In The United States Court of Federal Claims

NOT FOR PUBLICATION

No: 95-706 V

(Filed Under Seal: April 27, 2005)

(Reissued: May 12, 2005)[1]

DILEMA MORENO,

***Petitioner*,**

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

***Respondent*.**

Ronald C. Homer, Conway, Homer & Chin-Caplan, Boston, MA, for petitioner.

Vincent J. Matanoski, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

Block, *Judge*.

This case is before the court under the National Childhood Vaccine Injury Act[2] for review of the Special Master's decision to award compensation to the petitioner, Dilema Moreno.[3] Ms.

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[1]This opinion originally was issued under seal on April 27, 2005. The court afforded the parties an opportunity to propose redactions in the opinion prior to it being filed unsealed, but no such redactions were proposed. Accordingly, the opinion is herein reissued unsealed.

[2]Public Health Services Act, § 2111(b)(1)(A) (codified as amended at 42 U.S.C. §§ 300aa -1 to -34).

[3]The Special Master issued a "Ruling Concerning 'Entitlement' Issue" in which the petitioner's entitlement to compensation was established. *See Moreno v. Sec'y of Health & Human Servs.*, No.

Moreno claimed that she suffers chronic arthropathy caused by the rubella vaccine. The entitlement decision was based, in part, on an earlier decision by the Special Master in a related case that concluded the rubella vaccine *can* cause chronic arthropathy. *See Snyder v. Sec'y of Health and Human Servs.*, No. 94-58V, 2002 WL 31965742 (Fed. Cl. Spec. Mstr. Dec. 13, 2002) (the "2002 Decision"). Respondent, the Secretary of the Department of Health and Human Services, now challenges the Special Master's entitlement decision in this case on the grounds that certain empirical evidence that the Special Master relied upon was flawed and that the Special Master failed to address those flaws when he concluded petitioner was entitled to compensation. Furthermore, respondent argues that this empirical evidence was not relevant to petitioner's case and that the Special master erred in relying upon it. For the reasons set out below, the court sustains the Special Master's entitlement decision awarding compensation.

I. The Vaccine Act and Proof of Causation

The Vaccine Act provides a program in which individuals that have been injured by certain vaccines may be compensated for their injury. The workhorse of the Program is, of course, the "Vaccine Injury Table." *See* 42 U.S.C. § 300aa-14(a). If the petitioner's injury is "on-Table" then the Act establishes a presumption that the vaccine caused the injury if the petitioner demonstrates that the onset or "significant aggravation" of predicate injuries occurred within a statutorily prescribed time period. *See* § 300aa-11(c)(1)(C)(I); *Bunting v. Sec'y of the Dep't of Health and Human Servs.*, 931 F.2d 867, 872 (Fed. Cir. 1991). If the petitioner establishes the presence of an on-Table injury, then the Act authorizes compensation so long as the presumption is not rebutted by "a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B); *see also Grant v. Sec'y of the Dep't of Health and Human Servs.*, 956 F.2d 1144, 1146-47 (Fed. Cir. 1992).

Often, however, a petitioner will be unable to demonstrate the presence of an on-Table injury or the predicate symptoms within the prescribed time period. In those instances, the Act authorizes a petitioner to seek compensation provided the petitioner can prove causation-in-fact. § 300aa-11(c)(1)(C)(ii); *Grant*, 956 F.2d at 1147. The presumption of causation does not attach to so-called "off-Table" injuries. Instead, to satisfy a causation-in-fact inquiry the petitioner must demonstrate by a preponderance of the evidence that the vaccination in question, more likely than not, was in fact the cause of the alleged injury. *Grant*, 956 F.2d at 1147-48. To marshal this inquiry, the courts often rely on a two-prong analysis that first determines whether it is biologically plausible for one of the vaccines to cause the alleged injuries. "First, a petitioner must provide a reputable medical theory causally connecting the vaccination and the injury." *See Pafford v. Sec'y of the Dep't of Health and Human Servs.*, 64 Fed. Cl. 19, 24 (2005). If this plausibility, or "general causation" inquiry, is satisfied then the petitioner must next "prove that the vaccine actually caused the alleged symptoms in her particular case." *Id.*

95-706V (Fed. Cl. Spec. Mstr. Dec. 16, 2003). That entitlement decision was subsequently followed by a final decision on damages. *See Moreno v. Sec'y of Health & Human Servs.*, No. 95-706V (Fed. Cl. Spec. Mstr. Oct. 28, 2004). To the extent that this court cites to the Special Master's decision below, it will refer only to the entitlement decision, not the damages decision.

II. Factual and Procedural Background

A. Facts

Dilema Moreno received a measles/mumps/rubella ("MMR") vaccination on October 27, 1992 when she was 44 years old.[4] Two weeks later, she visited her physician, Dr. John Schwartz, complaining of swollen glands, a facial rash, and joint pain ("arthralgia") in her elbows, knees, and ankles. These symptoms had persisted for a week prior to the visitation. Dr. Schwartz concluded these symptoms were an adverse reaction to the MMR vaccination. He did not recognize any objective visible signs of arthritis (*i.e.*, noticeable swelling or inflamation of the joints) at that time. Since then, Ms. Moreno has experienced chronic pain in her joints and continued to see Dr. Schwartz and other physicians. On March 26, 1996, Dr. Schwartz noted that Ms. Moreno had recently developed actual, observable swelling in two joints.

B. Procedural Background

Petitioner has not claimed that her injury is "on-Table" but instead presented a causation-in-fact argument. The petition was filed October 26, 1995 and subsequently transferred to the docket of Special Master Hastings. At the time, Special Master Hastings was conducting an omnibus proceeding regarding the "general causation issue" of whether it is plausible for the rubella vaccine to cause chronic arthropathy. It appears that there were a number of cases at the time raising similar causation issues, and many were consolidated for an inquiry into the general "plausibility" issue to gather and evaluate evidence that might be later applied in individual cases. Petitioner's own case was then stayed, pending the outcome of the general causation proceeding.

1. The Issue Presented

During the early 1990s, several petitioners claimed that the rubella vaccine had caused chronic arthropathy that should be compensated under the Vaccine Program. *Moreno*, No. 95-706V at 3 (Dec. 16, 2003). The term "arthropathy" broadly includes both swelling, stiffness, and pain in the joints. It encompasses both "arthritis" and "arthralgia." Arthritis involves *objective* findings of swelling, redness, heat, and/or limitation of motion in the joints, and its effects are both noticeable and measurable by a physician. *Snyder*, No. 94-58V, 2002 WL 31965742 at * 3. On the other hand, arthralgia refers to a patient's reported joint pain that is not accompanied by an objective finding of arthritis; arthralgia involves subjective pain. *Id.* A petitioner suffers from a "chronic" condition if the symptoms are either steadily present, without any period of time when the symptoms are absent, or the symptoms "come and go" intermittently. *Ahern v. Sec'y of the Dep't of Health and Human Servs.*, No. 90-1435V, 1993 WL 179430 at *3 (Fed. Cl. Spec. Mstr. Jan. 11, 1993) (the "1993 Decision"). A petitioner's chronic symptoms are distinguished from his or her "acute" symptoms, which usually begin one to six weeks after the vaccination and last from one week to several months. *Id.*

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[4]The facts of this case are reported in the Special Master's entitlement decision, and are recited in part here for completeness. *See Moreno*, No. 95-706V at 7 (Dec. 16, 2003).

In the early 1990s, neither arthritis nor arthralgia were established on-Table injuries. Accordingly, each of the petitioners had the burden of demonstrating that it was "more probable than not" that his or her condition was "caused-in-fact" by the rubella vaccination. *Id.* at *2. These cases were all assigned to Special Master Hastings, who noted that "each case has an issue in common with the other cases, *i.e.*, whether it can be said that it is 'more probable than not' that a rubella vaccination can cause chronic or persistent [arthropathy]." *Id.* The Special Master therefore conducted an inquiry into this "general" question for the benefit of each of the related cases "with the hope that knowledge and conclusions concerning the general causation issue . . . could be applied to each individual case." *Id.*

2. The Special Master's 1993 Decision

In 1992, when the Special Master conducted the inquiry that preceded the 1993 Decision, there was "only a very, very limited amount of data directly applicable" because "this issue really ha[d] not been scientifically studied." *Id.* at *4. While there seemed to be a well-accepted causal relationship between the rubella vaccine and the onset of *acute* arthropathy, there was no established opinion regarding the relationship between rubella and *chronic* arthropathy. *Id.* at *3-5. The Special Master evaluated a range of evidence, including several isolated cases of chronic arthritis following the rubella vaccination, a study that discussed several cases of chronic joint pain, two medical studies that were of little relevance,[5] certain evidence of pathological markers,[6] and expert testimony.

The experts generally agreed that the evidence tended to indicate that it was "more probable than not" that the rubella vaccine could in fact cause chronic *arthritis*. *Id.* at *5. They also agreed that, for a petitioner to demonstrate that the vaccine was the cause-in-fact of the petitioner's condition, a number of factors would have to be established in each case. Among these, a petitioner would have to be an adult, demonstrate that he or she had been symptom free for at least three years prior to the vaccination, and prove an onset of symptoms during the "acute" period after vaccination. *Id*. Furthermore, the petitioner must demonstrate the absence of some other plausible cause of the arthritic symptoms. *Id.*

The issue on which the experts disagreed involved the causal relationship between rubella and symptoms of chronic arthralgia. The respondent's experts argued that a causal relationship could only be assumed if objective signs of arthritis were present and confirmed by a physician. They argued that the chronic condition could not be deemed vaccine-related if *only* subjective symptoms

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[5]One of these studies, which did not reveal a causal relationship between chronic arthralgia and rubella vaccination involved children, who in general are less inclined to experience arthralgic reactions. *Id.* at 4. Another only tracked vaccine recipients for less than six weeks, so was of little value in examining *chronic* reactions.

[6]"In a number of instances, the rubella virus has been found, months or years after vaccination, in the blood and/or synovial fluid (joint fluid) of women with chronic arthritis following rubella vaccination." *Id.* at 5. The Special Master did not take this evidence as proof of a causal connection, but noted that "it adds to the *plausibility* of the hypothesis that the virus can remain active in the human body and cause persistent joint symptoms indefinitely." *Id.*

of arthralgia (and not arthritis) were present at either the acute or chronic stage. The petitioners' experts, however, "vigorously disputed" that assertion. *Id.* at *6.

In evaluating this "difference of opinion" the Special Master ultimately concluded that "the argument of the petitioners' witnesses is more persuasive." *Id.* at *8. He noted:

> [T]he available data supports causation for the arthralgia cases to virtually the same degree as it does for the cases where evidence of actual arthritis might be seen. Note for example, that in many of the relevant published studies and case reports, *no* distinction was made between arthritis and arthralgia, but it was simply noted that the subjects had "joint manifestations" or "joint symptoms" or "arthropathy."

Id. The Special Master conceded that "the evidence is not overwhelming for either proposition, it seems as strong for one as for the other." However, he thought it seemed illogical to restrict findings of causation only to those cases involving arthritis where such a restriction "simply does not conform to the available evidence." *Id.* at *9. Accordingly, the Special Master concluded that a causal relationship between the rubella vaccine and arthropathy (including both arthritis and arthralgia) did in fact exist and that petitioners would be permitted to demonstrate that their own arthropathies were caused-in-fact by the rubella vaccine. *Id.* at *8-11.

3. The Special Master's 2002 Decision

Following the 1993 Decision, over 130 related cases were either resolved or voluntarily dismissed based upon the Special Master's findings. *Moreno*, No. 95-706V at 5 (Dec. 16, 2003). In 1995 the Vaccine Injury Table was administratively modified to include "chronic arthritis" as a Table injury associated with the rubella.vaccine. *See* 60 Fed. Reg. 7678 (1995), *revised* 62 Fed. Reg. 7685, 7688 (1997). As a condition of establishing a table injury for chronic arthritis, a petitioner must demonstrate that a physician observed actual arthritis (joint swelling) in both the acute and chronic stages. 42 C.F.R. § 100.3(b)(6)(A) & (B) (1997 ed.). This modification did not, however, affect a petitioner's opportunity to prove causation-in-fact as to any chronic arthropathy.

In the late 1990s, several medical studies relevant to the "general causation" issue addressed in the 1993 Decision were finalized and published. *Moreno*, No. 95-706V at 6 (Dec. 16, 2003). In light of this contemporary information, the Special Master deemed it appropriate to re-analyze the general causation issue. *Id.* After reviewing the new medical studies and taking additional expert witness testimony, the Special Master concluded in the 2002 Decision "that while the overall argument for the general proposition that the rubella vaccine causes chronic arthropathy had been somewhat weakened, nevertheless a sufficient 'causation-in-fact' case can still conceivably be made in an individual case." *Id.*

a. The "Ray" and "Slater" Studies

The evidence that "somewhat weakened" the Special Master's conclusion in the 1993 Decision were two empirical medical studies, the "Ray study" and the "Slater study," that tended to show no causal correlation between the rubella vaccine and chronic arthropathy. *See Snyder*, No. 94-58V, 2002 WL 31965742 at *10-14. The Ray study was a retrospective study of 971 women who

received rubella vaccinations and 3345 women who had not. The study examined the medical records of the women over the one-year post-vaccination period for the vaccinees, and a random one-year period for the non-vaccinees. The study concluded that vaccinated women were no more likely than their non-vaccinated counterparts to report chronic *arthropathic* symptoms during the period of review. *Id.* at *10.

The Slater study also was also an historical study, in which postpartum (the period following childbirth) women were interviewed by telephone between 2 and 8 years after the vaccination dates or corresponding times for non-vaccinated subjects. Of the 485 women receiving the rubella vaccine and 493 who did not, the Slater study concluded that no statistically significant difference existed between the instances of chronic arthropathy in each group. *Id.*

The petitioners' experts criticized both the Ray and Slater studies. As for the Ray study, the Special Master was not persuaded by the petitioners' arguments and he found "no good reason to disregard or discount the results of that study." *Id.* at *13. As for the Slater study, the Special Master conceded that certain concerns, including the fact that women were interviewed so long after the relevant period that they may have forgotten arthropathic symptoms, made the Slater study not "perfect" but he did not see any reason why that study should be disregarded. *Id.* at *13-14.

Evaluating these studies, the Special Master noted that they "supply significant evidence supporting the view that the rubella vaccine probably does not cause chronic arthropathy in very many cases, if any at all." *Id.* at *17. The Special Master was of the suspicion that either or both of these studies would have evinced a causal relationship between rubella and chronic arthralgia if there was in fact such a relationship. "Indeed, if the only studies to be published in recent years had been the Ray and Slater studies, I would certainly conclude that the available evidence preponderates against the likelihood that the rubella vaccine causes chronic arthropathy." *Id.*

b. The "Tingle" Study

The Ray and Slater studies were not, however, the only contemporary studies that the Special Master considered in his 2002 Decision. He also considered a study by Dr. Aubrey Tingle (the "Tingle study"), who served as an expert witness for the petitioners during both the 1992 and 2001 reviews. Unlike the Slater and Ray studies, the Tingle study did reveal an appreciable increase in both acute and chronic arthralgic symptoms in the vaccinated subjects. The study focused on approximately 550 postpartum women, about half of whom received the rubella vaccine and half that did not. *Id.* at *10, 15. Of these women, the rate of acute arthropathic symptoms was much greater in the vaccinated group. As for chronic arthropathic symptoms, 22% of the vaccinated women and 15% of the "placebo group" fell within the study's definition of chronic arthropathy. The difference between chronic arthropathy rates between the two groups was deemed "marginally significant" by the authors of the study. *Id.* at *10.

The Tingle study, however, drew "heavy" criticism from respondent's experts, which the Special Master considered "genuine cause for caution." *Id.* at 14. Notwithstanding those criticisms, the Special Master concluded that, like the Ray and Slater studies, the Tingle study could not be "disregarded." *Id.*

Among other flaws, respondent argued that the Tingle study showed a far higher rate of joint complaints—in both the vaccinated group and the placebo group—than would be normally expected, and that these rates were so extraordinary that the study's methodology was undermined. *Id.* at *14. Specifically, the number of women experiencing acute symptoms was 30% of the vaccinated group and 20% of the non-vaccinated group. *Id.* While these high numbers are "enough to give one pause in evaluating the study" the Special Master thought that reasonable explanations existed for the results. *Id.* at *15. First, the Special Master noted that the Tingle study methodologies might have resulted in a higher response rate among study subjects because the Tingle study involved "actively visiting or telephoning the study participants to ask them if they were experiencing or had recently experienced any join pain." *Id.* In light of this, the Special Master deemed it "unsurprising" that the study would yield higher positive response rates than would studies focusing only on medical records or after-the-fact recollections (which the Slater and Ray studies employed). *Id.* Second, the Special Master noted that the subjects of the Tingle study were all women in the postpartum period, one typically recognized "as a time when women report more joint symptoms than usual." *Id.* Finally, it was pointed out that the Tingle study used consent forms that disclosed to the study participants that they might receive the rubella vaccine and subsequently experience joint symptoms. Respondent argued that this had the effect of "unblinding" the study participants and might have subtly influenced participants to report joint symptoms more readily than they would otherwise. *Id.* at *15. The Special Master noted that this criticism might help explain the unusually high incidence of acute arthropathy, but would probably not account for the excess incidence of chronic arthropathy in the vaccinated group versus the non-vaccinated group. "[W]hile again there is reason to be cautious," the Special Master concluded, "I do not see a reason to wholly disregard the results of the Tingle study because of this potential problem." *Id.*

c. Reconciling the Studies

The Special Master was therefore confronted with empirical studies that pointed in different directions. The Ray and Slater studies very clearly showed no significant correlation between the rubella vaccine and chronic arthropathy. The Tingle study, however, made the analysis "much less clear." *Id.* at *18. Despite flaws in the Tingle study, the Special Master considered it to be "scientifically valid" and noted that the study "gives us a substantial piece of evidence supporting a causal relationship between rubella vaccination and chronic arthropathy." *Id.* at *17. The Special Master recognized his task of either reconciling or assigning different weights to the recent studies and the other evidence he had considered on the general issue of causation. *Id.* at 17.

The Special Master tried to reconcile the studies, focusing primarily on the different methodologies employed to gather data. Since the Ray and Slater studies looked at medical records or relied upon after-the-fact interviews, the results of those studies might "make it seem unlikely that the rubella vaccine causes severe cases of chronic arthropathy in a significant number of cases" because there were relatively few reported or recalled incidents of chronic symptoms. *Id.* at *18. On the other hand, the Tingle study could be interpreted to "indicate that the rubella vaccine can cause lower-severity joint symptoms, symptoms at a level sufficient that a sufferer would report such symptoms to a contemporaneous interviewer, but would not seek medical attention for those symptoms." *Id.*

Ultimately, the Special Master weighed all of the evidence before him, including evidence

considered for the 1993 Decision, the contemporary epidemiological studies, and the extensive expert testimony taken in 2001. While he opined that "the overall argument for the general proposition that the rubella vaccine causes chronic arthropathy has been somewhat weakened," by the Ray and Slater studies, there was still sufficient evidence to support a finding of causation in an individual case. *Id.* at *20. In conclusion, the Special Master made a finding of fact "that the Tingle study, in conjunction with the preexisting evidence [from the 1992 inquiry] supplies enough evidence to support a causation conclusion . . . despite the countervailing evidence contained in the Ray and Slater studies."

4. The Special Master's Entitlement Decision In This Case

Turning to the entitlement decision in Ms. Moreno's case, the Special Master reviewed the history of the "rubella/arthropathy" cases outlined above. *See Moreno*, No. 95-706V (Dec. 16, 2003). It was noted that petitioner did not seek compensation for chronic arthritis as an on-Table injury because her physician did not note any objective arthritis during the acute period. Petitioner argued that the record of her case fit squarely within the causation-in-fact analysis that the Special Master outlined in the 2002 Decision. *Id.* at 8. Respondent did not oppose petitioner's factual assertions, but instead challenged the Special Master's findings in the 2002 Decision. *Id.*

First, respondent argued that the Vaccine Act "is limited to compensating individuals with serious injuries, *i.e.*, those requiring some medical attention." *Id.* at 13. Ostensibly, the respondent was concerned that the 2002 Decision might permit compensation for petitioners that had not experienced sufficiently serious symptoms of chronic arthropathy. The Special Master concluded that, in this case, that concern was a non-starter because petitioner had suffered chronic joint pain that had been sufficiently severe to cause her to seek repeated medical attention. *Id.* Accordingly, there was nothing in the Vaccine Act that suggested excluding this petitioner from its protections.

Second, respondent argued that applying the 2002 Decision in individual cases would amount to a *de facto* Table Injury because the Special Master outlined the types of evidence a petitioner would have to demonstrate to satisfy causation-in-fact.[7] This the Special Master flatly rejected,

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[7]These factors initially appeared in the Special Master's 1993 Decision, *see Ahern*, No. 90-1435V, 1993 WL 179430 at *13 (Jan. 11, 1993), and were subsequently revised by the 2002 Decision. As the Special Master noted in the entitlement decision:

> In that 1993 Order, I concluded that a petitioner "more probably than not" has suffered a condition "caused-in-fact" by a rubella vaccination, and is thus entitled to a Program award, if that petitioner's case meets *all* of the following criteria:
>
> 1. The petitioner received a rubella vaccination at a time when the petitioner was 18 years of age or older.
>
> 2. The petitioner had a history, over a period of at least three years prior to the vaccination, of freedom from any sort of persistent or recurring polyarticular joint symptoms.

because "in this case, as in all of the rubella/arthropathy cases that I have compensated over the past ten years, I am *not* employing any 'presumption.'" *Id.* at13. Instead, the Special Master maintained that in each individual case he considered all of the evidence available to determine if, "based upon all of that evidence, it is 'more probable than not' that this *particular vaccinee's* condition of chronic arthropathy was vaccine caused." *Id.*

The Special Master ultimately concluded that petitioner was entitled to compensation in this particular case because the record satisfied the factors outlined in the 1993 and 2002 Decisions, and, significantly, because there was additional relevant evidence in the record tending to support the petitioner's specific causation claim. *Id.* at 10-12. First, petitioner's own primary care physician indicated that he believed petitioner's chronic arthropathy to be vaccine caused. *Id.* at 10. Dr. Schwartz had considered other possible causes, but concluded that the chronic arthralgia was "secondary to the adverse MMR reaction." *Id.* The record also contained the statements of two other physicians, one immunologist and a rheumatologist, who opined that petitioner's chronic arthralgia was vaccine caused. Finally, both Dr. Tingle and Dr. Brenner, who testified before the Special Master during the 2001 general inquiry, had specifically addressed petitioner's case at that time. Dr. Tingle (the author of the Tingle study) reviewed petitioner's medical history and found her specific chronic arthralgia to be likely vaccine-caused. The Special Master "found Dr. Tingle to be a knowledgeable and honest medical scientist and expert witness, so his opinion, too, adds considerable weight to petitioner's case." *Id.* at 11. On the other hand, Dr. Brenner testified that petitioner's acute symptoms were likely vaccine-caused, but that her chronic symptoms were not. *Id.* While the Special Master found Dr. Brenner to be a "knowledgeable and honest expert witness"

> 3. The petitioner has developed an antibody response to the rubella virus.
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> 4. The petitioner experienced the *onset* of polyarticular arthropathic symptoms during the period between one and six weeks after the vaccination.
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> 5. Polyarticular arthropathic symptoms continued for at least six months after the onset; or, if symptoms remitted after the acute stage, polyarticular arthropathic symptoms recurred within one year of such remission.
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> 6. There is an absence of another good explanation for the arthropathy; the petitioner has not received a confirmed diagnosis of rheumatoid arthritis, nor a diagnosis of any of a series of specific conditions [cited in the 1993 order].
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> . . . .
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> [In the 2002 Decision] I modified those criteria in the two areas suggested by the recent evidence. That is, (1) the petitioner need only have been *past puberty* (not 18 years of age) at the time of vaccination; and (2) the onset of polyarticular symptoms must have taken place between *seven and 21 days* after vaccination (rather than between one and six weeks post-vaccination).

Moreno, No. 95-706V at 4, 6 (Dec. 16, 2003).

whose opinion "adds substantial weight to the case *against causation*" his expert opinion did not change the Special Master's findings in this case. *Id.* This was primarily so because Dr. Brenner was of the opinion that "in the absence of objective arthritis it can *never* be shown that a petitioner's chronic arthralgia was, more probably than not, caused by a rubella vaccine," and the Special Master had rejected that approach in the 2002 Decision. *Id.* at 12. Accordingly, the Special Master found that Dr. Brenner's testimony was not persuasive.

III. Discussion

Respondent filed its motion for review of the Special Master's entitlement decision in this case on November 29, 2004. The only issue raised by respondent was the Special Master's reliance on a single item of evidence, the Tingle study. Respondent lodged two criticisms of the Special Master's evaluation of the Tingle study, challenging (1) the conclusions of the study, which respondent alleges to be the product of a "mathematical error," and (2) the relevance of the study to petitioner's specific case.

A. Standard of Review Under the Vaccine Act

The review of a Special Master's entitlement decision in the Court of Federal Claims is a record review. The Vaccine Act defines the court's standard of review:

> the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—
>
> > (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
> >
> > (B) set aside any findings of fact or conclusion 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, or
> >
> > (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The issues that the respondent has raised in this case are all ones of fact, which the court reviews under the arbitrary and capricious standard. *See* Mot. for Review at 7-9; *see also Turner v. Sec'y of HHS*, 268 F.3d 1334, 1337 (Fed. Cir. 2001); *Munn v. Sec'y of HHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992); *Hines v. Sec'y of HHS*, 940 F.2d 1518, 1527 (Fed. Cir. 1991).

Under the arbitrary and capricious standard, "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the

decision, reversible error will be extremely difficult to demonstrate." *Hines,* 940 F.2d at 1528.[8] According to the Federal Circuit:

> arguments as to weighing of evidence, particularly where, as here, witness credibility is involved, do not demonstrate reversible error. Regardless of whether the Claims Court, or we, would have found different facts on a retrial of the case, the issue which the Claims Court resolved and which we now review is only whether the findings and conclusions of the special master were arbitrary [and] capricious.

Id. at 1527; *see also Munn,* 970 F.2d at 869, 871 ("[I]t is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all maters within the purview of the fact finder.").

"The [Vaccine Act] makes clear that, on review, the Court of Federal Claims is not to second guess the Special Master['] s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." *Hodges v. Sec'y of HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993). "That level of deference is especially apt in a case in which the medical evidence of causation is in dispute." *Id.* Thus, the arbitrary and capricious standard "is highly deferential to the factual findings of the special master" and "well understood to be the most deferential [standard] possible." *Munn,* 970 F.2d at 869, 870.

Of course, the arbitrary and capricious standard is not impossible to satisfy: "It is possible to hypothesize a case . . . in which a special master rendered a decision when no factual basis whatever existed under which the decision could be justified." *Id.* at 871. However, it is clear that the court must give "great deference" to "findings and conclusions by the special master." *Id.* at 870. Of course, "refusing to consider" evidence is not the same as finding evidence unpersuasive or judging evidence "to fall short of proving the case by the standard the law requires." *Hodges,* 9 F.3d at 961 n.4. The Vaccine Rules, however, require the Special Master to "consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties." Vaccine Rule 8(c). One of the focuses of the arbitrary and capricious review, then, is to consider whether "the special master has considered the relevant evidence of record." *Hines*, 940 F.2d at 1528.

B. Analysis

The respondent's Motion for Review raises a narrow challenge to the Special Master's entitlement decision in this case. The only issue that it calls into question is the relevance and probative weight assigned to the Tingle study, a single item of evidence that the Special Master considered during the 2001 review of the "general causation" question. As respondent would make it seem, the Tingle study alone is the linchpin upon which both the 2002 Decision and the entitlement decision in petitioner's case turn. *See* Mot. for Review at 7 ("The Special Master's [2002

[8] *Hines* noted that the arbitrary and capricious standard has been defined in numerous ways and declined to adopt one single definition, stating that "no uniform definition of this standard has emerged." 940 F.2d at 1528-29.

Decision] turned on his examination of one piece of evidence, the Tingle study."), 8 ("Thus, the validity of the [2002 Decision] solely hinges on the validity of the Special Master's assessment of the Tingle study."). According to respondent, if its challenge to the Tingle study is upheld, then "this case should be remanded to the Special Master with direction that he dismiss the case absent probative evidence demonstrating that petitioner's condition was actually caused by her rubella immunization. *Id.* at 16.

The main problem with the respondent's argument is that it wholly overlooks an extensive body of evidence that the Special Master considered in reaching the entitlement decision in this case and both the 1993 and 2002 Decisions. While the Special Master did concede in the 2002 Decision that the Tingle study was the lone piece of empirical evidence that tended to counterbalance the empirical evidence of the Slater and Ray studies, and that without the Tingle study the empirical evidence of the Slater and Ray studies might have been given controlling weight in his analysis at that time, the Special Master relied on far more evidence to conclude that petitioner's chronic arthralgia was in-fact caused by her rubella vaccine in this particular case. Empirical studies, or epidemiologic studies, are just one of a number of different types of evidence that the Special Masters routinely analyze to evaluate causation-in-fact in a given case.

To establish causation-in-fact the petitioner must demonstrate "a medical theory causally connecting the vaccination and the injury" that must be supported by "reputable medical or scientific explanation." *Grant*, 956 F.2d at 1148. As this court has noted before, the first step that a petitioner takes in proving causation is to demonstrate that the vaccine at issue *could* cause the petitioner's condition. *See Pafford*, 64 Fed. Cl. at 27-30. If the petitioner lacks evidence that establishes causation with scientific certainty,[9] then the petitioner may resort to a litany of types of circumstantial evidence to establish causation. Among those types of circumstantial evidence the Special Master may consider are:

> Epidemiology (evidencing a relative risk less than two), animal studies, case reports/case series studies, anecdotal reports, manufacturing disclosures, Physicial 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.

Id. at * 29. Once the petitioner has established that the vaccine could cause the petitioner's condition, the petitioner must then demonstrate some "nexus" between her own injury and the vaccine. *Id.* (citing *Munn*, 970 F.2d at 867).

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[9]For example, the petitioner might be able to provide epidemiological studies that support causation to a near scientific certainty or demonstrate pathological or clinical markers that conclusively establish a causal link between the vaccine and subsequent condition. *Pafford*, 64 Fed. Cl. at 28 & n.12 ("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.") (quoting *Stevens v. Sec'y of the Dep't of Health and Human Servs.*, No. 99-594V, 2001 WL 387418 at *12 (Fed. Cl. Spec. Mstr. Mar. 30, 2001).

Here, the Special Master considered a range of relevant circumstantial evidence on three separate occasions (the 1992 and 2001 general inquiries, and the petitioner's own case-specific evidence) that all factored into the entitlement decision and support his conclusion that petitioner's condition was vaccine-caused.

First, petitioner introduced evidence of causation specific to her own particular case that the Special Master found persuasive. Petitioner's personal physician believed that her chronic arthralgia was vaccine-caused. *Moreno*, No . 95-706V at 10 (Dec. 16, 2003). The physician noted that he had considered other possible causes of her condition but ruled them out. *Id.* Two other physicians, Drs. Lewell and Benneman, provided written evaluations of petitioner's case and both opined that her condition was vaccine caused. *Id.* at 11.

Two physicians, Drs. Tingle and Brenner, testified about petitioner's specific condition during the 2001 general inquiry.[10] Both were of the impression that petitioner's *acute* symptoms were vaccine caused. Dr. Tingle "offered the specific opinion that *petitioner's* chronic arthralgia was likely vaccine-caused." *Id.* The Special Master found Dr. Tingle to be particularly credible. *Id.* Dr. Brenner did not believe that petitioner's *chronic* condition was vaccine-caused, but the Special Master did not find Dr. Brenner persuasive on this point. *Id.* at 11-12.

Ultimately, the Special Master concluded that this specific evidence tended to support petitioner's causation analysis, and that causation in her case was supported *even further* by the additional evidence from the 1992 and 2001 general causation proceedings that the Special Master used to *supplement* petitioner's own evidence. *Id.* at 13 ("[I]n the rubella/arthropathy cases I have an additional body of evidence– from the *general causation proceedings*– upon which to draw, in order to *supplement* the evidence brought forth in the individual case record. I am able to *put together* the evidence from the general causation proceedings and the individual case record, and, based upon *all* of that evidence, determine whether it is 'more probable than not' that the *particular vaccinee's* condition was vaccine-caused.").

The 1992 and 2001 inquiries, in turn, provided even more evidentiary support for the Special Master's conclusion. In 1992, the Special Master considered the testimony of six experts as well as an "extensive search of relevant medical literature." *Ahern*, 1993 WL 179430 at * 2. The Special Master also considered evidence of some "isolated cases" of "persistent joint symptoms" following rubella vaccinations. *Id.* at *4. There were some "limited" studies available that tended to suggest some causal relation between the rubella vaccine and chronic arthralgia. *Id.* There was also some scientific evidence of pathological markers of the rubella virus being present in the synovial fluid of women with chronic arthritis even years after receiving the rubella vaccine. *Id.* at *5. Based on all of this evidence, the Special Master made a finding of fact that he considered the argument of the petitioners' experts to be more persuasive than those of respondent. *Id.* at * 8. This was based, in part, on a credibility assessment that was made in light of the available body of evidence.

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[10]As noted above, several individual case studies were discussed during the 2001 inquiry and addressed by the experts. Petitioner's case was one of those specifically discussed during the general causation inquiry. *See Moreno*, No. 95-706V at 11 & n.9.

Later in 2001, the Special Master considered more evidence that he concluded supported causation. In addition to the Tingle study, which respondent focuses on, the Special Master also examined the testimony of six experts that offered their opinions on the relationship between the rubella vaccine and chronic arthralgia, as well as their assessment of the Tingle, Ray and Slater studies. *See Snyder*, 2002 WL 31965742 at *11. Again, the Special Master weighed the persuasiveness and credibility of these experts and the three medical studies they discussed, and made appropriate findings of fact. *See id.* at *11-20.

When the Special Master concluded in the entitlement decision that a causal relationship existed between the rubella vaccine and chronic arthralgia, that conclusion was not based solely on the Tingle study. Instead, there was a substantial body of evidence that the Special Master considered in reaching that conclusion, and he explicitly drew on that entire background when he determined that petitioner herself had demonstrated that the rubella vaccine was the cause-in-fact of her own condition. *Moreno*, No. 95-706V at 12 (Dec. 16, 2003) ("In short, when I consider *all* of the evidence of record before me, including the fact that petitioner's case meets my criteria set forth in my 2002 Analysis, *along with* the various medical opinions concerning petitioner's specific case discussed above, I find that it is 'more probable than not' that petitioner's chronic joint pain has been vaccine-caused.").

This ongoing evaluation by the Special Master, which relied equally on contemporary evidence of causation presented by the petitioner to support her own particular case and the historical analyses of the 1993 and 2002 Decisions, is consistent with a sound causation-in-fact analysis. The Special Master's evaluation of causation in a specific case is not static and should not be limited to general determinations he made years earlier. Instead, the Special Master must continually reevaluate causation issues based on the ever-developing body of evidence presented by each individual petitioner. This is so because the evidence presented by a petitioner concerning his or her specific case is relevant to resolving whether the vaccine in question was the cause-in-fact of the petitioner's own condition. Indeed, the specific evidence that a petitioner presents to establish a nexus between "general causation" issues and that petitioner's own condition may be the *most* relevant evidence that the Special Master considers in any given case.

All of this leads back to the point that there seems to be ample evidence in the record, in addition to the Tingle study that respondent challenges, to support the Special Master's entitlement decision in this case. While the Tingle study may have been the only available empirical evidence to weigh against the Slater and Ray studies, it was not the only evidence that the Special Master considered regarding causation. The respondent's challenge to the Tingle study, alone, then must be considered in light of all of the other evidence available in the record of this case. Even if the court were to examine respondent's limited challenge to the Tingle study in the proverbial vacuum and disregard the overwhelming record evidence supporting the Special Master's decision discussed above, the Special Master's entitlement decision would still withstand scrutiny. This is so because respondent's challenges to the Tingle study are exagerated and there is adequate support in the record for the Special Master's finding that the Tingle study is both probative and relevant to this case.

1. "Mathematical Error" in the Tingle Study

The respondent argues that the Special Master failed to address "critical evidence" that

purportedly undermines the conclusions of the Tingle study. At its heart, respondent's critique amounts to a disagreement over the methodology employed by the Tingle study.

As discussed, the Tingle Study monitored the appearance of acute and chronic arthropathic symptoms in postpartum women. For the purposes of the study, "chronic" symptoms were defined to include the occurrence of arthropathy at any time during the twelve months following vaccination, but only in those women who first experienced an acute reaction and for whom joint complaints could not be attributed to other causes. *See* Rubella Omnibus File, Part D, Second File of Expert Reports (Year 2000 Reports) at D-23 to D-27 (Dr. A.J. Tingle, *et al*, *Randomised Double-Blind Placebo-Controlled Study On Adverse Effects of Rubella Immunisation In Seronegative Women*, 349 The Lancet 1277 (May 3, 1997)). Therefore, if a study participant experienced chronic symptoms but had not reported acute symptoms, that participant was not deemed to have experienced chronic symptoms for the purposes of the study.

The study subjects were divided in two groups: 268 women received the rubella vaccine, and a control group of 275 women received a placebo. *See* Mot. for Review at 10-12. Of these women, 81 in the vaccine group and 55 in the placebo group experienced arthropathy in the first 28 days after injection (the acute phase). *Id.* at 12. Out of those women experiencing acute symptoms, the Tingle Study reported that 58 of those in the vaccine group (out of 81) and 41 of the placebo group (out of 55) also experienced arthropathy at least once in the following year. *Id.* at 12.

The respondent argues that in expressing its results, the Tingle Study committed a "mathematical error" that causes it to "overstate the rate of chronic arthropathy in those receiving the rubella vaccine." *Id.* at 10. In general, the respondent contends that the Tingle Study is flawed because the study expressed the relative rate of chronic arthropathy in each group as a percentage of the entire population of each group. *Id.* at 12. Simply put, the Tingle study divided the number of participants in each group reporting chronic symptoms by the total number of participants in that group (22%, or 58 of 268 women of the vaccine group suffered chronic arthropathy; 15%, or 41 of 275 women of the placebo group suffered chronic arthropathy).[11] *Id.* The Special Master found that the Tingle Study could have reasonably concluded that this difference (22% versus 15%) was

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[11]At least facially, it seems entirely appropriate for the Tingle study to calculate the incidence of chronic arthralgia among both the vaccinated group and the non-vaccinated group as a percentage of the respective test population. In laymen's terms, the goal of the epidemiological study was to answer the questions: "How many people who receive the rubella vaccine demonstrate chronic arthralgic symptoms, and how does that compare with the number of people who do not receive the vaccine?" To accomplish this goal, the only real calculation of interest is the one that the Tingle study used - the percentage of each test population that ultimately demonstrated chronic arthralgic symptoms. Indeed, that is the *same* calculation that was used in the Slater study to express the incidence of joint symptoms. *See* Rubella Omnibus File, Part D, Second File of Expert Reports (Year 2000 Reports) at D-34, D-36 (Paul E. Slater, *et al*., *Absence of an Association Between Rubella Vaccination and Arthritis In Underimmune Postpartum Women*, 13 VACCINE 1529-32 (1995)) ("Taken together, 23 of the 485 study group women (4.7%) and 19 of the 493 control group women (3.9%) had any joint complaints meeting study definitions.") (percentages in parentheticals original). The respondent does not object to the use of this calculation in the Slater study.

statistically significant, even though the study authors concluded the result to be "marginally significant." *See Snyder*, 2002 WL 31965742 at *16.

More specifically, the respondent argues that the Tingle study's calculation of percentages was misleading and that it should have instead expressed and compared the rates of chronic arthropathy as the percentage of participants in each group who had *first experienced acute arthropathy*. Mot. for Review at 12. According to the respondent's argument, rather than dividing the number of participants reporting chronic symptoms by the total population of that group, it should instead be divided by the number of participants who reported symptoms of acute arthropathy. By the respondent's proposed calculation, 72% (58 of 81) of the vaccinated participants who suffered acute arthropathy also suffered chronic arthropathy, while 75% (41 of 55) of those in the placebo group who suffered acute arthropathy also suffered chronic arthropathy. *See id.* As the respondent would make it seem, since 72% is roughly the same as 75%, there is no significant statistical difference between the incidence of chronic arthropathy between the vaccinated group and the placebo group (indeed, the placebo group has a "higher" rate of incidence under the respondent's proposed calculation).

The respondent seeks a remand of this case based on its assertion that the Special Master failed to consider evidence that the respondent presented suggesting that the Tingle study should have used the mathematical calculation proposed by the respondent (*i.e.*, the one that yielded a lesser correlation between rubella and chronic arthralgia). *See* Mot. for Review at 9-14. During one exchange between the Special Master and respondent's expert, Dr. Moulton, the issue arose over the Tingle study's calculations. Dr. Moulton's testimony indicates that he feared the Tingle study might have involved what he called a "selection bias." *See* Rubella Omnibus File, 2001 Hearings Transcripts at 190-91 ("Tr."). Since the Tingle study defined "chronic arthralgia" to be present *only* in those cases where the same study participant first experienced acute arthralgia, Dr. Moulton argued that the Tingle study was predisposed to finding a higher rate of chronic arthralgia in vaccine recipients because it is known that the rubella vaccine does cause a higher rate of *acute* arthropathy. In other words, as respondent noted in the Motion for Review, "[b]ecause a far greater number of those who received rubella vaccine reported acute arthropathy, far more of them were potentially available for a 'chronic' arthropathy." Mot. for Review at 11.

The problem with the respondent's argument is that it is never really explained why one calculation would be better than the other. As petitioner's expert, Dr. Hirsch, explained, the Tingle study *could* have used either of the two denominators (*i.e.*, the one it actually used or the one proposed by Dr. Moulton and the respondent) to calculate the incidence of chronic arthralgia. Tr. at 256. The choice between these two denominators depended on competing assumptions underlying the study. *Id.* As Dr. Hirsch explained, the Tingle study was based on an assumption of a direct relationship between chronic and acute arthropathy. That is, that chronic arthropathy will only manifest after acute symptoms. *Id.* The respondent's proposed calculation, on the other hand, reflects an assumption that there is no such relationship between acute and chronic symptoms. *Id.* According to Dr. Hirsch, the calculation proposed by the respondent is inconsistent with the assumption adopted by the Tingle study, and *vice versa*.

The Special Master and the parties' experts debated the merits of these competing assumptions and calculations at length. *See* Tr. at 190-211, 249-68, 384-89. There appeared to be

an honest difference of opinion between the experts on the issue; clearly, no consensus could be reached. Ultimately, respondent's argument and Dr. Moulton's testimony seems to challenge the credibility of the Tingle study and its findings. If the study did have a "selection bias" as Dr. Moulton suggested, then its findings might be entitled to less probative weight.

It is the Special Master's duty to decide among competing experts and make factual findings as to credibility. *See Bradley v. Sec'y of the Dep't of Health and Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). While the Special Master did not specifically address the selection bias argument that Dr. Moulton raised in his testimony in the 2002 Decision, it is clear that the issue was considered by the Special Master, as evidenced by his engaged participation in a lengthy discussion on the issue. *See* Tr. at 190-211, 249-68, 384-89; *see also* Mot. for Review at 13 ("The Special Master understood the issue at trial . . . .").

The respondent seems to argue that the Special Master is bound to specifically address every single challenge to the credibility of evidence that is deemed probative. *See* Mot. for Review at 10 ("[T]he Special Master's failure to address [evidence of a mathematical flaw, or bias, in the Tingle study] constitutes a failure to perform his duty under Vaccine Rule 8(c) which requires that he consider 'all relevant, reliable evidence.'"). While respondent is correct to point out that the Special Master's findings of fact are "indispensable prerequisites to effective and timely review" and that the Special Master must "carefully scrutinize the entire record,'" *id.* at 10 (quoting *McClendon v. Sec'y of the Dep't of Health and Human Servs.*, 23 Cl. Ct. 191, 196 (1991), it does not necessarily follow that the Special Master must issue a finding on every bit of minutiae that guides his findings as to credibility, so long as there is support in the record for his conclusions. *See, e.g.*, *Guillory v. United States*, 59 Fed. Cl. 121, 126 (2003), *aff'd* 104 Fed. Appx. 712 (2004); *Snyder v. Sec'y of the dep't of Health and Human Servs*., 36 Fed. Cl. 461, 466 (1996) ("The special master need not discuss every item of evidence in the record so long as the decision makes clear that the special master fully considered a party's position and arguments on point.") (citing *Murphy v. Se'cy of the Dep't of Health and Human Servs.*, 23 Cl. Ct. 726, 734 n.8 (1991), *aff'd* 968 F.2d 1226); *Dickerson v. Sec'y of the Dep't of Health and Human Servs.*, 35 Fed. Cl. 593, 601 (1996) (noting that the Special Master must "examine the full record" and "provide *sufficient* findings") (emphasis added).

In this case, the Special Master conducted two inquiries (in 1992 and 2001), considered the reports and testimony of several experts, reviewed extensive medical literature and made a decision that clearly articulated the grounds upon which his decision was based. The 2002 Decision was explicitly based upon "all the evidence available at [that] time." *Snyder*, No. 94-58V, 2002 WL 31965742 at *20. That decision confronted a number of criticisms of the Tingle study, and the Special Master implicitly considered the other challenges when he evaluated the credibility of the Tingle study. This court declines to saddle the Special Master with the burden of addressing every single purported evidentiary flaw in his decision, provided that the decision satisfies applicable standards of review by demonstrating that relevant arguments were considered and articulating a rational explanation for the Special Master's findings. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (noting that the court, in reviewing findings of fact under the arbitrary and capricious standard, must consider "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment"); *Hines v. Sec'y of Dep't of Health and Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991) ("If the special master has considered the relevant evidence in the record, drawn plausible inferences and articulated a rational

basis for the decision, reversible error will be extremely difficult to demonstrate.").

Accordingly, based on the record before the court, including the testimony from the 2001 inquiry and the Special Master's thorough 2002 Decision, the Special Master did not act arbitrarily or capriciously in finding the Tingle study credible, notwithstanding the issues of selection bias that Dr. Moulton raised during his testimony but that the Special Master did not specifically address in his findings. The Special Master was well aware that the Tingle study was not without its flaws. The Special Master addressed and tried to account for a number of these flaws in the 2002 Decision. *See Snyder*, No. 94-58V, 2002 WL 31965742 at *14-16. His ultimate conclusion, that the Tingle study was "scientifically valid if slightly flawed" conceded that the study's value was somewhat undermined by the respondent's various challenges. Nonetheless, the Special Master found the study probative.

This credibility assessment is entitled to great deference by this court on review. "[W]here the medical evidence of causation is in dispute, a high level of deference is due the [Special Master]'s fact-finding. *Ryman v. Sec'y of the Dep't of Health and Human Servs.*, No. 99-591V at 8 (Fed. Cl. Apr. 8, 2005) (citing *Hodges v. Sec'y of the Dep't of Health and Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)). It is of no matter whether this court "might have weighed the evidence differently" or assigned different weight to credibility challenges lodged by the respondent. *See id.* Instead, the court focuses on whether the Special Master has evaluated the evidence before him and made a decision that is adequately explained and supported by the record. Notwithstanding "heavy criticism" from the respondent's experts, the Special Master determined that the Tingle study was probative and that it was a "substantial piece of evidence supporting a causal relationship between rubella vaccination and chronic arthropathy." *Snyder*, No. 94-58V, 2002 WL 31965742 at *14, 17. This credibility decision is entitled to deference by the court and must be affirmed because there is no indication that it was either arbitrary or capricious.

2. Relevance of the Tingle Study to Petitioner's Condition

Turning to the second contention that the Special Master's decision should be remanded, the respondent argues that the Tingle Study is irrelevant to Ms. Moreno's condition, and that therefore, it was arbitrary for the Special Master to rely on it. *Id.* at 9. The respondent characterizes the Tingle Study as having "examined cases of minor, self-limited pain." *Id.* at 14. Because Ms. Moreno suffers from "severe, debilitating joint pain," the respondent argues that the Tingle Study is simply not applicable in the present case. *Id.* Respondent apparently raised this challenge to the 2002 Decision before the Special Master in the context of Ms. Moreno's entitlement proceedings. It argues that the Special Master failed to address the issue then, and instead focused on whether Ms. Moreno's own condition was sufficiently serious to qualify as a basis for compensation under the Vaccine Act. *Id.* at 15.

In response, petitioner argues that the respondent's contention that the Tingle Study is not relevant misses the point because it fails to acknowledge that tolerance for pain is subjective, and that therefore a study regarding joint pain must inevitably deal in generalities. Pet.'s Response at 16.

The fuel for respondent's argument seems to be a statement from the 2002 Decision in which

the Special Master tried to reconcile the Slater, Ray, and Tingle studies. In trying to explain how the Tingle study could reveal a much higher incidence of arthropathy than had either the Slater or Ray studies, the Special Master observed:

> One could conclude that while the Ray and Slater studies make it seem unlikely that the rubella vaccine causes *severe* cases of chronic arthropathy in a significant number of cases, the Tingle study nevertheless may indicate that the rubella vaccine can cause *lower-severity* joint symptoms, symptoms at a level sufficient that a sufferer would report such symptoms to a contemporaneous interviewer, but would not seek medical attention for those symptoms.

2002 WL 31965742 at *18. Seizing on this language, respondent argues that it was inappropriate for the Special Master to rely on the Tingle study to establish a causal connection between the rubella vaccine and chronic arthropathy that is compensable under the Vaccine Act, primarily because the Act only provides for compensation when a petitioner's condition is serious.

The respondent's argument is somewhat misleading. While the Tingle study may have taken into consideration cases of chronic arthropathy of differing severity, there is no indication that it exclusively studied "minor, self-limited pain" as respondent suggests. Mot. for Review at 14. Instead, given the real-time responses that study participants provided in the Tingle study, the Special Master could reasonably conclude that the Tingle study participants reported all levels of arthropathic symptoms, including some less severe symptoms that might not have been reported in the Slater and Ray studies.

The problem with the respondent's argument is that it assumes that a causal relationship between the rubella vaccine and chronic arthropathy that manifests itself in only lower-severity symptoms has nothing to do with a causal connection between the rubella vaccine and petitioner's own symptoms—ostensibly because hers were severe enough to require medical attention. The respondent's argument misses the mark mainly because it fails to account for the subjective nature of chronic arthralgia. While an individual study participant in the Tingle study might have reported symptoms in a contemporaneous interview, she might not have subjectively deemed the symptoms severe enough to visit a doctor or committed the symptoms to memory such that she might recall them in an interview years later (and thus, would not have shown up on the Slater or Ray studies as demonstrating chronic symptoms). In any other individual, however, the very same symptoms could subjectively merit much greater concern and attention—perhaps severe enough to require a physician's care or to be recalled years later in an interview. As petitioner noted, "[t]he precise severity of any one person's pain is impossible to measure. Tolerance for pain varies from individual to individual. . . . It is largely subjective. One person may seek medical attention, while another [may not]." Pet.'s Resp. to Respondent's Mot. for Review at 16.

Thus, the Special Master could have inferred that the Tingle study was probative of a causal connection between the rubella vaccine and chronic arthropathy, regardless of the severity of the symptoms in the study participants. Such an inference is at least plausible. "[A]rguments as to the weighing of evidence, particularly where, as here, witness credibility is involved, do not demonstrate reversible error." *See Hines,* 940 F.2d at 1527. Again, "whether [this court] would have found different facts on a retrial of the case, the issue . . . we now review is only whether the findings and

conclusions of the special master were 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'" *Id.* (quoting 42 U.S.C. § 300aa-12(e)(2)(B)).

Accordingly, it was entirely appropriate for the Special Master to conclude that the Tingle study was relevant to petitioner's case and to find it probative of at least some causal connection between the rubella vaccine and chronic arthropathy. It does not strike this court as arbitrary or capricious to reach that conclusion notwithstanding the fact that some Tingle study participants might have experienced joint pain that was, subjectively, less severe than petitioner's was in this case. Indeed, it matters not that the Tingle study participants themselves did not seek a physician's care for their own pain, because that same pain in any other person might have been deemed serious enough to seek treatment and, thus, could satisfy the Vaccine Act's criteria for compensation. Ultimately, this court will not "reweigh the factual evidence, or . . . assess whether the special master correctly evaluated the evidence. And of course [the court shall] not examine the probative value of the evidence or the credibility of the witnesses. These are all maters within the purview of the fact finder." *See Munn,* 970 F.2d at 869, 871. Affording the Special Master's fact-intensive decision the deference to which it is entitled, *see id.* at 870, the court concludes that the Special Master's reliance on the Tingle study was neither arbitrary nor capricious.

In light of this entire discussion, it appears that the Special Master's entitlement decision is supported by adequate evidence in the record. The totality of that evidence, including case-specific evidence petitioner provided as well as supplemental evidence from the 1992 and 2001 general inquiries, is sufficient to uphold the Special Master's findings of fact that petitioner demonstrated that her chronic arthralgia was caused-in-fact by the rubella vaccination. Notwithstanding all of that evidence, the record also indicates that it was neither arbitrary or capricious for the Special Master to accord the Tingle study, itself, probative value in his evaluation of the evidence. Despite respondent's challenges, there is adequate support in the record for the Special Master to have concluded that the Tingle study was relevant to the causation issue and that it provided probative evidence of a causal relationship between the rubella vaccine and chronic arthralgia.

IV. Conclusion

For the foregoing reasons, the court concludes that the Special Master's entitlement decision satisfies the appropriate legal standards. Accordingly, that decision is **AFFIRMED**.

IT IS SO ORDERED.

s/ *Lawrence J. Block*
Lawrence J. Block
Judge