In the United States Court of Federal Claims

No. 99-628V

(Filed November 24, 2004)

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NANCY MANVILLE,	*	Vaccine Act, 42 U.S.C.
	*	§§ 300aa-1 to 34 (West 2003 &
Petitioner,	*	Supp. 2004); causation-in-fact;
	*	rheumatoid arthritis; proof of
v.	*	causation via "rechallenge"; role
	*	of Daubert v. Merrell Dow
SECRETARY OF THE	*	Pharmaceuticals, Inc., 509 U.S.
DEPARTMENT OF HEALTH AND	*	579 (1993), in Vaccine cases;
HUMAN SERVICES,	*	preponderance of the evidence.
	*	
Respondent.	*	
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* *		

Ronald Craig Homer, Boston, MA, for petitioner.

Ann K. Donohue, Washington, DC, with whom was Assistant Attorney General Peter D. Keisler, for respondent.

OPINION

MILLER, Judge.

This matter is before the court after argument on petitioner's 1/ challenge to the denial of compensation under the National Vaccine Injury Compensation Program, 42 U.S.C.A.

1/ On November 9, 2004, petitioner's counsel filed a Motion To Amend the Caption due to petitioner's untimely death. At defendant's suggestion, petitioner's counsel withdrew this motion at argument on November 15, 2004. Defendant took the position that if remand was ordered, the chief special master should be required to address the imposition of the substitution of petitioner's estate for petitioner on eligibility for damages. See Cohn v. United States, 44 Fed. Cl. 658 (1999). Petitioner's counsel agreed with this procedure. Defendant viewed the issue as one regarding the statutory authority to award compensation, and not as a jurisdictional matter.

§§ 300aa-10 to 34 (West 2003 & Supp. 2004) (the "Vaccine Program"). Petitioner argues that the chief special master's finding that the hepatitis B vaccine did not cause her rheumatoid arthritis ("RA") was arbitrary, constituted an abuse of discretion, and was not in accordance with the law. See 42 U.S.C. § 300aa-12(e)(2)(B). Her three objections are that the use of an analytical construct was an abuse of discretion and not in accordance with the law, that the failure to consider the opinions of petitioner's treating physicians was arbitrary and an abuse of discretion, and that the rejection of relevant Vaccine Adverse Event Reporting System ("VAERS") 2/ reports was arbitrary and an abuse of discretion.

FACTS

Congress enacted the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3756, now codified at 42 U.S.C. §§ 300aa-1 to 34 (the "Vaccine Act"), "in response to worries about the safety of currently licensed childhood vaccines and in response to the economic pressures that were threatening the integrity of childhood immunization programs." Inst. of Medicine, Adverse Events Associated with Childhood Vaccines 2 (Kathleen R. Stratton et al. eds., 1994) (hereinafter "Adverse Events"). The Vaccine Program comprises Part 2 of the Vaccine Act and was established as a no-fault compensation program so that litigation costs associated with vaccine claims did not continue to harm the research, development, and production of vaccines by companies defending against litigation brought by or on behalf of those harmed by vaccines, id. Hence, the Act and Program were created to lessen manufacturer liability so that research and development of vaccines would not be impeded. The Vaccine Program is administered by the Federal Government and is funded through an excise tax on vaccines under the Program. Id.

1. Background

The facts found by Chief Special Master Gary J. Golkiewicz, as confirmed by this court's independent examination of the record, follow. 3/ See 42 U.S.C. § 300aa-12(e)(2)(B)

2/ VAERS is a database that compiles the reporting of any reaction to any immunization. Much of the reporting is voluntary, as only health care providers must report adverse reactions to vaccines listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a). See Adverse Events at 279. The Institute of Medicine of the National Academy of Sciences is an adviser to the Federal Government and was enlisted by the Secretary of Health and Human Services to study the adverse effects of childhood vaccines. Id. at 2.

3/ In a Joint Status Report, the parties requested that the chief special master resolve the factual issues in this matter based solely on the evidence presented in petitioner's medical records, and not on petitioner's affidavit. The chief special master complied with this

(granting Court of Federal Claims jurisdiction to review decisions of special masters and then set aside any findings of fact or conclusions of law found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law).

Nancy Manville ("petitioner") 4/ received hepatitis B vaccinations on June 23, 1992, August 11, 1992, and March 9, 1993. After the second vaccination, petitioner experienced pain, swelling, and redness in her hands and feet, which she temporally linked to the August vaccination. To alleviate this pain, including pain in her ankles, petitioner eventually consulted a sports massage therapist on October 30, 1992. Although the massage treatment temporarily relieved the pain, petitioner's symptoms reoccurred several days after her visit to the therapist. In addition to these symptoms, petitioner experienced fatigue, malaise, and difficulties in working at her job due to pain in her hands and wrists and with walking. Petitioner eventually pursued further medical evaluation on March 22, 1993, when she visited Dr. Edward Cutshaw and complained of severe swelling and pain in her left wrist and chronic pain and swelling in various joints. Dr. Cutshaw prescribed Hiprex for petitioner's burning arthralgia. However, petitioner still continued to have pain and swelling in her hands and wrists, along with difficulty walking. Petitioner returned to Dr. Cutshaw on June 15, 1994, complaining of severe pain in her shoulders, arms, wrists, and hands. Dr. Cutshaw ordered various tests and an RA profile, and during an October 20, 1994 visit, he diagnosed petitioner with RA. Dr. Cutshaw advised petitioner to limit her intake of ibuprofen and

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3/ (Cont'd from page 2.)

request. See Manville v. Sec'y of HHS, No. 99-628V, slip op. at 2-3 (Fed. Cl. Spec. Mstr. July 9, 2004) (unpubl.). In her brief to this court, petitioner notes this evidentiary parameter in a footnote; she argues that the chief special master wrongly determined that petitioner "forfeited her opportunity to show 'rechallenge'" when she requested the affidavit not be considered, Pet.'s Br. filed Aug. 9, 2004, at 2 n.2, although it is notable that the chief special master discussed the possibility of rechallenge in his decision, Manville, No. 99-628V, slip op. at 4. (Rechallenge, defined *infra* note 9, refers to a sequence whereby the second vaccination produces a reaction that first occurred after the initial vaccination.) Moreover, even had the chief special master reviewed the affidavit, he would not have found evidence of a rechallenge based on petitioner's own timeline of occurences. See Pet.'s Aff., Oct. 9, 1999, ¶¶ 2-4. Regardless of the curious relegation of that argument to a footnote, this court has reviewed the entire record below, including petitioner's affidavit, in order to ensure that the facts found in the opinion on review are in accord with all relevant documents in the record.

4/ See *supra* note 1.

placed her on steroids Methotrexate and Prednisone. At an October 27, 1994 examination, Dr. Cutshaw attributed Prednisone to an improvement in petitioner's condition.

Petitioner continued to see Dr. Cutshaw until March 22, 1995. Overall, Dr. Cutshaw indicated petitioner's improvement in these visits. On November 28, 1994, he noted a "marked improvement" in her arthritic pain; on December 5, 1994, he recorded that her arthritic pain was subsiding, although she was still taking five milligrams daily of Prednisone, and increased her dosage of Methotrexate; on December 12, 1994, he reported significant improvement in petitioner's arthritis since the increase of the Methotrexate and her condition as "active and ambulating," with her major problems occurring at night and in the morning, when she was stiff and experienced more pain; on January 4, 1995, Dr. Cutshaw noted that petitioner was experiencing more pain with her RA, possibly due to the weather or a decrease in her Prednisone dosage and that her joints were still swollen and painful; on February 1, 1995, Dr. Cutshaw wrote that petitioner was "definitely in remission" and that the Methotrexate "seems to be doing an excellent job in controlling" the RA symptoms; and on March 22, 1995, he noted that petitioner had been doing well over the past few months, but that her RA had worsened recently after she discontinued use of the Prednisone, which she subsequently resumed. After the March 22, 1995 visit, petitioner did not return to Dr. Cutshaw until January 22, 1998.

In the meantime, petitioner was examined by Dr. John Lisse, a rheumatologist, on April 19, 1995. Although Dr. Lisse noted petitioner's RA; that the pain included her knees, ankles, wrists, elbows, and shoulders; and that petitioner had told him the symptoms developed after her second hepatitis B shot, Dr. Lisse's report is unremarkable in that it does not reflect any correlation between the vaccination and petitioner's RA.

When petitioner returned to Dr. Cutshaw on January 22, 1998, he reported her relative success in the use of Ibuprofen and Tylenol in place of Prednisone, Plaquenil, and Methotrexate. He also noted pain and swelling in petitioner's hands, shoulders, and knees, and the initial signs of deformity in her hands. Finally, Dr. Cutshaw expressed concern for petitioner's risk of osteoporosis. The thrust of Dr. Cutshaw's report, however, only continues the recitation of petitioner's pain and injuries; it does not connect them with her receipt of the hepatitis B vaccination.

Petitioner saw another rheumatologist, Dr. Roger Porter, on November 12, 1998. Dr. Porter's report described petitioner's medical history with regard to RA and treatment options. Although it is true, as petitioner's brief indicates, that petitioner and Dr. Porter "discussed the possible role of the hepatitis B vaccine in her RA[,]" Pet.'s Br. filed Aug. 9, 2004, at 5, petitioner's limited description of this discussion fails to note Dr. Porter's explanation in his notes of November 12, 1998: "I told [petitioner] that rheumatoid affects

0.8% of the population in their lifetime and that means that if 1000 people got hepatitis B and you followed them long enough, up to 8 of them would show up with [RA] without that being an increased risk of the hepatitis B [vaccine] causing the problem." Pet.'s Notice of Filing Docs. filed Jan. 4, 2000, Ex. 5 at 2.

Reports of subsequent medical visits to Drs. Porter and Cutshaw indicated a deterioration in petitioner's condition. Petitioner's brief continues its lawyerly attempt to show a connection between the hepatitis B vaccination and RA by quoting medical reports that merely indicate petitioner's report of her temporal correlation of the vaccine and her symptoms. For example, petitioner's quoting of a medical record from The University of Texas Medical Center that "[p]atient with arthritis following Hep B vaccine after 2nd shot" does not reflect a medical professional's correlation of the vaccine with petitioner's RA, but, rather, is a temporal report of events. In an unfortunate turn, petitioner's health decreased to the point of requiring the services of a home health provider.

2. Procedural history

Petitioner filed a petition on August 4, 1999, for compensation under the Vaccine Program. Initially, twenty-two RA cases were filed. From those, petitioners' attorneys selected five representative cases to be litigated as "test cases," including that of this petitioner. 5/ These cases proceeded before the chief special master in two phases: The first part of the hearing determined the general issue of whether the hepatitis B vaccine can cause RA. The second part of the hearing examined specific evidence on causation in each individual case. Once a finding on the general causation issue was reached, it was applied to the remaining RA cases to determine whether or not the vaccine caused the injury in each specific case.

5/ For the other test litigation petitions, see Ashby v. Sec'y of HHS, 01-221V (filed Apr. 12, 2001); Capizzano v. Sec'y of HHS, 00-759V (filed Dec. 15, 2000); Ryman v. Sec'y of HHS, 99-591V (filed Aug. 4, 1999); and Analla v. Sec'y of HHS, 99-609V (filed Aug. 4, 1999). For entitlement decisions, see Ryman v. Sec'y of HHS, No. 99-591V (Fed. Cl. Spec. Mstr. Sept. 24, 2004) (unpubl.), motion for review filed Oct. 25, 2004; Analla v. Sec'y of HHS, No. 99-609V (Fed. Cl. Spec. Mstr. June 15, 2004) (unpubl.), *sua sponte* remand with instructions (Fed. Cl. Sept. 13, 2004) (unpubl.), order on remand (Fed. Cl. Spec. Mstr. Oct. 22, 2004) (unpubl.); Capizzano v. Sec'y of HHS, No. 00-759V, 2004 WL 1399178 (Fed. Cl. Spec. Mstr. June 8, 2004), motion for review filed July 8, 2004. Judgment was entered dismissing the petition in Ashby on October 20, 2003.

At argument, petitioner's counsel allowed that, of the five test cases, the instant case has "the weakest proof." Nevertheless, petitioner believes that there is "some" evidence, although not strong, that meets the threshold for compensation. In rendering a decision, this court restricts its ruling to the facts of this case and does not attempt to apply criteria for proof of causation or an analytical approach that would affect the two other test cases that remain on review.

3. The opinion on review

On July 9, 2004, the chief special master ruled on petitioner's request for compensation under the Vaccine Program for injuries, specifically RA, that allegedly resulted from the administration of a hepatitis B vaccination. Manville v. Sec'y of HHS, No. 99-628V (Fed. Cl. Spec. Mstr. July 9, 2004) (unpubl.). He determined that petitioner "failed to establish by a preponderance of the evidence that the hepatitis B vaccination caused her RA." Id. slip op. at 1. As RA is not included in the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a) (the "Table"), it is not entitled to the Vaccine Program's presumed causation. 6/ Instead, petitioner must prove, by a preponderance of the evidence, that the hepatitis B vaccine "in-fact" caused her RA. See 42 U.S.C.A. § 300aa-11(c)(1)(C)(ii).

After a two-day hearing regarding the issues of general and specific causation with regard to petitioner, a subsequent hearing and order directing the parties to file particular documents, and the submission of post-hearing briefs discussing the analytical framework proposed by the chief special master for resolving actual causation claims, the parties asked the chief special master to rely solely on petitioner's medical records, and not petitioner's affidavit. 7/ The chief special master ruled accordingly.

In rendering his decision, the chief special master relied on his opinion in the lead case, Capizzano v. Secretary of Health and Human Services, No. 00-759V, 2004 WL 1399178 (Fed. Cl. Spec. Mstr. June 8, 2004), which resolved the issue of whether the hepatitis B vaccine can "in fact" cause RA. 8/ The chief special master had found that the

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6/ Injuries listed on the Table that occur within a prescribed time period create a rebuttable presumption that the vaccine caused the injury. Munn v. Sec'y of HHS, 970 F.2d 863, 865 (Fed. Cir. 1992).

7/ See *supra* note 3.

8/ In essence, this court is reviewing the Capizzano decision, as the ruling in the present case was "based on the concepts and analysis articulated" in Capizzano. Manville, No. 99-628V, slip op. at 4.

petitioner in Capizzano "did not demonstrate by a preponderance of the evidence that the hepatitis B vaccine caused her RA." Id. at *27. Even though the petitioner in Capizzano showed that the vaccine "*can* cause RA," she could not show by a preponderance of the evidence that the vaccine "*did* cause her RA." Manville, No. 99-628V, slip op. at 3. The petitioner failed in this effort because she did not submit an epidemiologic study or evidence of general acceptance; did not establish that she experienced a rechallenge 9/ event, which, as a proxy for proof of causation, recognizes the appearance of symptoms after a dose and their worsening after a second dose; did not possess the genetic markers that were necessary to link RA to the vaccine, according to her expert; and did not show that the mechanism proposed by her expert is linked to the occurrence of her RA. Capizzano, 2004 WL 1399178, at *28.

Drawing on Capizzano, the chief special master framed petitioner's burden in this case as proving that she suffered a rechallenge to the vaccine. Although no dispute was present that petitioner in the instant case had RA, the chief special master found that petitioner did not establish the rechallenge. The timeline presented by the chief special master indicates that petitioner received hepatitis B vaccinations on June 23, 1992, August 11, 1992, and March 9, 1993. Petitioner saw a sports massage therapist on October 30, 1992, and a physician on March 22, 1993. In the latter visit, petitioner complained of arthralgia, or joint pain; pain in her right shoulder; and pain and swelling in both hands. The chief special master deemed petitioner's visit to the massage therapist of little probative value in linking her RA symptoms to the first vaccination because petitioner failed to provide records of evaluation, an affidavit of her therapist, or the therapist himself to testify at the hearing. That petitioner's symptoms required a sports massage two months after the second vaccine was not sufficient for proof of a reaction to that vaccine.

The chief special master gave attention to petitioner's medical records, which did not show any reaction after the first or second hepatitis B vaccinations and thus, in his view, thereby eliminated the possibility of a rechallenge event. Of critical note was that the only symptoms reported after the immunizations were made note of at the March 22, 1993 physician visit, which occurred subsequent to the third and final vaccination. Due to an overall lack of evidence that "a recurrence or exacerbation of symptoms following her immunizations" was experienced "and in the absence of expert testimonial support," the chief

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9/ "A rechallenge case is one where adverse symptoms are noted after a dose of the vaccine, an additional dose of the vaccine is given, and the symptoms reoccur and/or worsen." Manville, No. 99-628V, slip op. at 3 n.5; see also Adverse Events at 24 ("*Rechallenge:* Was the vaccine readministered? If so, did the adverse event recur?").

special master found that no rechallenge had been established. Manville, No. 98-628V, slip op. at 4.

DISCUSSION

1. Standard of review

The Court of Federal Claims is authorized to "set aside any findings of fact or conclusion[s] of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law[.]" 42 U.S.C. § 300aa-12(e)(2)(B). As the Federal Circuit explained:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by [the Federal Circuit], as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard.

Munn v. Sec'y of HHS, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

2. Operation of the Vaccine Act

Contending that the chief special master's approach to determining liability undermines a compensation program that Congress intended to be applied liberally, petitioner draws on the statutory framework and requirements of the Vaccine Program. To obtain compensation through the Vaccine Program, a petitioner must initially establish causation, which can be accomplished in one of two ways: either by showing that the condition emanates from an injury listed in the Table or that the vaccine caused the injury. Munn, 970 F.2d at 865. Regardless of the avenue used to establish causation, once causation has been shown, respondent has the opportunity to show by a preponderance of the evidence that "a factor unrelated to the vaccine caused the . . . injury." Knudsen v. Sec'y of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994) (citing 42 U.S.C. § 300aa-13(a)(1)(B)).

A petitioner may allege that the injury suffered is one that is listed on the Table. Munn, 970 F.2d at 865. 42 U.S.C.A. § 300aa-11(c)(1)(C)(i) requires that a petition contain materials, including an affidavit, that show that a petitioner "sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the" Table in association with a vaccine on the Table. In this manner a petitioner establishes causation-in-law by showing, by a preponderance of the evidence, that the petitioner received a listed vaccine and

sustained an injury after receiving the vaccine within the time frame required on the Table. After a petitioner demonstrates causation-in-law, the respondent has the opportunity to show that the petitioner's injury was caused by a factor unrelated to the vaccine. Grant v. Sec'y of HHS, 956 F.2d 1144, 1146-47 (Fed. Cir. 1992).

Because RA is not a so-called Table injury, petitioner qualified for the alternative methodology to establish liability. A petitioner who does not put forth an injury listed on the Table, or has a listed injury but sustained that injury outside of the stipulated Table time frames, may prove causation-in-fact. 10/ See 42 U.S.C.A. § 300aa-11(c)(1)(C)(ii). However, "'the petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine.'" Grant, 956 F.2d at 1147-48 (quoting H.R. Rep. No. 908, pt. 1, at 15 (1986)). While the Vaccine Program relaxes its proof of causation for Table injuries, in that a temporal connection between certain injuries and vaccines is deemed sufficient for causation, causation-in-fact for non-Table injuries equates to the elements for a traditional tort, and a mere "[t]emporal association is not sufficient . . . to establish causation in fact." Id. at 1148. The Federal Circuit's language on this matter is instructive:

> When a petitioner relies upon proof of causation in fact rather than proof of a Table Injury, a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury. To prove causation in fact, petitioners must show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Id. (citations omitted).

The Federal Circuit expanded on this requirement for a *prima facie* showing of entitlement for a non-Table injury, stating that the causation-in-fact method "would require the petitioner to prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface

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10/ Defendant reminds that the Federal Circuit has stated that the causation-in-fact method for off-Table injuries requires a petitioner to do the "heavy lifting" for proof. Hodges v. Sec'y of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993). Conversely, the statute itself does the "heavy lifting" for a Table injury because of the presumption created for such injuries. See id. As this description of the burden of proof has not been reiterated, the court follows the less stringent formulation in the decisions discussed in the body of this opinion.

v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Shyface further clarified that the "substantial factor" alluded to in Grant consists of a causal connection between a vaccination and the injury as shown by a medical theory. Id. at 1352-53. 11/

The Office of the Special Master recently began to explicate the standard of proof required under either causation-in-fact or causation-in-law. See Althen v. Sec'y of HHS, 58 Fed. Cl. 270, 278 (2003); Capizzano, 2004 WL 1399178; Stevens v. Sec'y of HHS, No. 99-594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001).

Pertinent to petitioner's objections in this case is the chief special master's discussion in Stevens about the issue of causation in vaccine cases and his assertion that a petitioner's burden to demonstrate by a preponderance of the evidence that the vaccine caused the injury alleged has not been defined clearly in terms of the type and amount of evidence required. Stevens, 2001 WL 387418, at *23. To alleviate the perceived confusion, the chief special master enunciated a five-prong test that, if satisfied *in toto*, would meet the required preponderance of the evidence standard and entitle petitioners to compensation under the Vaccine Program. He identified the prongs as: (1) "[p]roof of medical plausibility"; (2) "[p]roof of confirmation of medical plausibility from the medical community and literature"; (3)"[p]roof of an injury recognized by the medical plausibility evidence and literature"; (4) "[p]roof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury"; and (5) "[p]roof of the elimination of other causes." Id. at *23-*26. The chief special master has applied, in one form or another, the Stevens test in subsequent decisions, see, e.g., Capizzano, 2004 WL 1399178; Althen v. Sec'y of HHS, 2003 WL 21439669 (Fed. Cl. Spec. Mstr. June 3, 2003), rev'd and vacated by Althen, 58 Fed. Cl. 270, but has acknowledged "that the five criteria are not binding on other special masters in the Vaccine Program," although he has advised parties that they would be controlling in cases before him. Capizzano, 2004 WL 1399178, at *4. In essence, this court's task is to determine the propriety of the Stevens factors as a method for evaluating compensatory rights under the Vaccine Program.

11/ Petitioner cites Golub v. Secretary of Health and Human Services, 243 F.3d 561 (table), 2000 WL 1471643 (Fed. Cir. Oct. 3, 2000) (unpubl.), as setting forth a standard for sufficient proof under the Vaccine Program. Not only are unpublished opinions non-precedential and non-citable, see In Re Violation of Rule 28(c), Misc. No. 774 (Fed. Cir. Nov. 5, 2004), but the unpublished case in question neither alters Grant or Shyface, nor provides further insight or clarification into the standard of proof under the Vaccine Program.

The Vaccine Act itself addresses the required standard of proof. 42 U.S.C. § 300aa-13(a) states the preponderance of evidence standard in a straightforward manner:

> (1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole–
> (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and
> (B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

A preponderance of the evidence, "the most common standard in the civil law, simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before [the trier] may find in favor of the party who has the burden to persuade [the trier] of the fact's existence." Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal., 508 U.S. 602, 622 (1993) (citations omitted). The Federal Circuit has transported this requirement to the Vaccine Program arena, as follows: "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." Munn, 970 F.2d at 865. The standard, however, is "simple preponderance of evidence; not scientific certainty." Bunting v. Sec'y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991). A petitioner is not tasked with defending against every possible ground of causation suggested by respondent, id., and, as such, to "require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen, 35 F.3d at 549.

The present case is part of an ongoing, well-intentioned attempt by the chief special master to create a useable "evidentiary standard" to assist in determining whether a petitioner seeking compensation under the Vaccine Program has met the preponderance of the evidence standard. 12/ He created this construct due, in his opinion, to the inconsistency in case law and the unknown type and amount of evidence that will suffice to meet the preponderance

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12/ The Federal Circuit in Knudsen defined the role of the special masters in vaccine cases: Their role is not to diagnose vaccine-related injuries but, instead, to consider the totality of the record and determine "whether it has been shown by a preponderance of the evidence that a vaccine caused the . . . injury or that the . . . injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused" the injury. Knudsen, 35 F.3d at 549.

standard. See Stevens, 2001 WL 387418, at *23. The effort has not been embraced as a prescribed analysis for Vaccine Program cases. See Althen, 58 Fed. Cl. at 281-84. This court concludes that the Vaccine Act and binding precedent provide sufficient guidelines.

While the chief special master did acknowledge that the five-prong analysis was flexible and pragmatic, he also stated that

> [i]n 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 parties' proof, the special masters may establish additional or different criteria. In addition, the criteria are not limiting; petitioners may present evidence outside of the five prongs.

Stevens, 2001 WL 387418, at *37 (footnote omitted). Overall, the chief special master describes the five-prong test as a framework that is a work-in-progress toward "defining acceptable proofs." Id. His focus is to set an outline for Vaccine Program cases, but the fact is that such cases must be resolved on a case-by-case basis, and, while the Stevens prongs may be considerations in an appropriate case, they should not, and need not, redefine the preponderance of evidence standard. The looseness – and thereby its inappropriate application – of the Stevens framework aside, such a construct is unnecessary when an established standard of proof governed by established caselaw is available.

Moreover, petitioners in the test cases reject the Stevens criteria. That this approach has not captured the Government's endorsement, either, relegates it to the status of an orphan. Perhaps such a "framework" is both superfluous and unnecessary because the Stevens construct attempts to redefine a standard that needs no new definition.

Of particular relevance to this discussion is Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). In Daubert the Supreme Court determined the standard for the admissibility of scientific expert testimony in a federal trial. Initially, Daubert posed the issue broadly:

> [T]he trial judge must determine at the outset, pursuant to [Fed. R. Evid.] Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Id. at 592-93 (footnote omitted). In essence, the Supreme Court ordained federal trial court judges with a "gatekeeping" function so as to "exclude expert testimony that is irrelevant or does not result from the application of reliable methodologies or theories to the facts of the case." Micro Chem., Inc. v. Lextron, Inc., 317 F.3d 1387, 1391 (Fed. Cir. 2003) (citing Daubert, 509 U.S. at 589-92); see also Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc., 249 F.3d 1341, 1349 (Fed. Cir. 2001). Special masters are guided by the Daubert standards, as well. See Terran v. Sec'y of HHS, 195 F.3d 1302, 1316 (Fed. Cir. 1999).

In prescribing this gatekeeping function, Daubert "set forth a non-exclusive list of factors that district courts may use in evaluating expert testimony" under Rule 702 of the Federal Rules of Evidence. Micro Chem., 317 F.3d at 1391. These factors are (1) whether the theory or technique offered for scientific knowledge can be or has been tested; (2) whether the theory or technique has undergone peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) the degree of acceptance, or the "general acceptance," of a theory or technique within the scientific community. Daubert, 509 U.S. at 593-94. The Court emphasized that the "inquiry envisioned by Rule 702 is . . . a flexible one. Its overarching subject is the scientific validity – and thus the evidentiary relevance and reliability – of the principles that underlie a proposed submission." Daubert, 509 U.S. at 594-95 (footnote omitted).

Subsequently, in Kuhmo Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 149 (1999), the Supreme Court explained that "the principles of Daubert apply not only to scientific testimony, but to all expert testimony." Micro Chem., 317 F.3d at 1391. Kuhmo again highlighted the flexible nature of Daubert's factors when ruling a trial court may consider several factors other than those listed in Daubert. Kuhmo Tire, 526 U.S. at 149-50. The Court stated that

> we can neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in Daubert, nor can we now do so for subsets of cases categorized by category of expert or by kind of evidence. Too much depends upon the particular circumstances of the particular case at issue.

Id. at 150. Indeed, Daubert itself established that its list of factors was a "helpful, not definitive[,]" list and that all of those factors might not apply in every instance where the admissibility of scientific testimony is at issue. Id. at 151.

Based on Daubert and Kuhmo, Rule 702 was amended in 2000, Micro Chem., 317 F.3d at 1391-92, to allow an expert with "scientific, technical, or other specialized knowledge" to give opinion testimony "if (1) the testimony is based upon sufficient facts or

data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case[,]" Fed. R. Evid. 702.

Daubert's and Kuhmo's applicability to the case at hand is in the structure that these leading cases provide to evaluating evidence and their impact on a petitioner's ability to meet the preponderance of evidence standard in Vaccine Program cases. Petitioners attempting to prove causation-in-fact for an off-Table injury must introduce evidence that demonstrates by a preponderance of evidence that the vaccine in question caused petitioner's particular injury. An examination of Daubert confirms that many of the chief special master's concerns were addressed by the Supreme Court prior to Stevens; in fact, Prongs 1-3 relate to the valuation of scientific evidence and are Daubert material. Hence, several of the considerations in the Stevens prongs already are applied as tools to evaluate the admissibility of evidence before it becomes necessary to analyze whether petitioner's scientific evidence constitutes sufficient proof. Insofar as this case is concerned, the chief special master created a construct that perhaps is more complicated than necessary: Daubert adequately serves the gatekeeping function for analysis of the admissibility of evidence; once evidence has passed that test, the trier of fact's process, simply, is to determine the probativeness of that evidence. Not only does Daubert serve its evidentiary purpose, but through its non-exclusive list of factors, it accounts for many of the Stevens considerations without elevating particular facts to a bright-line requirement, as the five-prong test does.

3. Whether use of the Stevens factors can be sustained

Petitioner makes three objections to the decision on review. First, petitioner challenges the use of the Stevens prongs as an abuse of discretion and not in accordance with law. Petitioner contends that the denial of compensation was based on the chief special master's finding that petitioner failed to satisfy Prong II of Stevens, which requires proof of confirmation of medical plausibility from the medical community and literature.

The chief special master's finding that petitioner failed to satisfy the second prong of the Stevens test was derived from his findings in Capizzano, 2004 WL 1399178, at *28; see Manville, No. 99-628V, slip op. at 4. To proceed to the second prong, the chief special master found that the first prong of medical plausibility was satisfied. In doing so, he thoroughly described the testimony with regard to whether the hepatitis B vaccine can cause RA. Petitioners' expert, Dr. David Bell, in both the instant case and in Capizzano, proposed a "medically/scientifically-based mechanism explaining how the hepatitis B vaccine can cause RA in potentially susceptible individuals." Capizzano, 2004 WL 1399178, at *14. Dr. Bell relied on a scientific paper that provided evidence of three rechallenge cases where symptoms worsened after a further vaccine injection. See J.F. Maillefert et al., "Rheumatic

Disorders Developed After Hepatitis B Vaccination," Rheumatology, 1999:38:978-983 at 979 (the "Maillefert study") (cited in Capizzano, 2004 WL 1399178, at *14).

Drs. Burton Zweiman and Lawrence Moulton, respondent's experts in the two cases, corroborated this finding by testifying that evidence of a rechallenge can be indicative of causality. See Capizzano, 2004 WL 1399178, at *15. The chief special master also found persuasive findings from the Institute of Medicine about rechallenge and biologic plausibility, which stated that a rechallenge is probative of a causal relationship. In combination, he found that the material presented supported a "logical sequence of events based on scientific and medical evidence that hepatitis B vaccine *can* cause RA." Id. at *16.

What the chief special master did not find persuasive in Capizzano, however, and what constitutes petitioner's first objection in this case, was the presentation, or lack thereof, of an epidemiologic study and evidence of a general acceptance in the medical community of the relationship between the hepatitis B vaccine and RA. According to the chief special master, this results in failing to satisfy the second prong of the Stevens construct and thereby yields a failure to meet the preponderance of the evidence standard.

Petitioner's disagreement with the application of the Stevens prongs in this instance is warranted. The chief special master's initial discussion question of "*Can* the Hepatitis B Vaccine Cause RA?" elicits an answer that falls into Prong I's analysis. After finding Prong I was satisfied, however, the chief special master used an amalgamation of considerations under the topic of "*Did* the Hepatitis B Vaccine cause RA in this individual?" Remnants of Prong II are included in that discussion but are mingled with other elements of evidence presented by petitioner. The chief special master ultimately found that petitioner did not present "an epidemiologic study, nor has she presented evidence of general acceptance – i.e., that the medical community is currently 'seeing' or 'talking about' a potential relationship between the vaccine and the injury" and that she did not demonstrate a rechallenge or the necessary genetic markers to link the development of the disease to the vaccine. Capizzano, 2004 WL 1399178, at *28.

The chief special master's use of evidence and the Stevens prongs presents three concerns: First, the Stevens factors were not applied in Capizzano – and, in fact, never have to be applied – in specific fashion so as to define them as a construct. The chief special master has defined the Stevens framework as "flexible." Stevens, 2001 WL 387418, at *37. Such flexibility would be appropriate if applied in the manner of Daubert's evidentiary considerations – namely, that one prong not hold petitioner's compensation claim in the balance. Instead, the "flexible" Stevens framework requires petitioners to meet all five prongs, even though evidence outside of the prongs may be introduced, see id., in a strict fashion, thereby creating confusion as to what might actually satisfy the construct.

Second, "general acceptance" in the medical community, while important, is not the sole criterion that calls for denial of a petitioner's claim. Indeed, this factor overlaps Daubert: Not only is general acceptance already considered via Daubert when ruling on the admissibility of evidence, but general acceptance itself, as noted in Daubert, is not the final word on the admissibility of evidence. Similarly, once evidence has been admitted, the "general acceptance" of a theory no longer is a dispositive concern.

Finally, the chief special master's variety of considerations demonstrates a common premise: Vaccine Program determinations require case-by-case analysis. Once evidence is admitted via the Daubert standards – and it can be any evidence that satisfies Daubert's considerations that petitioner determines necessary to meet her burden – the only question remaining is whether petitioner has demonstrated by a preponderance of the evidence that the vaccine caused her injury. While the Stevens factors may be valid considerations from case-to-case, they cannot stand for a strict formula in which every factor must be met in order to demonstrate a standard of evidence that already has been defined.

4. Whether the chief special master failed to consider medical evidence

Petitioner's second objection is that the chief special master's failure to consider the opinions of petitioner's treating physicians was arbitrary and an abuse of his discretion. Petitioner argues that the chief special master "trivialized the significance of the opinions of treating physicians as valuable evidence in Vaccine Program cases." Pet.'s Br. filed Aug. 9, 2004, at 29. Petitioner contends that the lack of early "[p]ersuasive medical evidence linking this vaccine with RA" in temporal conjunction with when petitioner received her vaccinations was a reason for petitioner's physicians to not link her RA to the hepatitis B vaccine. Id. at 30-31. The early nature of petitioner's receipt of the hepatitis B vaccine, along with the general link between RA and the vaccine, are petitioner's strongest arguments. Problematic to this cause, however, is the lack of temporal significance between petitioner's vaccinations and her RA. Nevertheless, petitioner still attempts to demonstrate that her physicians provided significant evidence in linking the hepatitis B vaccine to her RA.

Petitioner notes that her symptoms began after she received her second hepatitis B vaccine on August 11, 1992, and that those symptoms "worsened significantly" after she received her third shot on March 9, 2003. Id. at 31. Although petitioner argues that her progression of symptoms is indicative of RA, these above facts bring two points to light: First, petitioner fails to demonstrate a rechallenge, which would be acceptable proof for causation-in-fact. Second, petitioner's progressive argument is weak, not only because she cites her affidavit, which the parties had asked the chief special master to omit from consideration, but also because the notion that the progression of a disease links it to a cause lacks merit.

Petitioner highlights the medical reports of Drs. Lisse and Porter and attempts to draw a causal conclusion from the doctors' notes in relation to petitioner's RA and the hepatitis B vaccine. Id. at 31-32. Particularly, petitioner claims that Dr. Lisse's notes of April 19, 1995, "recorded as significant Nancy's statement that her symptoms began after her second hepatitis B vaccine," id., when, in fact, Dr. Lisse's notes merely say that "[patient] states [symptoms] developed [after] her 2nd hepatitis injection[,]" Pet.'s Notice of Filing Docs. filed Jan. 4, 2000, Ex. 3 at 2. No causal connection is made; Dr. Lisse's notes simply reflect what petitioner told him. The same is true with respect to Dr. Porter's notes of November 12, 1998. Whereas petitioner attempts to frame Dr. Porter's notes in a causal manner, the actual nature of Dr. Porter's narrative that "[petitioner] thinks [the RA] came on quickly on the heels of a hepatitis B vaccination program five years ago[,]" id. Ex. 5 at 1, is, once again, revealing the doctor's notes as a mere recitation of petitioner's complaints and statements at the time of visit. Finally, the same holds true for the medical report from the University of Texas Medical Hospital on May 31, 2001, which noted a "patient with arthritis following Hep B vaccine." None of the medical evidence cited by petitioner demonstrates a causal connection through a temporal relationship between the hepatitis B vaccine and petitioner's RA; all serve merely as statements or recitations of a timeline of events.

In any event, the chief special master discussed petitioner's expert witness, Dr. Bell, a rheumatologist, at length, focusing on Dr. Bell's explanation of and support for the hypothesis that the hepatitis B vaccine can cause RA. Capizzano, 2004 WL 1399178, at *13-*28. Although the chief special master's discussion of petitioner's medical records was brief, see Manville, No. 99-628V, slip op. at 3-4; Capizzano, 2004 WL 1399178, at *25, he examined the record in sufficient detail in rendering his decision. Indeed, petitioner's own quotation of language from the governing Capizzano case concedes as much:

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

Capizzano, 2004 WL 1399178, at *25 n. 42 (emphasis added).

This court's own review of petitioner's medical records supports the conclusion that those records do not, by themselves or in connection with other evidence, help petitioner prove by a preponderance of the evidence that the hepatitis B vaccine caused her RA. The demonstration of a temporal relationship between the hepatitis B vaccine and petitioner's RA was inadequate, and it was not shown that the vaccine was a substantial factor in petitioner's RA. 13/ Although petitioner's thorough discussion of the Vaccine Program during argument was appreciated, the argument that "the truth" is not relevant in Vaccine Program cases misses the mark. While the Program's intent may be to provide liberal compensation to victims, the fact remains that legal cause must be shown by a preponderance of the evidence through the standards set by the Federal Circuit in Grant and Shyface in order to receive compensation for an off-Table injury.

Fact findings by a special master are reviewed under an arbitrary and capricious standard, affording the chief special master wide latitude in addressing the facts and evidence presented. See Whitecotton v. Sec'y of HHS, 81 F.3d 1099, 1108 (Fed. Cir. 1996) ("Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence."); Burns v. Sec'y of HHS, 3 F.3d 415, 417 (Fed. Cir. 1993) ("A special master . . . has wide discretion in conducting the proceedings in a case."); Munn, 970 F.2d at 871 ("It is, after all, the special masters to whom Congress has accorded the status of expert, entitling them to the special statutory deference in fact-finding normally reserved for specialized agencies."). With this wide berth charted for his analysis, the chief special master did not act arbitrarily and capriciously when reviewing the facts of petitioner's case. The quoted language is illustrative of the medical evidence available to the chief special master, and his acknowledgment of it and discussion of its probative value are sufficient to pass muster under the arbitrary and capricious standard.

Petitioner's third and final objection is that the chief special master's failure to consider the relevance of VAERS reports was arbitrary and an abuse of discretion. Petitioner admitted the lessened statistical significance of VAERS data in comparison with an epidemiological study, but still argued their value. Pet.'s Br. filed Aug. 9, 2004, at 33. The use of the VAERS data was relied on by petitioner to show that the medical community is seeing and reporting a causal connection between the hepatitis B vaccine and RA. This consideration of the VAERS material is interwoven with the second prong of the Stevens construct, which requires medical plausibility from the medical community and literature.

13/ As the analysis of petitioner's causation-in-fact argument is doomed by the lack of a temporal relationship between the vaccine and petitioner's injuries, any claim of a rechallenge to prove causation must also fail.

In this regard the value of the Stevens factors already has been addressed; hence, to the extent that the use of VAERS data is used in determining whether a petitioner met Prong II of Stevens, it is moot. The crux of the matter is whether evidence itself is admissible under Daubert, whose factors include considerations restated in the Stevens factors, and then, once that evidence is admitted, whether petitioner in an off-Table vaccine case has shown causation-in-fact by a preponderance of the evidence. Nevertheless, for thoroughness, the court addresses petitioner's objection to the chief special master's consideration of the VAERS data.

The chief special master dismissed petitioner's use of the VAERS reports, stating that he "finds problematic petitioner's reliance on the 153 VAERS reports as indicating that the medical community is seeing and reporting a causal relationship." Capizzano, 2004 WL 1399178, at *24. He initially noted that a VAERS report can be filed by anyone, thereby bringing into question the quantity and quality of the information gathered and creating the possibility of bias "toward pre-existing or prevailing concepts of adverse events." Id. The chief special master relied heavily on Dr. Moulton, "without a doubt the most qualified expert in this case on statistical matters," to dismiss any significant value of VAERS because of the manner of data collection, the "lack of confirmation of the reported information and the lack of any systematic analysis." Id. The special masters were tasked with handling vaccine compensation cases, thereby rendering them vaunted experts in the methods, data, and theories of vaccine injuries. See Whitecotton, 81 F.3d at 1108; Burns, 3 F.3d at 417; Munn, 970 F.2d at 871. This court, therefore, is satisfied that the chief special master properly reviewed the VAERS reports. His "failure" to delve further into the data does not constitute arbitrary action or an abuse of discretion.

CONCLUSION

After a review of petitioner's medical records, the hearing testimony, the decision of the chief special master, and oral argument, this court concludes that the chief special master did not render any findings that were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. Although the chief special master's Stevens construct is not an appropriate substitute for the preponderance of the evidence standard, the fact remains that petitioner did not meet her burden under the Vaccine Act.

Accordingly, based on the foregoing, the decision of the chief special master is sustained. The Clerk of the Court shall enter judgment for respondent in accordance with the decision of the special master.

IT IS SO ORDERED.

No costs on review.

s/ Christine O. C. Miller

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Christine Odell Cook Miller
Judge