleged.[69]

> live attenuated virus might induce in the susceptible host an autoimmune response by deregulation of the immune response, by nonspecific activation of the T cells directed against myelin proteins, or by autoimmunity triggered by sequence similarities of proteins in the vaccine to host proteins such as those of myelin. The latter mechanism might evoke a response to a self-antigen, so-called molecular mimicry (Fujinami and Oldstone, 1989).

IOM 1994 Report at 48.

[68]The special masters frequently rely on the IOM's conclusions as a sound source for answering the first and second prongs outlined above; the court considers their determinations authoritative and subject to great deference. See supra n. 5, at 3-4 and n. 92, at 53. For this discussion, the IOM uses "biologic plausibility" in assessing causality in a manner different than proposed here. But, some of the committees' language is useful for explaining what this court will be looking for in prong one. For instance, in its 1994 report, the IOM reported that biologic plausibility meant the following:

> The vaccine-adverse event association [is] plausible and coherent with current knowledge about the biology of the vaccine and the adverse event. Such information includes experience with the naturally occurring infection against which the vaccine is given, particularly if the vaccine is a live attenuated virus. Animal experiments and in vitro studies can also provide biologic plausibility, either by demonstrating adverse events in other animals that are similar to the ones in humans or by indicating pathophysiologic mechanisms by which the adverse event might be caused by receipt of the vaccine.

IOM 1994 Report at 22; see also Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines 4, 59 (1991) (hereinafter "IOM 1991 Report") (reviewing biologic plausibility evidence that included "background knowledge concerning the pathophysiology of an adverse event, attributes of a particular vaccine, or other biologic information derived from research in such areas as immunology and physiology"). In the words of the IOM, what is important is that petitioner demonstrate "a possible causal association [which] fits existing biologic or medical knowledge." IOM 1991 Report at 54; see also supra IOM 1994 Report at 22.

[69]See, e.g., Rogers, 2000 WL 1337185, at *14 (stating that although the IOM's 1994 report does not find it probable "by the high confidence level required by laboratorian standards" that the

Knudsen, 35 F.3d. at 549. Instead, the court is looking for a basis for how the vaccine could cause the alleged injury.[70]

PRONG TWO: Proof of confirmation of medical plausibility from the medical community and literature

Once petitioners proffer a medically or scientifically supported mechanism by which a vaccine component could cause the injury alleged, the petitioners must satisfy this second prong to complete the "*can cause*" inquiry. *Here, petitioner must establish that peer-reviewed literature reports that the vaccine is related in some sense to the injury alleged.* The question to ask is whether the medical or scientific community is seeing the alleged injury in relation to the vaccine administered. The court is concerned with the *fact* that a relationship is reported, rather than how that relationship is defined or by what criteria. In practical terms, Prong One establishes the possibility for the vaccine, through one of its components, to cause injury, and Prong Two establishes that in fact the medical community is seeing and reporting a suspected or potential association. This is also not a demanding burden.[71] Petitioners' evidence in support of this may

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tetanus toxoid vaccination causes MS, and this convinced the special master in her original decision that petitioner did not prove the vaccine can cause MS, the court finds otherwise now based on all the evidence in the record, including additional hearing testimony, and her belief that "[d]ecisions in vaccine cases need not be based on scientific or laboratorian standards of proof, but on a preponderance").

[70]As the IOM reported, "[t]he existence of a possible mechanism . . . increase[s] the likelihood that the vaccine-event association could be causal." IOM 1991 Report at 54.

[71]See, e.g., Johnson, 2000 WL 1141582, at *3, *9, *10, *11 (Special Master Millman accepting petitioners' theory that the tetanus-diphtheria (Td) vaccine can cause ADEM based on (1) medical literature linking various vaccines (tetanus toxoid and diphtheria/pertussis/polio) and bacterial infections to various demyelinating episodes (including GBS, relapsing acute encephalopathy, and ADEM), and despite that (2) there is no known mechanism for the injury, (3) the IOM could not provide any specific background rates for Td and ADEM, and (4) the IOM stated the evidence was inadequate to accept or reject a causal relation between Td and demyelinating diseases of the central nervous system); Corder v. Secretary of HHS, No. 97-125V, 1999 WL 476256, at *7 (Fed. Cl. Spec. Mstr. May 28, 1999) (the undersigned concluding that it is possible that the DPT vaccine can cause ADEM based on references to a few published studies discussing a possible correlation, including one that found "relapsing acute encephalitis . . . may occur as a very rare complication of diphtheria-tetanus-poliomyelitis vaccination," the IOM's non-specific finding that "injection of an inactivated virus, bacterium, or live attenuated virus might induce an autoimmune response in the susceptible host," case reports where "ADEM in association with tetanus toxoid have been described," and finally an article stating that "the diagnosis of . . . postvaccinal encephalomyelitis [which included ADEM] should be considered when neurologic signs develop 4 to 21 days following . . . vaccination").

include: epidemiological studies, animal studies, case series, case reports, anecdotal reports, journal articles, manufacturing disclosures, Physician Desk Reference citations, and institutional findings, like those reported by the Institute of Medicine.[72] Satisfaction of this prong succeeds in moving petitioner's mechanistic theory under Prong One beyond that which is only theoretically plausible

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But see Fadelalla v. Secretary of HHS, No. 97-573V, 1999 WL 270423, at *1, *2, *5 (Fed. Cl. Spec. Mstr. Apr. 15, 1999), aff'd, 45 Fed. Cl. 196 (1999), wherein Special Master Millman rejected petitioner's claim that the rubella vaccine caused her GBS based on her expert's knowledge of GBS and past experience with a similar GBS patient, literature supporting an association (including the Physicians' Desk Reference citing an association between the rubella vaccine and GBS and literature showing an association between the wild rubella virus and the vaccine and GBS), and a treater's medical record relating the GBS to a post-immunization serum sickness. The literature discussed the rubella disease rather than the vaccine itself, studied a vaccine no longer administered, or was purely anecdotal. Id. at *5. In short, while petitioner demonstrated medical or biologic plausibility, she failed to prove legal probability in any of the ways permitted, in other words, through biological mechanism (the science was not yet so advanced), in vitro testing (none available here), animal experimentation (insufficient proof here), clinical experience (the court found respondent's expert's clinical experience much more extensive and persuasive), or epidemiology (which did not show an increase in the baseline here) – mere anecdotal literature and a handful of practical cases doomed petitioner's case. Id. at *4, *6.

Incidentally, Johnson, 2000 WL 1141582, reveals, there may be those instances in which the court finds the evidence sufficient to warrant a finding of entitlement even though neither petitioner nor science can explain the mechanism by which the vaccine causes the injury. The court's five-pronged criteria are the best tests the undersigned can generate based on twelve years of experience, but they are also meant to be flexible. See infra the closing comments at page 62. Indeed, it would hardly be fair to reject a claim under Prong One if science itself accepts a causal relation even in the absence of an explained mechanism for injury.

[72]In the case *sub judice*, petitioner relies on two types of medical literature to demonstrate medical plausibility. First, petitioner points to the IOM's report of "several additional cases of transverse myelitis following vaccines, including hepatitis B vaccine, during the period November 1, 1990 through July 31, 1992." P. MSJ at 10. Petitioner also relies on the IOM's finding of biologic plausibility between hepatitis B and demyelinating diseases (including transverse myelitis) although she concedes the IOM considered the evidence insufficient to either accept or reject a causal relation between the two. Id. Second, petitioner references the Physician's Desk Reference wherein it states that transverse myelitis is a possible nervous system reaction to each of the vaccines received. See P. Ex. 11 (Physician's Desk Reference 1789 (51st ed. 1997)) (product information for Recombivax HB) (stating that transverse myelitis occurs in equal to or greater than 1% of the injections); P. Ex. 12 (Physician's Desk Reference 2658 (51st ed. 1997)) (product information for Engerix-B) (stating that transverse myelitis occurs in less than 1% of the injections). The court declines comment at this time on the sufficiency of this evidence to prove the first and second prongs.

to that which is being reported by the medical community for the vaccine received and injury suffered.[73]

Prongs one and two are critical prerequisites to assessing whether a vaccine harmed a *particular* petitioner.[74] Logically, if the vaccine cannot be plausibly and empirically linked to the injury alleged, petitioners cannot show that the vaccine caused the injury in their particular case. The court would be hard-pressed to find causation in an individual case if the medical community is not even witnessing or contemplating a causal association.[75] Petitioner's successful satisfaction of these two prongs also complies with Daubert which seeks to ensure that petitioner presents a medical theory based on medically or scientifically valid concepts, and ones preferably rooted in published

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[73]See, e.g., Rogers, 2000 WL 1337185, at *14, n. 20, and Trojanowicz v. Secretary of HHS, No. 95-215V, 1998 WL 774338, at *5 (Fed. Cl. Spec. Mstr. July 1, 1998), aff'd, 43 Fed. Cl. 469 (1999) (suggesting that an expert may successfully prove the vaccine can cause the injury alleged by extrapolating from similarities in pathogenesis to a conclusion of shared causative agents – or vice versa, see McCummings, 1992 WL 182190, at *13 – *if* medical literature or support from the relevant medical community exists to support petitioner's theory (petitioner failed in this endeavor in Trojanowicz)). Accord Daubert, 43 F.3d at 1319.

[74]It is possible, but highly unlikely, that the medical records in some cases will sufficiently address these two prongs. In the absence of such evidence, petitioners will need to provide an expert report or testimony addressing the criteria.

[75]For example, in Perreira v. Secretary of HHS, No. 90-847V, 1991 WL 117740, at *1 (Fed. Cl. Spec. Mstr. June 13, 1991), the undersigned determined:

> [T]his court has not seen any literature – and petitioners' expert conceded that he is aware of none – that supports the onset of an injury two weeks after the DPT shot. While petitioners' expert proposed a theory of causation, petitioners could point to no acceptance of that theory by any segment of the medical community. In fact, even the most liberal writings on the time frames for causal relationship between DPT and injuries do not support petitioners.

Also, in McCummings, 1992 WL 182190, at *13, the undersigned found:

> While Dr. Shinnar offers the rare occurrence of injuries from DPT and the need for an impractically large sample size to do a study of DPT reactions as an explanation for the lack of studies, this begs the question of why are [sic] there are no anecdotes, case reports, or any literature questioning even the possible relationship between DPT and transverse myelitis. . . . Dr. Shinnar has offered not one shred of medical support beyond the theoretical. . . . From both the logical and legal standpoint, Dr. Shinnar's theory that all immunizations may be associated with transverse myelitis is unexplained, ill-supported and therefore deficient.

or peer-reviewed literature. Finally, the value of these prongs finds support in the Institute of Medicine's 1994 report which recognized that, theoretically, vaccines can cause almost any adverse event, but confirmation of an association from the medical literature is required to move the association beyond the theoretical.[76]

To further explain the importance and differences in these prongs, the following IPV and DPT cases are illustrative. In Gherardi, petitioner alleged that the IPV caused her polio based on the theory that portions of the live virus remained in the vaccine after the manufacturing process, thereby infecting her. Gherardi, 1997 WL 53449, at *1. In evaluating petitioner's claim, the undersigned noted the following:

> [T]here is a very real issue as to whether it is biologically plausible for IPV, a vaccine in which the live virus is inactivated [or killed], to cause polio in the recipient. . . . [T]he primary question presented in the[] 164 IPV cases was *how* could an inactivated polio vaccine cause polio? The answer, which has never been contested, is that an IPV can cause polio **if** the vaccine contains some residual live polio virus.

Id. at *1 (emphasis added). The court recognized that in vaccine batches containing some residual live polio virus then, the IPV was arguably capable of causing polio by the same mechanism as wild polio. When respondent conceded, based on epidemiological evidence, that Cutter Laboratories employed a flawed manufacturing process in two specified batches of the vaccine, causing the live virus to remain in the IPV which resulted in vaccine-induced polio, the evidence moved beyond theoretical plausibility and into that which was *empirically supported*. Id. at *1. Unfortunately, Ms. Gherardi failed to prove either that she received one of the two infected Cutter pools or another compromised batch and her claim was ultimately dismissed. Id. at *3.

Conversely, in Trojanowicz, the court rejected petitioners' claim that the DPT vaccine or its tetanus component caused their daughter's chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) because the expert failed to support his theory with medical literature. Trojanowicz, 1998 WL 774338, at *5, *6. In the absence of any epidemiology, case reports or other literature outright supporting a DPT-CIDP causal relationship, petitioners' expert proffered a mechanism for injury based on an analogy. Id. at *2, *5. The expert first opined that CIDP and GBS, both inflammatory neuropathies, were similar clinically and pathogenically. Id. at *2. The expert then argued that whatever could cause GBS could cause CIDP. Id. at *2, *5. Since the literature related the DPT vaccine to GBS, then the vaccine could cause CIDP as well. Id.

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[76]While the IOM conceded that all of the vaccine-adverse events studied in their 1994 report were *theoretically* biologically plausible ("a knowledgeable person could postulate a feasible mechanism by which the vaccine could cause the adverse event"), only a few had *demonstrated* biologic plausibility which meant the finding was "based on the known effects of the natural disease against which the vaccine is given and the results of animal experiments and in vitro studies." IOM 1994 Report at 5, 28. The IOM only considered *demonstrated, not theoretical*, biologic plausibility when making the causality judgments. Id. at 28.

Although a novel idea, in the end petitioners' expert failed to support his proposition that CIDP and GBS are sufficiently similar processes so as to have the same causes; the court determined that "not one medical article submitted or cited makes this analogy" and the literature noted "significant causation differences" between the two conditions. Id. at *5. Thus, while petitioners presented a mechanism for injury, it was not one supported by the medical community or literature.

PRONG THREE: Proof of an injury recognized by the medical plausibility evidence and literature

Having established that the vaccine in question is capable of causing the alleged injury and the medical community is reporting a possible relationship, the case at issue must conform to the medical evidence presented in Prongs One and Two. This is a relatively straightforward prong. Petitioners need only demonstrate that the vaccinee *in fact* suffered the injury which is associated with the vaccine under the preceding prongs. The medical records will typically offer the requisite evidence in this regard.

PRONG FOUR: Proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury

Petitioners must demonstrate that the injury suffered occurred within a medically accepted temporal relation to the vaccine's administration. *The medically acceptable time frame is defined through peer-reviewed literature, most likely submitted to establish Prong Two.* An argument that the onset of the injury was merely or literally temporally related to the vaccination is insufficient. Instead, petitioners must satisfactorily prove that the onset occurred within a time frame deemed *medically appropriate* according to the scientific or medical evidence relied upon to prove the first and second prongs.[77] This distinction is important because a literal temporal relationship may not be medically acceptable, and in itself is nothing more than a "mere temporal relationship" which the case law clearly holds insufficient to demonstrate causation.[78] For example, an encephalopathy occurring within one day of a MMR vaccination is certainly temporally related in a literal sense, but not temporally related in a medical sense. This is because the medical community does not accept that such a reaction will manifest any sooner than five days following the vaccine administration. See 60 Fed. Reg. 7678, 7692 (Feb. 8, 1995) (codified at 42 C.F.R § 100.3); 57 Fed. Reg. 36878, 36880-36881 (Aug. 14, 1992) (codified at 42 C.F.R. § 100.3).

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[77]See supra n. 6, at 4 and n. 8, at 6, for the distinction between literal and scientific temporal relationships.

[78]See, e.g., Hellebrand v. Secretary of HHS, No. 90-372V, 1991 WL 152837, at *3 (Cl. Ct. Spec. Mstr. July 23, 1991) (finding that the court "cannot come to the conclusion that a temporal relationship to an unexplained death [occurring within 24 hours of the DTP vaccination] alone yields causation in fact"), rev'd on other grounds, 24 Cl. Ct. 756 (1991), rev'd and remanded, 999 F.2d 1565 (1993).

Meeting the medically recognized temporal relationship is a *sine qua non* legal requirement and one considered equally important by science. For instance, the IOM recognizes the value of a medically accepted temporal relationship in assessing causality ("Is the timing of onset of the adverse event as expected if the vaccine is the cause? How does that timing differ from the timing that would occur given the alternative etiologic candidate(s)? How does the timing, given vaccine causation, depend on the suspected mechanism (e.g., immunoglobulin E versus T-cell-mediated)?") and finds notable the repeated and temporal occurrence of injuries following multiple vaccinations ("Was the vaccine readministered? If so, did the adverse event recur?"). IOM 1994 Report at 24.[79] In practice, this prong has proven easily satisfied as the experts are cognizant of and routinely testify to medically accepted time frames for the onset of injuries.

PRONG FIVE: **Proof of the elimination of other causes**

In addition to meeting the four preceding prongs, petitioners must affirmatively demonstrate by a preponderance of the evidence that there is no reasonable evidence that an alternate etiology is the more probable cause of the alleged injury.[80] Petitioners may successfully support this prong with evidence from a treating physician indicating that alternate causes were considered and eliminated as the more likely causative agent; this evidence may include oral testimony, written reports, and/or contemporaneous medical records showing the completion of a differential diagnosis. Reasonable

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[79]The IOM's 1991 committee also considered a "temporally correct association" in inferring causality:

> If an observed association is causal, exposure must precede the event by at least the duration of disease induction. The committee, in addition, considered whether the adverse event occurred within a time interval following vaccination that was consistent with current understanding of its natural history. The committee interpreted the lack of an appropriate time sequence as strong evidence against causation, but recognized that insufficient knowledge about the natural history and pathogenesis of any of the adverse events under review limited the utility of this consideration.

IOM 1991 Report at 53.

[80]Under Shyface, a competing cause may play a role in the vaccinee's illness; however, to be awarded compensation, the vaccine must be considered a substantial factor and the more probable cause of the injuries alleged. See, e.g., Herkert v. Secretary of HHS, No. 97-518V, 2000 WL 141263, at *10-*12 (Fed. Cl. Spec. Mstr. Jan. 19, 2000) (finding the vaccinee's cytomegalovirus infection was a factor but not the substantial factor in the development of his transverse myelitis).

efforts to rule out known alternate causes is sufficient to meet the preponderance standard. The reasonableness of the efforts is usually apparent from the medical records.[81]

The court rejects respondent's contention that petitioners must exclude, in addition to any apparent alternate causes, those factors which are otherwise "unapparent" (subclinical) or "spontaneous." See R. Opp. at 9-10, 18-19. To the extent that respondent's position may be interpreted to require petitioner to eliminate *known* potential causes of her illness, regardless of whether those alternate causes manifest clinically, the court agrees with this position; *reasonable efforts* should be made to rule out *known* causes.[82] The court disagrees, however, that to be entitled to compensation under an actual causation theory, a petitioner must eliminate potential *unknown, unidentified, speculative, unapparent, or spontaneous causes* with or without a subclinical nature. Requiring this from petitioners would necessarily prevent any petitioner from prevailing.[83] This is so because there is always the possibility, given the nature of science, that certain causes cannot be

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[81]See, e.g., In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 760 (3rd Cir. 1994), cert. denied sub nom., 513 U.S. 1190 (1995), aff'd following appeal of remand decision, 113 F.3d 444 (3rd Cir. 1997); Globetti, 111 F. Supp. 2d at 1177.

[82]For instance, physicians may eliminate a subclinical infection through laboratory testing. However, a spontaneous or asymptomatic infection or illness which cannot be tested through laboratory or other means is necessarily speculative, and the court refuses to require that petitioners eliminate speculative alternate causes.

[83]In a similar discussion in Johnson, Special Master Millman stated:

> [Respondent's expert] Dr. Sriram posits that he prefers to believe that a subclinical infection is the cause of Hillary's ADEM rather than the known immunological challenge, i.e., the Td vaccine. This position is also not reassuring to the undersigned. A subclinical infection and no infection have the same visible effect: no symptoms. Hillary seemed perfectly healthy. For the special master to assume Hillary had a subclinical infection in order to conclude that Td vaccine was not the only immunological challenge to her system would require an unsubstantiated evidentiary leap.

Johnson, 2000 WL 1141582, at *10. But see Watson v. Secretary of HHS, No. 90-1316V, 1993 WL 196880, at *5 (Fed. Cl. Spec. Mstr. May 27, 1993) (Special Master Baird concluding that even if evidence existed to show that the measles vaccine can cause SSPE, he would still be inclined to find that it is at least as likely that a subclinical measles infection caused the injury); Robles v. Secretary of HHS, No. 90-3001V, 2000 WL 748169, at *6 (Fed. Cl. Spec. Mstr. May 19, 2000) (the undersigned dismissing petitioners' claim for failure to prove the measles vaccine can cause SSPE and declining to "accept petitioners' assertion that Inesita could not have had subclinical measles based on the fact that her mother and doctors never noticed any symptoms" since by definition a subclinical illness does not manifest clinically).

identified or conclusively excluded. However, petitioners are not held to the level of scientific certainty in vaccine cases.[84]

This court proposes the above five prongs as an evidentiary standard for weighing causation-in-fact cases. Individually, the tests do not appear daunting. However, all five prongs must be satisfied to prove causation; no singular criterion is sufficient on its own to demonstrate causation-in-fact. In proposing this criteria, the undersigned recognizes they are not the sole basis for evaluating the evidence presented. Instead, they are the undersigned's effort, based on experience and the review of legal precedent. Of course, other means of establishing causation can be considered. See infra the closing comments at pages 62-63. For instance, the undersigned can anticipate a situation in which petitioner successfully demonstrates all five prongs with circumstantial evidence, only to be challenged by a contrary epidemiologic study. The question of which evidence should be given greater weight will certainly arise. See supra the discussion of "direct evidence" at pages 16-19. However, this question is not presently at issue in the case *sub judice* so the court will leave the consideration of such a situation for an appropriate time. The court is convinced that legal precedent and the court's experience support that this five prong test meets the Program's preponderance of the evidence standard and is consistent with the goals and purposes of this Vaccine Program. The court emphasizes that well-credentialed, unbiased experts, from top teaching facilities, routinely opine to a reasonable degree of medical probability, relying upon the information in these five prongs. Their testimony, evaluated in the context of legal precedent, substantiates both the medical sufficiency of these standards and their legal sufficiency. However, additional support exists, as is outlined in the next section.

D. ADDITIONAL SUPPORT FOR THE COURT'S PROPOSED PRONGS AS GARNERED FROM THE ACT'S LEGISLATIVE HISTORY, OTHER PROGRAM DECISIONS, THE INSTITUTE OF MEDICINE, AND NON-PROGRAM PRECEDENT

The undersigned explained in Section B that the inconsistency in decision-making and the goals of the Program called for clear evidentiary standards. The court then set forth in Section C its findings of what evidence would preponderate in petitioner's favor. Now, in Section D, the court sets forth additional supportive information. Support for the court's proposed prongs can be found

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[84] See Almeida, 1999 WL 1277566, at *21 ("The possibility of some other, unknown, unidentifiable [cause] exists in every vaccine case. Scientific certainty, however, is not required. The requisite standard requires a reasonable degree of medical certainty.") (footnote omitted). See also Lampe, 219 F.3d at 1371, 1373 (Plager, J., dissenting) (stating that the lack of an alternate cause is a necessary part of petitioner's proof of a logical sequence of cause and effect, not a separate showing in response to the Secretary's factor unrelated evidence, and petitioners' proof here of a "total lack of evidence of alternative causation, as demonstrated by the negative results from the extensive tests for alternative causes . . . [was] very strong evidence in support of a well developed theory of causation such as the one presented here") (citations omitted).

in the Act's legislative history, other Program decisions, the Institute of Medicine's reports, and non-Program precedent.

1. The Program's Legislative History

The legislative history unequivocally supports a generous actual causation framework which serves to render expeditious, fair, and certain determinations. The purpose of the Act's "no-fault" compensation scheme to make awards for vaccine-related injuries in an *expeditious, uncomplicated, fair, certain, and generous* manner is clearly stated.[85] This is a goal borne out of the federal government's responsibility to ensure that *all* children who are injured by vaccines (and not just those suffering Table injuries) have access to compensation through a medium more responsive than the unsatisfactory civil tort or settlement routes.[86] It is also a goal based on a Congressional

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[85]"Part A of the system amends the Public Health Service Act to establish a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3 (1986).

"The bill establishes a compensation system for those persons injured by routine pediatric vaccines. The system is intended to be expeditious and fair. It is also intended to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury and without a demonstration that a manufacturer was negligent or that a vaccine was defective." Id. at 12.

"The Committee anticipates that the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation." Id. at 13.

"The Committee has endeavored to create a swift, uncomplicated compensation system . . ." Id. at 16.

[86]"H.R. 5546 is the result of the Committee's re-evaluation [of all current vaccine and vaccine-related activities]. It reflects five principal findings . . . made by the Committee during its study of this issue: . . . (2) The Federal government has the responsibility to ensure that all children in need of immunization have access to them and to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries. (3) Private or non-governmental activities have proven inadequate in achieving either of these goals." H.R. Rep. No. 99-908, at 5.

"But for the relatively few who are injured by vaccines – through no fault of their own – the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered. Currently, vaccine-injured persons can seek recovery for their damages only through the civil tort system or through a settlement arrangement with the vaccine manufacturer. Over time, neither approach has proven satisfactory. Lawsuits and settlement negotiations can take months and

motivation to lessen suits against the manufacturers and furnish legal remedies where state law may not.[87] *The Act's express goals make no distinction between Table and off-Table claims and, in fact, the language unambiguously relates the goals to the entire "compensation system."* Because the "no-fault" compensation system requires that petitioners seek redress here first, *regardless of the theory of recovery pursued*, the system's goals apply equally to all claims filed under the Program. Insulating actual causation claims from the Act's purposes then makes little sense under the remedial nature of the Act or its express language. Nor is it rational in terms of judicial economy. To demand that petitioners sue here first, apply a burden or judicial analysis no different than in the civil tort arena, and then offer the opportunity to reject the judgment and pursue a civil action, is illogical and a waste of judicial resources.[88] The import of the goals upon actual causation claims simply cannot be dismissed.

Moreover, the application of the goals to actual causation claims is validated by several Federal Circuit decisions. In Knudsen, the Circuit ruled, in discussing the burdens associated with a causation-in-fact claim, that requiring petitioners to prove a specific biological mechanism would

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even years to complete. Transaction costs – including attorneys' fees and court payments – are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met." Id. at 6.

"Thus, two overriding concerns have led to the development of this legislation: (a) the inadequacy – from both the perspective of vaccine-injured persons as well as vaccine manufacturers – of the current approach to compensating those who have been damaged by a vaccine; . . ." Id. at 7.

[87]"While the bill does not prohibit a vaccine-injuried [sic] person who has completed compensation proceedings from going on to court, the system is intended to lessen the number of lawsuits against manufacturers." H.R. Rep. No. 99-908, at 12.

"The Committee anticipates that the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation." Id. at 13.

"The Committee also recognizes that because of many States' standards of proof of liability, many vaccine-injured persons are presently without legal remedy under current tort law. The Committee anticipates that many of these persons will be compensated for their injuries under the compensation system." Id.

[88]See also H.R. Rep. No. 99-908, at 29 ("Compensation standards, evidence, and proceedings are sufficiently different from civil proceedings in tort that the findings made in compensation are not likely to be based on the more rigorous requirements of a tort proceeding and [the introduction of these findings] might confuse such civil actions.").

violate the "purpose and nature of the vaccine compensation program." Knudsen, 35 F.3d at 549. The court was "not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others." Id. The Circuit elaborated:

> The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, supra, at 3, 1986 U.S.C.C.A.N. at 6344. The program is supposed to be "fair, simple, and easy to administer." Id. at 7, 1986 U.S.C.C.A.N. at 6348; Koston, 974 F.2d at 161. The program stems from Congress's recognition that "[w]hile most of the Nation's children enjoy great benefit from immunization programs, a small but significant number have been gravely injured." Id. at 4, 1986 U.S.C.C.A.N. at 6345. And "it is not always possible to predict who they will be or what reactions [to the immunizations] they will have." Id. at 6, 1986 U.S.C.C.A.N. at 6347.

Id. Similarly, in Lampe, on an appeal of the lower court's denial of petitioners' actual causation case, dissenting Judge Plager submitted:

> The Vaccine Act provides a "compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity," despite the virtual impossibility of actually proving that a particular injury was the result of receiving the vaccine. See H.R. Rep. No. 99-908 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. The primary vehicle for this compensation is the Vaccine Injury Table, which established an assumed scientific certainty by legal fiat. However, Congress recognized that not all injuries that can be deemed caused by vaccines would fit within the table. Rather than ignore this category of injury in favor of certainty, Congress chose to provide the injured with the option of demonstrating actual causation. If the interpretation, on the facts of this case, of what constitutes "actual causation," expressed by the Special Master, accepted by the Court of Federal Claims, and affirmed by the majority here, is correct, *the decision will have effectively nullified the clearly expressed Congressional purpose that underlines the Vaccine Act.*

Lampe, 219 F.3d at 1375 (Plager, J., dissenting) (emphasis added).

Finally, Congress's resolute purpose underpinning the compensation system is clear. In 1989, after determining that the participants of the Program were still "maintain[ing] their traditional adversarial litigation postures," in violation of the Act's charges "'to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation to injury,'" to provide "a quick, flexible, and streamlined system," and to "administer[] awards 'quickly, easily, and with certainty and generosity,'" Congress fervently called upon the parties and

the court to rededicate themselves "to the creation of an expeditious, non-adversarial, and fair system." H.R. Rep. No. 101-247, at 509 (1989), reprinted in 1989 U.S.C.C.A.N. 1906, 2235. Congress observed:

> In proposing this legislation, the Committee reiterates its intent that the vaccine injury compensation system be informal, flexible, and expeditious, and that all participants proceed accordingly. The re-invention of the adversarial process will serve neither to compensate injured children nor maintain the stability of the immunization programs of the U.S. . . .With such re-dedication to the original goals of the program, the Committee anticipates that all participants will benefit. The system will provide compensation, eliminate the need for litigation, and assure the continued availability of and public confidence in immunizations in the U.S.

Id. The Federal Circuit recently emphasized the Program's goals in Brice while finding that equitable tolling is not available to post-Act petitioners:

> Congress intended awards under the Act to be made "quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3, reprinted in 1986 U.S.C.C.A.N. at 6344. Congress also emphasized the importance of speed and the quick resolutions of petitions: "The entire proceeding – from date of filing through Special Master proceedings and court review – is to take place as expeditiously as possible. . . . [M]uch of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment; without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner." H.R. Rep. No. 99-908, at 17, reprinted in 1986 U.S.C.C.A.N. at 6358.

Brice, 240 F.3d at 1368-1369. The court believes its effort here to distill twelve years of practice into an evidentiary standard for causation-in-fact cases is not only logical but meets squarely the Congressional mandate to resolve these cases fairly, generously, consistently, and expeditiously.

2. Supportive Program Decisions

As discussed earlier, decisional law under the Program has been less than consistent, but evidence meeting the proposed five prongs has been considered sufficient to award compensation in a number of other Program cases. In McCarren v. Secretary of HHS, 40 Fed. Cl. 142, 150 (1997), although petitioners failed to eliminate other known or likely causes, Judge Tidwell agreed that petitioners need only demonstrate four factors to be entitled to compensation (assuming that respondent also fails to prove a factor unrelated). Those four factors are: "(1) that it is medically possible for the vaccine to cause the injury, (2) that there is a temporal association between the vaccination and the illness, (3) that there are no other known causes for the illness, and (4) that there is a reasonable medical explanation and effect." Id. (citing Strother v. Secretary of HHS, 18 Cl. Ct.

816, 819-822 (1989), aff'd, 950 F.2d 731 (Fed. Cir. 1991)).[89] Moreover, recent cases have advanced similar analyses for finding causation. In Liable, discussed above, Special Master Hastings established a test for DPT-related injuries based on evidence of medical plausibility (demonstrated by the NCES), the occurrence of an injury recognized by the NCES (seizures and subsequent seizure disorder), the onset of that injury within the NCES–accepted time frame (seven days), and the elimination of other causes. In addition, Special Master Millman awarded compensation in Johnson, based upon similar requirements, including the following: (1) several treaters' diagnoses and opinions that the child's ADEM was related to the Td vaccination, (2) a finding of a relationship between vaccinations and demyelinating diseases of the central nervous system generally, based on medical literature, (3) a plausible proposed mechanism for injury – an immunological challenge, (4)

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[89]Respondent bases her counter-arguments largely on an attack of each individual prong, in other words, each prong as an isolate of the whole of the evidence. However, as noted, the case law supports that petitioner's proposed criteria, when viewed together, hold merit. Other cases which have, in the undersigned's opinion, directly or indirectly employed the five-prong analysis include: Latorre v. Secretary of HHS, No. 89-27V, 1990 WL 290313, at *3-*4 (Cl. Ct. Spec. Mstr. June 15, 1990); Grant, 1990 WL 293410, at *10; Borchardt, 1990 WL 293875, at *2-*4; Sumrall, 1991 WL 20074, at *5; Sharpnack v. Secretary of HHS, No. 90-983V, 1992 WL 167255, at *1, *6 (Cl. Ct. Spec. Mstr. June 29, 1992) (amended July 28, 1992), aff'd, 27 Fed. Cl. 457, 462 (1993); Estep v. Secretary of HHS, No. 90-1062V, 1992 WL 357811, at *6 (Fed. Cl. Spec. Mstr. Nov. 3, 1992), aff'd, 28 Fed. Cl. 664 (1993); Jay, 998 F.2d at 984; Rogers, 2000 WL 1337185, at *6-*7, *10, *14.

Incidentally, the undersigned specifically relied on these factors in the early part of the Program. In this court's unpublished opinion in Barnard v. Secretary of HHS, No. 90-3527V, slip op. (Fed. Cl. Spec. Mstr. Nov. 17, 1993), petitioner demonstrated that the DPT vaccine caused her glomerulonephritis and renal disease based on expert testimony grounded in the following:

> (1) the temporal relationship between vaccination and the onset of symptoms; (2) lack of other known antigens that petitioner was exposed to within the applicable time frame; (3) his own clinical experience and treatment of petitioner; and (4) support from medical literature that glomerulonephritis has been reported in association with the DPT vaccine.

Id. at 5; see also id. at 4, 9. As the undersigned noted,

> [t]his case boil[ed] down to how much proof is necessary to establish a causal link in a very rare situation. . . . Dr. Ginn provided an unrebutted medical theory which provided the medical 'possibility' of such an occurrence. Dr. Ginn testified further, with the subsequent support of Dr. Boulton-Jones, that medical literature provid[ed] a level, albeit a low lever [sic] of support for the possible occurrence. Lastly, Dr. Ginn testified to his first-hand experience with two cases which he believes represent DPT caused glomerulonephritis . . . .

Id. at 9.

the occurrence of an illness expected to follow an immunological challenge, and (5) the onset of the illness within a time frame considered medically appropriate to allow for the demyelination process. Johnson, 2000 WL 1141582, at *10. While Special Master Millman did not require the elimination of alternate causes as part of petitioners' burden, petitioners' evidence revealed that the vaccinee did not suffer from any other exposures (ill contacts, animals, travel, tick or animal bites, tuberculosis, or preceding illness) or infections, her Lyme's disease and other infectious agents tests returned negative, and her expert relied on this evidence to support his opinion that the vaccine caused the ADEM. Id. at *5. Special Master Millman also ruled similarly in Tufo v. Secretary of HHS, No. 98-108V, 2001 WL 286911, at *11 (Fed. Cl. Spec. Mstr. Mar. 2, 2001):

> Petitioners have satisfied their burden of showing a logical sequence of cause and effect between MMR vaccine and Jerry's ADEM based on: (1) the testimony of Dr. Renfroe, Jerry's treating pediatric neurologist, (2) the medical literature which supports that vaccinations are a known cause of ADEM; (3) the understanding of immune-mediated disease, particularly those manifesting hypersensitivity to MBP; (4) the time sequence here which was appropriate for an immune-mediated response; and (5) the simultaneous occurrence of cold-like symptoms and bowel dysfunction, which means that the former could not have caused the latter due to the lack of time for an immune-mediated response to occur.

In Lampe, the Federal Circuit majority postulated, although affirming the special master's denial of petitioners' causation claim, that "a finder of fact might well have been persuaded that the Lampes had shown that the third DPT vaccination – or the entire series of DPT vaccinations – caused Rachel's seizure condition, which in turn ultimately led to her mental retardation" based on the strong evidence presented, which included "plausible theories of causation, and . . . evidence show[ing] that medical examinations of Rachael eliminated many of the possible non-vaccine-related causes of her seizure condition." Lampe, 219 F.3d at 1368.

In Johnson, Special Master Millman proposed an even more lenient test. She suggested that a lesser showing of proof, a persuasive mechanism combined with a medically supported temporal relationship, might suffice to establish causation:

> Where an immunological process requires a certain number of days or weeks to manifest itself (as it does here) and the challenge and effect are so linked temporally, that process is sufficient legally to support an expert opinion of causation. But there is more evidence that just an appropriate temporal process in Hillary's case. The medical literature submitted herein is replete with causal relationships between vaccinations and illness . . . [and] show[s] that non-viral antigens can result in immune-mediated illnesses such as ADEM.

Johnson, 2000 WL 1141582, at *10.

Finally, the proposed legal construct also properly enforces the Act's express legal sufficiency standard stated in § 13(a)(1)(A) and reinforced in Bunting, 931 F.2d at 873: "[t]he standard of proof required by the Act is simple preponderance of evidence; not scientific certainty."[90] The five-prong analysis appropriately requires some reliance on medically or scientifically sound evidence or principles, but only to the extent that such evidence preponderates to a finding that the vaccine can and did cause the alleged injury.[91]

3. Scientific Precedent From the Institute of Medicine

In promulgating the Act, Congress mandated that the Institute of Medicine conduct scientific reviews of the possible adverse consequences of vaccines. The first IOM committee, the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines, assembled experts in "infectious diseases, pediatrics, internal medicine, neurology, epidemiology, biostatistics, decision analysis, biologic mechanisms of vaccines, immunology, and public health." IOM 1991 Report at *v-vi*. These experts were responsible for the review of available medical and scientific literature (including the National Childhood Encephalopathy Study) and other information regarding the possible adverse consequences of pertussis and rubella. Id. at *vi*. Specifically, the committee considered the "nature, circumstance, and extent of the relationship, if any, between vaccines containing pertussis (including whole cells, extracts, and specific antigens) [and rubella] and . . . [listed] illnesses and conditions." Id. The committee also assessed the causal relation between the pertussis vaccine and permanent neurologic damage. Id. The Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines issued its final report in 1991, entitled Adverse

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[90]See also Grant, 1990 WL 293410, at *12; Estep, 1992 WL 357811, at *5; Knudsen, 35 F.3d at 548-549; Lampe, 219 F.3d at 1371 (Plager, J., dissenting).

[91]In Lampe, Judge Plager opined:

> The Special Master also erred in the burden he placed on Rachael's expert medical witnesses. He rejected their testimony at least in part because they would not state unequivocally that the vaccine caused Rachael's injuries. However, a significant part of the theory underlying the Vaccine Act is that it is difficult if not impossible to demonstrate conclusively that a particular injury was caused by a particular vaccine. Given the current state of scientific knowledge in the field, no responsible doctor can state unequivocally that a particular vaccine caused a particular injury (or, for that matter, that it did not cause such injury). Indeed, any doctor who was willing to make such a statement would be immediately (and rightly) attacked as stating more than science can prove. . . . *Demonstrating actual causation does not require certainty; rather, it requires a plausible scientific explanation supported by a credible, reputable witness.* See Grant, 956 F.2d at 1148. This is exactly what Rachael provided.

Lampe, 219 F.3d at 1374 (Plager, J., dissenting) (emphasis added).

Effects of Pertussis and Rubella Vaccines. See Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines (1991). The second committee, the Vaccine Safety Committee, convened in 1992 and also assembled a panel of interdisciplinaried members. IOM 1994 Report at 3. Its charge was similar:

> [to] (1) review[] the relevant scientific and medical literature on specific risks to children associated with the vaccines or vaccine components directed against tetanus, diphtheria, measles, mumps, polio, *Haemophilus influenzae* type b, and hepatitis B currently licensed for use in the United States and (2) review[] the . . . circumstances under which administration of these vaccines increases the risk of an adverse event, characteristics of groups known to be at increased risk of an adverse event, and timing of vaccination that increases the risk of an adverse event.

Id. Because the committee was created "to describe as precisely as possible, on the basis of all available evidence, the relationships between the vaccines under review and specific adverse events," it asked with each vaccine-adverse event pair, "Can administration of the vaccine cause the adverse event?" IOM 1994 at *vi*. This committee issued in 1994 the lengthy report entitled, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality. See Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality (1994).

While the special masters are not legally bound by any of the IOM reports, the Institute's conclusions have been afforded great deference and authority in vaccine cases given its Congressional mandate and independent role in reviewing existing literature relating to the adverse consequences of vaccines.[92] Turning to the IOM's efforts, its reliance on the criteria proposed to infer causality lends further support to the court's proposed five-prong standard. For instance, in its first report from 1991, the IOM determined that in examining whether a vaccine *did cause* the adverse event, one should inquire if

> it may have been judged in general that the exposure can cause this type of event. In this instance the question concerning any particular case needs to consider the similarity between the circumstances of that case and the circumstances in which the general conclusion was reached that such causation can occur. If other causes of the same type of event are known, their possible role in this individual case must be considered also.

IOM 1991 Report at 36. The IOM committee also described the conclusions of a Japanese study which

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[92] See, e.g., Ashe Robinson v. Secretary of HHS, No. 94-1096V, 1998 WL 994191, at *7-*8 (Fed. Cl. Spec. Mstr. Dec. 22, 1998); Cohen v. Secretary of HHS, No. 94-353V, 1998 WL 408784, at *8 (Fed. Cl. Spec. Mstr. July 1, 1998); Aldridge v. Secretary of HHS, No. 90-2475V, 1992 WL 153770, at *2, n. 12 (Cl. Ct. Spec. Mstr. June 11, 1992).

> considered vaccination as the etiology of infantile spasms if cases met the following three criteria: (1) no other identifiable cause, (2) normal development prior to the onset of spasms, and (3) the interval from immunization to the onset of spasms was within 48 hours for pertussis-containing vaccines and within 18 days for smallpox, polio, and Japanese encephalitis vaccines. . . . The investigators acknowledged that because there is no biologic marker for vaccine-associated infantile spasms, the assignment of cause was made "solely from the clinical standpoint."

Id. at 68-69.

The 1994 IOM committee answered the *Can it?* question by considering a widely used set of criteria which included statistical evidence regarding the relative risks (medical probability through epidemiologic studies), confounding factor evidence (alternate causes), and separate evidence of biologic plausibility. IOM 1994 Report at 20-22. In assessing the utility of case reports, the IOM offered several questions one might ask including "Can a preexisting or new illness explain the sudden appearance of the adverse event?" and "Is the timing of onset of the adverse event as expected if the vaccine is the cause?" Id. at 23-24. In addition, the IOM relied on individual case reports and case series, "[i]n the absence of epidemiologic studies favoring acceptance of a causal relation," and "provided that the nature and timing of the adverse event following vaccine administration and the absence of likely alternative etiologic candidates were such that a reasonable certainty of causality could be inferred . . . from one or more case reports." Id. at 30-31.

Of course, the court's reliance on the committees' reports in no way suggests that a petitioner must demonstrate causality under the same strict scientific principles employed by the panel members. Petitioners must only demonstrate more probably than not (50% and a feather[93]) that the vaccine can and did cause the injury alleged; petitioners need not prove their case to a scientific certainty.

4. Support From Non-Program Cases

Finally, non-Program cases support the court's proposed standard. In traditional tort litigation, there simply exists no single standard for assessing causation-in-fact nor do the cases describe a plaintiff's minimum evidentiary burden. This is partly because traditional tort cases typically focus on questions of admissibility rather than evidentiary sufficiency. But, as successors of Daubert, these cases do offer a starting point for what type of evidence is admissible *and, therefore, could be considered sufficient by the factfinder to prove causation-in-fact*. While of course admissibility does not guarantee sufficiency, cases bearing on admissibility can prove illustrative to issues of weight and credibility. Examining civil tort cases for this purpose, it is apparent that most factfinders engaging in the actual causation analysis consider, and in some cases

[93] See McClendon, 24 Cl. Ct. at 333 (stating "petitioners' proof needs only to 'tip the scale' by the slightest of evidentiary margins").

find persuasive, a combination of a wide range of factors.[94] These factors include: the presence or absence of support from science or medicine for the causation theory espoused (for example, epidemiology, animal studies, in vitro studies, case reports, journal articles, textbooks, etc.); the injured's past medical or familial history; the results of physical examinations; the course and scope of the symptoms and illness suffered, as evidenced by the medical records; the temporal relationship between the onset of the illness or condition and the exposure to the offending agent; laboratory (including pathological) test results; the possibility of alternate causes; the credibility of expert testimony addressing the various factors; the training and experience of the treating physician and testifying expert; and other miscellaneous documentary proof, such as reports prepared by manufacturers on the effect of the alleged causative agent. It is further evident that at the heart of many traditional tort cases is whether, in line with Daubert and its progeny, plaintiff's causation theory is rooted in "good science." The undersigned's proposed standard synthesizes these elements of proof. Of course, the court's intent in advancing the standard is not simply to list the types of evidence which may be offered. Instead, the court expects that its suggested combination of evidence suffices to prove causation more probably than not. While the bulk of non-Program cases may not specifically state that this combination is the "holy grail"of the analysis, and many tort cases have demanded "hard scientific evidence" in the form of epidemiology or animal studies, there certainly exists an ample number of cases which have rewarded plaintiffs on lesser evidence, and more specifically, evidence based on the five-prong standard. A close examination of early swine flu cases confirms this.

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[94]In McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1040 (2nd Cir. 1995), the Circuit affirmed the admissibility of plaintiff's expert's opinion and the jury's finding that unventilated fumes from hot-melt glue manufactured by the defendant caused her respiratory problems and throat polyps. The Circuit stated:

> Fuller's contention that [plaintiff's expert] Fagelson did not base his opinion on "scientific knowledge" also fails. . . . Fagelson based his opinion on a range of factors, including his care and treatment of McCullock; her medical history (as she related it to him and as derived from a review of her medical and surgical reports); pathological studies; review of Fuller's MSDS [Material Safety Data Sheet]; his training and experience; use of a scientific analysis known as differential etiology (which requires listing possible causes, then eliminating all causes but one); and reference to various scientific and medical treatises.

Id. at 1043-1044. Similarly, in Zuchowicz v. United States, 140 F.3d 381, 385, 389-390 (2nd Cir. 1998), the Circuit affirmed the district court's finding that the plaintiff successfully demonstrated that a prescribed drug, Danocrine, more probably than not caused her primary pulmonary hypertension (PPH) although no epidemiologic or anecdotal reports supported her claim given the illness's rarity. Plaintiff's treating expert based his testimony on the following: the elimination of various other potential causes, the treater's pulmonary disease expertise, the temporal relationship between the overdose and the progression of symptoms, and the similarity of the timing and symptoms to other cases of drug-induced PPH. Id.

In Gassman v. United States, 589 F. Supp. 1534, 1537, 1540-1543 (M.D. Fla. 1984),[95] the plaintiff successfully demonstrated that the swine flu vaccine proximately caused her encephalitis and secondary polyradiculitis based on expert testimony rooted in the same type of evidence proposed under the court's standard: the treating expert's arrival at a diagnosis of postvaccinal encephalitis following the elimination of alternate explanations through a series of examinations and testing (including CSF and blood tests); the similarity of plaintiff's polyradiculitis to GBS, the latter having been related by literature to the vaccine; the relatively mild nature of the encephalitis and its recovery – classic characteristics of post-influenza vaccine encephalitis; and finally, a strongly suggestive temporal relationship.[96] Id. at 1540-1541, 1543. The court rejected defendant's argument that plaintiff failed to support her claim with epidemiology (which did not show a marked increase in the incidence of encephalitis or neurological disorders following the vaccine, as it did with GBS) or other scientific or medical literature. Id. at 1542. Significant to the court, the government's expert admitted that he could not rule out the swine flu shot. Id. In addition, the court "[did] not accept the leap of reasoning that from such statistical data [from the national surveillance studies] one must conclude that the swine flu vaccine could produce no neurological reaction other than Guillain-Barre Syndrome, and in particular that it could not have produced plaintiff's encephalitis." Id. In addition to its concerns that the studies focused primarily on reported *GBS* occurrences, the court also observed that the studies did in fact include reports of encephalitis, viral encephalitis and encephalopathy. Id. While those numbers were much lower that those reported with GBS, the court remained convinced that "clearly one cannot logically exclude the possibility that certain of these reported cases were caused by the swine flu vaccine." Id.

Unthank v. United States, 533 F. Supp. 703 (D. Utah 1982), aff'd, 732 F.2d 1517 (10th Cir. 1984) (also known as "In re Swine Flu Immunization Products Liability Litigation") is another early example of the federal courts' reliance, although not so specified, upon the five-prong evidence routinely submitted in Program cases. In this case, plaintiff successfully demonstrated that she developed transverse myelitis (TM) as a result of her swine flu inoculation. Id. at 706. Mrs. Unthank presented expert and treating testimony from highly qualified physicians who based their causal opinions on the following evidence (much as experts routinely do in past and present Program claims): physical and neurological examination and testing, medical history review, alleged mechanism for injury (post-vaccination autoimmune response to the antigenic challenge), and the elimination of other possible causes through a differential diagnosis. Id. at 710. At least two physicians related her injury to the swine flu vaccination although two others could not conclusively

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[95]The plaintiffs in Gassman sued under the Federal Tort Claims Act in connection with the National Swine Flu Immunization Program (established under the Swine Flu Act). Gassman, 589 F. Supp. at 1537. The swine flu litigation preceded the Vaccine Program's enactment and faced evidentiary quandaries similar to those encountered in Program claims.

[96]The court also found significant for purposes of determining the nature and cause of the neurological disorder that the treating expert, unlike defendant's expert, observed plaintiff daily from the onset of her illness through its progressive stages. Id. at 1541.

prove or disprove the causal relationship. Id. at 710-711. The government's expert, Dr. Arnason (a frequent expert for respondent in Program claims) rejected that the swine flu vaccine (or any other flu vaccine for that matter) could cause transverse myelitis. Id. at 711-713. The court disagreed, however, and offered two reasons for concluding that plaintiff sustained her burden:

> First, the process of reasoning by which Drs. Poser and Petajan supported their opinions persuades us that their opinions are entitled to greater weight. Both conducted a neurological examination of plaintiff as well as taking independent medical histories. They arrived at the swine flu vaccine as the cause of her transverse myelitis after ruling out all other possible etiologies. Second, the close temporal relation between the vaccination and onset of neurologic symptoms convinces us that the vaccine was in fact the proximate cause of those symptoms. The thirty-day interval between plaintiff's vaccination and the onset of her symptoms falls well within the ten week period in which the government concedes the vaccine may cause Guillain-Barre syndrome (GBS). Like GBS, many neurologists feel that transverse myelitis is an autoimmune reaction to an antigen challenge, resulting in the destruction of myelin in the nervous system. Although GBS involves the peripheral nervous system and transverse myelitis the central, the mechanism by which demyelination occurs is thought to be the same. It is logical to conclude that the time factor for demyelination in transverse myelitis is likewise similar.

Id. at 714 (footnotes omitted). In other discussions, the court indirectly concluded that plaintiff demonstrated general causation based on a British Medical Journal article (which recognized that transverse myelitis might occur after immunization), the CDC's reports to the Advisory Committee on Immunization Practices (which stated that the illness was a recorded neurologic reaction known to occur following previous immunization programs in this and other countries), other prominent physicians' testimony (who opined "that transverse myelitis was a recognized risk of influenza vaccination prior to the 1976 swine flu program"), and early medical literature (again reporting cases of TM following various vaccination forms). Id. at 712, 720, 721. Based on this evidence, the court determined that "Mrs. Unthank's neurological disorder was identified by persuasive medical authorities as a predictable and foreseeable risk of the swine flu immunization." Id. at 723. Although the district court adjudicated Mrs. Unthank's claim under the Federal Tort Claims Act, it arguably found plaintiff entitled based on the same five-prong standard proposed in this case. The court stated as much in its conclusion:

> [R]ecovery in the instant action is explicitly based on these requisites of proof: (a) causation between the immunization and the neurological disorder has been established by a preponderance of the credible medical and scientific evidence; (b) discernible symptoms of the disorder occurred within a proximate period to the immunization, (here, 30 days); (c) the injury to the vaccinee is severe and has been debilitating; (d) [i]n 1976 the neurological disorder – transverse myelitis was identified among medical authorities as being a predictable and foreseeable risk

> arising from the swine flu immunization program; and (e) the patient did not have a pre-existing malady, for example, Guillain-Barre Syndrome or multiple sclerosis.

Id. at 727-728 (footnote excluded).

Initial skepticism of this court's proposed standard may be further allayed by reviewing toxic tort cases which are probably the most comparable (aside from swine flu cases) to vaccine claims. Particularly, toxic tort litigation utilizes an approach similar to the one introduced here, asking first whether the toxic substance *can cause* the particular injury alleged (general causation), and if so, then determining whether the substance did in the particular case (specific causation).[97] To answer these causation questions, courts adjudicating toxic tort cases have, in conjunction with epidemiological evidence or in the absence thereof, sought further analytical guidance from defined causation criteria. That is, the courts have routinely applied fundamental methods of toxicology prescribed by the World Health Organization and the National Academy of Sciences and reported in the Toxicology Chapter of the Federal Judicial Center's Reference Manual on Scientific Evidence.[98] This methodology aids the court in its legal duty to determine whether a toxin caused a person's illness and requires the following:

> First, the level of exposure of plaintiff to the toxin in question must be determined; second, *from a review of the scientific literature, it must be established that the toxin is capable of producing plaintiff's illness – called "general causation"* – and the dose/response relationship between the toxin and the illness – that is, the level of exposure which will produce such an illness – must be ascertained; *and third, "specific causation" must be established by demonstrating the probability that the toxin caused this particular plaintiff's illness, which involves weighing the possibility of other causes of the illness – a so-called "differential diagnosis.*"

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[97]See, e.g., In re Breast Implant Litigation, 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998); Maiorana v. United States Mineral Products Company, 52 F.3d 1124, 1131 (2nd Cir. 1995) (otherwise known as "In re Joint Eastern & Southern District Asbestos Litigation").

[98]See, e.g., Mancuso v. Consolidated Edison Company of New York, Inc., 56 F. Supp. 2d 391, 394-395 (S.D.N.Y. 1999), aff'd in part and vacated and remanded in part on other grounds, 216 F.3d 1072 (2nd Cir. 2000), case dismissed, 2001 WL 173504 (S.D.N.Y. Feb. 16, 2001); Zwillinger v. Garfield Slope Housing Corp., 1998 WL 623589, at *19 (E.D.N.Y. 1998); Wintz v. Northrop Corporation, 110 F.3d 508, 513 (7th Cir. 1997). See generally Bernard D. Goldstein et al., Reference Guide on Toxicology, in Federal Judicial Center: Reference Manual on Scientific Evidence (1994).

Mancuso, 56 F. Supp. 2d at 399 (emphasis added).[99] Practically speaking, the "methodology" establishes a three-prong test for causation-in-fact which the courts expect plaintiff's expert to address when rendering an opinion.[100] Analogizing the toxicology methodology to vaccine claims, the second prong in Mancuso is akin to the first and second proposed by the court in this case. That is, plaintiff must demonstrate *general* causation or "that, according to scientific literature, levels of the toxin comparable to those received by the plaintiff can cause the specific types of injuries [plaintiff] alleges."[101] Zwillinger, 1998 WL 623589, at *19. This is likewise done by looking at evidence of biologic plausibility. See Wintz, 110 F.3d at 513. Additionally, to prove *specific* causation (proof that the toxin caused the injuries alleged in the particular case more probably than not) alternate causes must be eliminated; this is typically accomplished through the differential diagnosis process.[102]

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[99]Wintz announced a slightly different criteria:

> First, the toxicologist should analyze whether the disease can be related to chemical exposure by a biologically plausible theory. Second, the expert should examine if the plaintiff was exposed to the chemical in a manner that can lead to absorption into the body. Finally, the expert should offer an opinion as to whether the dose to which the plaintiff was exposed is sufficient to cause the disease.

Wintz, 110 F.3d at 513.

[100]See Zwillinger, 1998 WL 623589, at *19; Wintz, 110 F.3d at 513.

[101]Of course, because vaccines have set dosages, the special masters neither inquire about the dosage received nor ponder whether that dose was sufficient to cause the adverse reaction alleged. But, the court does consider other medical evidence, such as whether the adverse reaction occurred within a medically recognized time frame or whether petitioner suffered reactions to other administrations of the same vaccine.

[102]In Mancuso, 56 F. Supp. 2d at 394-395, the court stated,

> Dr. Schwartz had no reasonable basis for concluding that PCBs caused such illness in these particular plaintiffs – known as "specific causation" – because he did not rule out or apparently even consider the possibility that their illnesses could have resulted from other causes, and thus could not make the required "differential diagnosis." He thus totally ignored the methodology prescribed by both the World Health Organization (WHO) and the National Academy of Sciences (NAS) for determining whether a person has been adversely affected by a toxin.

(Citations omitted). Similarly, in Zwillinger, the court found that "[t]o establish specific causation, other possible causes for the symptoms experienced by plaintiff should be excluded by performing a 'differential diagnosis.'" Zwillinger, 1998 WL 623589, at *19. The court explained: "[a]

Support for the court's proposed standard is further garnered from Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C.Cir. 1984), cert. denied, 469 U.S. 1062 (1984). In Ferebee, the District of Columbia Circuit upheld the jury's wrongful death verdict against the manufacturer of a herbicide, namely paraquat, that had been dispensed by Mr. Ferebee in the course of his employment. Plaintiffs successfully argued, under a failure to warn theory, that Mr. Ferebee's long-term dermal exposure to the chemical caused his pulmonary fibrosis and subsequent death. In support of this theory, Mr. Ferebee's physicians relied on the following evidence: his clinical examinations, tests results, and medical studies "which suggested that dermal absorption of paraquat can lead to chronic lung abnormalities, such as pulmonary fibrosis." Id. at 1533. The physicians also relied on their own experience as eminent pulmonary specialists and their knowledge about several other similar cases. Id. On appeal, the defendant disputed the physicians' theory and argued that "there has never been any evidence nor any suggestion that paraquat can cause chronic injury of this sort [i.e., pulmonary fibrosis]."[103] Id. at 1535. The court disagreed:

> [A] cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical. In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency; if reasonable jurors could conclude from the expert testimony that paraquat more likely than not caused Ferebee's injury, the fact . . . that science would require more evidence before conclusively considering the causation question resolved is irrelevant. . . . [Simply because] Ferebee's case may

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differential diagnosis typically includes a physical examination, clinical tests, and a thorough case history." Id. (citations omitted). In In re Breast Implant Litigation, the court stated, "If other possible causes of an injury cannot be ruled out, or at least the probability of their contribution to causation minimized, then the 'more likely than not' threshold for proving causation may not be met." In re Breast Implant Litigation, 11 F. Supp. 2d at 1230. See also In re Paoli R.R. Yard PCB Litigation, 35 F.3d at 760, n. 31 (concluding that unless the experts considered the possibility that other potential causes were the sole cause, plaintiffs could not reliably establish that PCBs were in fact a substantial factor in causing their illnesses).

[103]Unlike in many vaccine claims, in Ferebee, scientific and medical evidence related dermal paraquat exposure to lung injuries. As the company readily admitted, the chemical was a known toxin capable of causing acute injuries. Ferebee, 736 F.2d at 1535. Moreover, the company did not dispute that as early as the 1960's it had been known that exposure to the toxin could lead to fibrotic lung disease. Id. at 1537. Finally, medical literature and the company itself, through incident reports, "catalogued cases in which dermal exposure to paraquat in some cases caused almost immediate death and in other cases caused rather immediate lung problems." Id.

> have been the first of its exact type, or that his doctors may have been the first alert enough to recognize such a case, does not mean that the testimony of those doctors, who are concededly well qualified in their fields, should not have been admitted.

Id. at 1535-1536. The Circuit expounded upon its Ferebee ruling later in Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 832 (D.C.Cir. 1988), cert. denied, 493 U.S. 882 (1989):

> Ferebee stands for the proposition that courts should be very reluctant to alter a jury's verdict when the causation issue is novel and "*stand[s] at the frontier of current medical and epidemiological inquiry*." If experts are willing to testify to causation in such situations and their methodology is sound, the jury's verdict should not be disturbed.

(emphasis in original) (quoting Ferebee, 736 F.2d at 1534). Lest it should be forgotten, Daubert seeks only to ensure that the "trial judge . . . determine[s] whether the testimony has 'a reliable basis *in the knowledge and experience of [the relevant] discipline.*'" Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137, 149 (1999) (citing Daubert, 509 U.S. at 592) (emphasis added). The Supreme Court has counseled that: "The objective of [Daubert's gatekeeping requirement] . . . is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom *the same level of intellectual rigor that characterizes the practice of an expert in the relevant field*."[104] Id. at 152 (emphasis added).

The undersigned's proposed evidentiary standard is entirely consistent with these cases.[105] After showing that the vaccine can cause the injury alleged based on literature or experience, the focus then turns to the clinical evidence in the particular case to show that the vaccine did cause the injury here.

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[104]See Benedi v. McNeil–P.P.C., Inc., 66 F.3d 1378, 1384 (4th Cir. 1995) ("We will not declare [the clinical medicine] methodologies invalid and unreliable in light of the medical community's daily use of the same methodologies in diagnosing patients.").

[105]Incidentally, the Restatement (Second) of Torts at § 433 looks to a temporal relationship and alternate causes in determining whether the cause was a substantial factor in producing the harm. Section 433 reads in relevant part:

> The following considerations are in themselves or in combination with one another important in determining whether the actor's conduct is a substantial factor in bringing about the harm to another: (a) the number of other factors which contribute in producing the harm and the extent of the effect which they have in producing it; . . . (c) lapse of time.

Restatement (Second) of Torts § 433 (1965).

E. COURT'S DISCUSSION OF OTHER STATED CONCERNS

Respondent argues that petitioner's proposed standard is tantamount to creating a new Table. See R. Opp. at 17. The court rejects this argument. While the courts have questioned the development of criteria in off-Table claims,[106] the undersigned's (and petitioner's, for that matter) proposed standard can be distinguished from those governing Table claims. First, in the criteria suggested in the case *sub judice*, petitioner possesses the burden to demonstrate that the vaccine received can cause the injury alleged. The court does not presume the existence of a causal relationship, as happens in Table claims. Second, the five-prong criteria require that petitioner affirmatively advance reasonable evidence that alternate causes were considered but rejected. In Table claims, the demonstration of alternate causes is a burden reserved for respondent which comes into play only after petitioner has met her *prima facie* claim. Third, the court's standard creates no specific temporal limitations, as the Table does. As discussed supra at pages 42-43, a medically accepted temporal relationship must be established, which can differ for each vaccine or injury. Finally, and 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. The natural evolution of the evidence warrants it and the court's proposed standard serves only to further advance the understanding of the Federal Circuit's opinions.

The court also dismisses respondent's contention that petitioner's proposed standard would "yield the absurd result of 'proving' virtually every vaccine causes every illness." R. Opp. at 12. Safeguards in the adjudicative process ensure that petitioners will not be impermissibly rewarded by an unacceptably lenient standard as respondent fears. These safeguards include the fact that petitioners must prove all five prongs proposed: first, a theory for their alleged injury; second, support for that theory; third, the suffering of a relevant injury; fourth, the onset of the injury within a medically accepted time frame; and fifth, that other causes were eliminated. This court has seen many cases fail each of these five prongs.

F. CLOSING COMMENTS ON THE PROPOSED FIVE-PRONG ANALYSIS

Finally, in proposing this five-prong analysis as a means of meeting the preponderance of evidence standard, the court stresses its flexibility and pragmatism. In reality, the proposed criteria simply categorize and focus the evidence typically presented; because of this, the criteria are flexible and should be suitable for every case. Of course, where the prongs fail to adequately address the

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[106] See, e.g., Schell, 1994 WL 71254, at *5, Kern, 1996 WL 477074, at *9; Lampe, 219 F.3d at 1368.

parties' proof, the special masters may establish additional or different criteria.[107] In addition, the 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. This five-prong standard is as much of a framework as the court can offer at this time with refinements, if necessary, to be made with each case decided.

In closing, the court is also mindful that other special masters and the reviewing courts may be initially guarded about the criteria. Even the undersigned has struggled over the years to devise an appropriate analysis, and the court's proposed standard is not infrequently contrary to the undersigned's own previous decisions which have held petitioners to stricter criteria.[108] Having humbly acknowledged this, the court also acknowledges that its application at this juncture is to the case *sub judice*. The criteria are not binding on other Program claims although the undersigned expects to follow this analysis in subsequent cases, absent compelling reasons otherwise. But, the

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[107]For instance, if the overwhelming evidence shows that dispositive clinical or pathological footprints are in fact typical of the vaccine-related injury alleged, a special master may wish to adjust the prongs accordingly and make such evidence a necessary part of petitioner's proof.

[108]For instance, in McCarren, the undersigned *rejected* petitioners' claim for a DPT-related injury due to their failure to produce a distinguishing "footprint":

> In the final analysis, [petitioners' expert] Dr. Gabriel failed to finger one identifying or distinguishing factor that would lead the court to conclude that it was more likely than not the DPT that caused the injuries in this case. In contrast, the other [three] experts presented credible testimony explaining why they could not ascribe causation to the DPT with any level of certainty. . . . The court was convinced that these three experts fairly and objectively considered the medical information and concluded that, for various reasons, the DPT could not be causatively fingered. . . . Petitioners failed to establish by a preponderance of the evidence the necessary cause and effect linkage between the DPT and Billy's neurological injuries.

McCarren, 1997 WL 341694, at *16. Similarly, in McCummings, petitioners failed to eliminate an asymptomatic viral cause despite evidence that during an eight day hospitalization, the vaccinee received an extensive diagnostic work-up which included serologic titer testing (for coxsackie virus, echo virus, mononucleosis virus, Esptein-Barr virus and others) and urine and cerebrospinal fluid cultures. McCummings, 1992 WL 182190, at *1, n. 9, *3, *14. In dismissing petitioners' expert opinion that these negative results deemed the vaccines the *more likely* cause of the child's injury, the undersigned stated: "Once again, the completely theoretical is chosen over the known, generally accepted cause. Dr. Shinnar neither produces convincing testimony to rule out what he concedes to be a possible cause – the asymptomatic virus – nor provides any evidence to point to the DPT or polio vaccine." Id. at *3, *14. Finally, in Corder, the undersigned rejected petitioner's claim, despite a finding of biologic plausibility, because the expert based his opinion only on a temporal relationship and the absence of any other cause. Corder, 1999 WL 476256, at *7-*9.

court again underscores that this proposed standard is not without support from the legislative history, vaccine jurisprudence, the medical and scientific fields, and traditional tort litigation as was discussed at length above. Of utmost significance is that a review of past cases clearly shows the need for clear evidentiary standards to be applied consistently. To that end, the undersigned believes the proposed analysis offers the guidance and fairness demanded by the Act's purposes.

V. CONCLUSION

Based on the foregoing, the court denies petitioner's Motion for Summary Judgment. The court further finds that a petitioner successfully satisfies his or her *prima facie* actual causation burden by proving by a preponderance of evidence each of the following five criteria: (1) that it is medically plausible for a component of the vaccine to cause the injury alleged, (2) that the association between the vaccine and the alleged injury is reported by peer-reviewed medical literature, (3) that the vaccinee suffered an injury which is medically accepted as a possible reaction to the vaccine, (4) that the injury occurred within a medically accepted time period, and (5) that alternate causes were considered but otherwise eliminated.

VI. ORDER

Petitioner is hereby ordered to file a status report by **Friday**, **May 4, 2001**, detailing how she intends to proceed in this case.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master

APPENDIX I

Attachment to the Ruling on Petitioner's Motion for Summary Judgment

Stevens v. Secretary of HHS
No. 99-594V