OFFICE OF SPECIAL MASTERS

No. 90-2208V

(Filed: September 22, 1997)

DONNA WAGNER,	*	
Petitioner,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald Homer, Boston, Massachusetts, for petitioner.

David Terzian, Department of Justice, Washington, D.C., for respondent.

RULING ON REMAND CONCERNING "ENTITLEMENT" ISSUE

HASTINGS, Special Master.

This is an action seeking an award under the National Vaccine Injury Compensation Program.[(1)] The case is currently before me on remand, pursuant to the opinion issued by Judge Eric G. Bruggink of this Court on January 6, 1997. *See Wagner v. Secretary of HHS*, 37 Fed. Cl. 134 (1997). For the reasons stated below, pursuant to the "law of the case" set forth in that opinion and other precedent, I conclude that petitioner is entitled to such a Program award.

I

STATUTORY BACKGROUND

Under the National Vaccine Injury Compensation Program (hereinafter "the Program"), compensation awards are made to individuals who have suffered injuries thought to be caused by certain vaccines. There are two basic means of establishing entitlement to compensation. First, if an injury listed in the "Vaccine Injury Table," found at 42 U.S.C. § 300aa-14(a), occurred within the time period from vaccination prescribed in that Table, then that injury may be *presumed* to qualify for compensation. Second, compensation may also be awarded for injuries not listed on the Table, but entitlement in such cases is dependent upon proof by a preponderance of evidence that the vaccine *actually caused* the injury. § 300aa-13(a)(1); § 300aa-11(c)(1)(C)(ii).

In this case, petitioner's claim is that certain joint pain and swelling symptoms that she has reported over the last several years were caused by a rubella vaccination that she received on December 3, 1987. That vaccination is one listed in the Vaccine Injury Table, but petitioner does not allege that she suffered any of the injuries listed in the Table for that vaccine. This case, therefore, does not involve an allegation of a "Table Injury;"[(2)] instead, the petitioner seeks compensation via the alternative "actual causation" route of § 300aa-11(c)(1)(C)(ii).[(3)]

II

PETITIONER'S CONDITION

The petitioner, Donna Wagner, born on January 29, 1948, has a history of various medical problems dating back to at least 1982. The portion of her history most relevant here concerns the time period since December 3, 1987, when petitioner received a rubella vaccination. About six days after that vaccination, petitioner experienced some aching in her knees and thighs, followed by a fever the next day, then a rash the day after that. The rash disappeared after about five days, but on December 20, 1987, petitioner experienced the onset of a new rash and some joint aching. Since that time, petitioner has experienced intermittent episodes of swelling and pain--*i.e.*, arthritis--in her wrist and hand joints.

III

MEDICAL BACKGROUND: THE "OMNIBUS PROCEEDING" CONCERNING THE GENERAL ISSUE OF THE RELATIONSHIP BETWEEN THE RUBELLA VACCINATION AND CHRONIC JOINT SYMPTOMS

The issue here--*i.e.*, whether the petitioner's chronic joint problems were caused by a rubella vaccination--is not unique to this case. Rather, a large number of cases under the Program have involved similar claims. Accordingly, upon assignment by the Chief Special Master, I undertook an inquiry into the *general* issue of whether rubella vaccinations can cause persistent joint pain and related joint symptoms,

and, if so, under what circumstances. That inquiry involved extensive research into the relevant medical literature, as well as evidentiary hearings in which I heard testimony from a number of qualified medical experts. The history of that inquiry was set forth in an Order filed in 70 such cases on January 11, 1993, and will not be repeated here. (That order, to which I will hereinafter refer as the "Omnibus Order," was placed into the record in this case by my Order filed on January 19, 1993. It was also electronically "published" under the caption *Ahern et al. v. HHS*, 1993 WL 179430, 1993 U.S. Cl. Ct. LEXIS 51.) As a result of that inquiry, for reasons also fully explained in the Omnibus Order, I reached the conclusion that if a person's chronic joint symptoms arose under a certain set of circumstances, it may reasonably be concluded--absent any additional evidence relevant to the particular case--that it is "more likely than not" that such symptoms were vaccine-caused. As explained in that Omnibus Order, this conclusion was based upon evidence showing that a large number of persons have experienced histories of joint pain that follow a typical pattern. This pattern involves, *inter alia*, the onset of significant, observable swelling in multiple joints between one and six weeks after a rubella vaccination, followed by some period of remission or reduction in symptoms, with a subsequent recurrence or persistence of more swelling or pain in the same joints. In general, I concluded that if a particular petitioner's history of joint symptoms falls into this pattern, *and there is no other apparent cause for the symptoms*, then one could reasonably--subject to any additional evidence introduced peculiar to the particular case--attribute the chronic symptoms to the vaccination. Accordingly, I set forth in the Omnibus Order a list of six specific criteria, stating that if a petitioner's case meets all six specific criteria, it would appear reasonable to attribute the petitioner's chronic arthropathic symptoms to the rubella vaccination. Those six criteria required a petitioner to demonstrate that:

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.

3. The petitioner has developed an antibody response to the rubella virus.

4. The petitioner experienced the *onset* of polyarticular arthropathic symptoms during the period between one and six weeks after the vaccination.

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.

6. There is an absence of another good explanation for the arthropathy; the petitioner has not received a diagnosis of one of a specified list of disqualifying conditions.

Omnibus Order, slip op. at pp. 21-22 (1993 WL 179430 at *13).

As will be seen in the pages that follow, the petitioner in this case has argued that her history of symptoms falls within the general pattern described in the Omnibus Proceeding. The respondent has pointed out, however, ways in which petitioner's history diverges from that pattern.

I also note at this point that in the pages to come, I will refer to my inquiry described above concerning the general issue of the relationship between the rubella vaccine and joint symptoms, including the extensive evidentiary hearings that I conducted, as the "Omnibus Proceeding."[(4)] I will

refer collectively to the Program cases to which that Proceeding has relevance as the "rubella arthropathy

cases." Further, I will sometimes refer to the above-described pattern of joint symptoms observed after rubella vaccinations as "chronic post-rubella arthropathy." Other terms that I will use are as follows. The term "arthropathy" will be used to encompass both "arthralgia," defined as *subjective pain* in a joint or joints, and "arthritis," defined as *objective findings* of swelling, redness, heat, and/or limitation of motion.

IV

RULINGS IN PETITIONER'S CASE

A. My initial decision

In this case, petitioner filed medical records detailing the history of her condition, both parties filed expert analyses of the case, and an evidentiary hearing was held in which the opposing experts explained their theories. After consideration of that record, I issued a Decision denying petitioner a Program award. *See Wagner v. Secretary of HHS*, No. 90-2208V, 1996 WL 515615 (Fed. Cl. Spec. Mstr. Aug. 28, 1996).

In reaching that conclusion, I began by acknowledging that petitioner's history does resemble in many ways the pattern of chronic post-rubella arthropathy described before me during the Omnibus Proceeding. Petitioner's history in fact does meet the first five of the six criteria set forth in my Omnibus Order (see pp. 3-4 above). Specifically, petitioner (1) received a rubella vaccination at age 39; (2) at the time had no prior history of multi-joint symptoms; (3) thereafter developed an antibody response to the rubella virus; (4) experienced the onset of polyarticular joint symptoms approximately one week after the inoculation; and (5) has continued to experience polyarticular arthropathy on an intermittent basis since then. I concluded, however, that petitioner's case failed to meet my sixth criterion, *i.e.*, that there be an absence of another good explanation for the chronic arthropathy. Rather, based both upon testimony that I had taken in the course of the Omnibus Proceeding and testimony of respondent's expert in this case, I concluded that petitioner's chronic arthropathy was likely due to a pre-existing autoimmune dysfunction in petitioner rather than her rubella vaccination.

This conclusion resulted from the fact that over a period of many years petitioner has displayed a *number* of different sets of chronic symptoms, in addition to her chronic arthropathy. These symptoms include Sjogren's Syndrome, which involves chronically dry eyes and dry mouth; a thyroid condition known as "Hashimoto's thyroiditis;" a condition involving tissue near the heart known as pericarditis; certain neuropathic symptoms in her feet; and a certain abnormal renal (kidney) condition. All of these symptoms can be caused by a dysfunctional autoimmune system--in other words, a person's immune system, designed to attack foreign agents that have invaded the person's body, inappropriately attacks the person's own body instead. In addition, it is also well-accepted that chronic arthropathy, of the type from which petitioner suffers, can also be caused by autoimmune dysfunction. I found persuasive the testimony of respondent's expert that given the facts of petitioner's case--*i.e.*, that petitioner has all these different conditions that can flow from an underlying autoimmune dysfunction; that certain aspects of her autoimmune dysfunction clearly *pre-date* petitioner's vaccination; and that chronic arthropathy itself is one of the conditions that can be caused by autoimmune dysfunction--it is likely that petitioner's chronic arthropathy is a product of her underlying autoimmune dysfunction, rather than from a wholly different type of source such as her rubella vaccination.

Further, this theory of respondent's expert was backed up by brief testimony that I had heard from the experts (including the experts presented by the petitioners' representatives) who testified during the Omnibus Proceeding. Those experts during the Omnibus Proceeding hearings expressed agreement with

the proposition that if an individual had one of a number of specified conditions, then it would be impossible to say that such individual's arthropathy was vaccine-caused *even if* that individual's history fit the other criteria, including the circumstance of onset shortly after a rubella vaccination.[(5)] That list of specified disqualifying conditions included Sjogren's Syndrome, one of the conditions suffered by the petitioner here. *See* Omnibus Order at 10 (1993 WL 179430 at *6).

Accordingly, based upon the testimony of respondent's expert in petitioner's case, as supported by the evidence from the Omnibus Proceeding, I concluded that petitioner's chronic arthropathy was *not* likely vaccine-caused, but was "more probably than not" caused by petitioner's autoimmune dysfunction, a dysfunction that predated the petitioner's rubella vaccination and therefore must be unrelated to the vaccination.

B. Ruling upon review

Petitioner sought review of my decision by a judge of this Court, pursuant to § 300aa-12(e). In her review motion, petitioner raised a new legal theory that not only had not been advanced before me prior to my Decision in this case, but, to my knowledge, had not been raised previously in the history of the Program. That is, petitioner suggested a new way of interpreting the scope of a petitioner's burden of showing "actual causation," arguing that my own interpretation of the statutory scheme, as applied to this case, was erroneous.

Petitioner's argument is based upon the structure of § 300aa-13(a), which provides as follows:

§ 300aa-13. Determination of eligibility and compensation

(a) General rule

(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.

* * *

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"--

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, * * *.

Thus, § 300aa-13(a)(1) provides that to grant a Program award, a special master must reach two conclusions. First, under subsection (A), the special master must find that the petitioner has demonstrated the matters required in § 300aa-11(c)(1). Second, under subsection (B), the special master must conclude that there is *not* a preponderance of evidence in the record that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine."

In turn, § 300aa-11(c)(1) provides that a petitioner must make a number of different showings. But in the area relevant here, subsection (C) of § 300aa--11(c)(1) provides the two different basic avenues for showing "causation" of the vaccinee's injury by the vaccination. Subsection (C)(i) provides the "Table Injury" route--*i.e.*, if an injury listed in the "Vaccine Injury Table," found at 42 U.S.C. § 300aa-14(a), occurred within the time period prescribed in that Table, then the injury may be *presumed* to qualify for compensation. Subsection (C)(ii) then provides the alternative route, often described as "actual causation" or "causation-in-fact." Under this alternative, if the injury does not fall within the Vaccine Injury Table, the petitioner simply must show that the injury was "caused by" the vaccine in question.

Looking at this overall scheme for demonstrating "causation," petitioner pointed to the fact that under § 300aa-13(a)(1)(B), it doesn't matter whether the petitioner made the initial "causation" showing under the "Table Injury" route or the "actual causation" route--in either event, the special master still must then make the additional finding that the injury was *not* due to "factors unrelated to the *** vaccine." Petitioner noted further that in making this finding, the special master is to disregard any potential "factors unrelated" that are "idiopathic" (meaning "of unknown cause"), pursuant to § 300aa-13(a)(2)(A). Petitioner argued that considering these statutory provisions together, one should conclude that when a petitioner attempts to make an *initial showing of "actual causation"* under § 300aa-11(c)(1)(C)(ii), as part of the showing under part (A) of § 300aa-13(a)(1), the special master should *disregard* any evidence in the record that relates to potential non-vaccine causes of the injury that are "idiopathic" in nature. Therefore, petitioner argued, my six-part test set forth above for use in the rubella arthropathy "actual causation" cases was erroneous, because as my sixth criterion I required the petitioner to demonstrate that she has never received any of a certain list of diagnoses. Petitioner noted that included in that list of diagnoses were a number of conditions--including a condition from which petitioner suffers, Sjogren's Syndrome--that are, in fact, "idiopathic" in nature. Therefore, petitioner argued, the sixth part of my test was erroneous in taking into account, in effect, potential causes for petitioner's condition that are "idiopathic."

In his opinion filed on January 6, 1977, Judge Bruggink found merit in petitioner's argument. The judge indicated that the sixth part of my six-part test erred (1) by in effect placing upon the *petitioner* the burden of "disproving" potential alternative causes for her condition, and (2) by considering potential arthritis causes that are "idiopathic." 37 Fed. Cl. at 139. Accordingly, the judge remanded the case to me "for further proceedings not inconsistent with this opinion." *Id.*

V

RESOLUTION OF ISSUES ON REMAND

My task on remand is to apply the legal principles set forth by Judge Bruggink, which are now the "law of the case," to the facts of this case. My understanding of those legal principles is summarized in the following two sentences. That is, petitioner retains the burden of demonstrating it "more probable than not" that her chronic arthritis was vaccine-caused. However, in deciding whether petitioner has carried that burden, I am to disregard any potential causes of her arthritis which would amount to "idiopathic" causes under § 300aa-13(a)(2).

Applying that law to this case, I find that petitioner has demonstrated "actual causation" in this case. For reasons fully set forth in my Omnibus Order, I have concluded that if a petitioner's case of chronic arthropathy arose under a particular set of circumstances (*i.e.*, the circumstances set forth in my first five criteria set forth above) and there is no other good explanation for the arthropathy (*i.e.*, the sixth criterion), then it would appear "more probable than not" that such arthropathy was vaccine-caused. Now,

it is clear that under the "law of the case," I am to *disregard* any potential causes of petitioner's arthritis that are "idiopathic" in nature. And in this case, it is clear that only one good non-vaccine explanation for petitioner's chronic[(6)] arthritis appears in the record--*i.e.*, petitioner's autoimmune dysfunction, which respondent's own expert acknowledges to be a dysfunction of unknown cause.[(7)] Therefore, because the cause of petitioner's autoimmune dysfunction is not known, I have no choice but to treat that dysfunction as an "idiopathic" factor, and *exclude* it from my consideration of whether petitioner has demonstrated "actual causation" in this case. And with that factor so excluded, all the other evidence in this case--*i.e.*, the fact that petitioner's chronic arthritis otherwise arose under a time frame and under circumstances such that it could plausibly have been vaccine-caused--points toward vaccine-causation of petitioner's chronic arthritis.

Respondent's arguments to the contrary on remand have not been persuasive. In her briefs filed on February 10 and April 2, 1997, her motion filed on March 7, 1997, and her counsel's oral argument presented on February 26, 1997, respondent raised several arguments. First, respondent pointed out that petitioner's symptoms began only *six days* after her vaccination, whereas in most vaccine-caused cases symptoms have their onset between *one week* and six weeks post-vaccine. But respondent's expert did *not* point to that fact as a disqualifying factor at the evidentiary hearing in this case. More importantly, my clear sense from the Omnibus Proceeding hearings was that the experts in that proceeding would not quibble about symptoms arising six rather than seven days post-inoculation. Their point, rather, was that it would take *about* one week for the rubella virus to sufficiently replicate in a person's system to cause significant symptoms. I thus find that the six-day history here is not a disqualifying factor.

Second, respondent's counsel has suggested or implied that petitioner's condition of Hashimoto's thyroiditis "caused" petitioner's chronic arthritis. However, this is clearly contrary to the testimony of respondent's own expert, who explained that the Hashimoto's thyroiditis did not cause the arthritis, but, like the arthritis itself, is merely another symptom of the underlying autoimmune dysfunction.

Third, respondent has at times seemed to suggest that petitioner's receipt of the drug Allopurinol in December of 1987 might have been the cause of her *chronic* arthritis. But such a notion would clearly be wrong. As discussed at pp. 9-10 and n. 9 of my initial Decision in this case, it is *possible* that a "serum sickness" reaction to her Allopurinol treatment could explain petitioner's symptoms for a *few months* after December of 1987, but such a "serum sickness" could *not* explain her *chronic* arthritis.

Finally, during oral argument, respondent's counsel pointed out that while Judge Bruggink's opinion seems to indicate the judge's assumption that I found the *Sjogren's Syndrome* to be the likely cause of petitioner's chronic arthritis, in fact it is the *autoimmune dysfunction* that I found to be the cause of *both* the chronic arthritis and the Sjogren's Syndrome. Respondent's counsel seemed to contend at that oral argument that while *Sjogren's Syndrome* might be an "idiopathic" factor, the "autoimmune dysfunction" should not be considered to be an idiopathic factor. Accordingly, by my Order dated March 14, 1997, I gave respondent the opportunity to explain why the *autoimmune dysfunction* should not be disqualified as an "idiopathic" factor. Respondent's resulting brief, filed on April 2, 1997, however, made no serious attempt to do so. Rather, respondent actually *conceded* that "the 'cause' of petitioner's underlying autoimmune dysfunction is idiopathic" (brief at 1), and then added little more than a general complaint that this statutory "idiopathic" restriction on the "factor unrelated" showing, as interpreted by the Federal Circuit (*see Koston v. Secretary of HHS*, 974 F.2d 157 (Fed. Cir. 1992), and *Whitecotton v. Secretary of HHS*, 17 F.2d 374, 377-78 (Fed. Cir. 1994), rev'd on other point, *Shalala v. Whitecotton*, 514 U.S. 268 (1995)) puts an unfairly difficult burden on respondent concerning the "factor unrelated" issue. Respondent may or may not be right in this complaint, but I am bound to interpret the statutory term "idiopathic" in a straightforward fashion, and I am also bound by the applicable Federal Circuit precedent. Under that precedent, petitioner's autoimmune dysfunction, the cause of which is unknown, would appear to be an "idiopathic" factor disqualified under § 300aa-13(a)(2), and I so conclude.

In short, for the reasons stated above, I conclude that under the "law of the case" handed down by Judge Bruggink in this proceeding, petitioner has met her burden of showing that her chronic arthritis was "actually caused" by her rubella vaccination. Also, it appears to me that she has fulfilled all the other requirements set forth in § 300aa-11(c)(1), so that petitioner has complied with § 300aa-13(a)(1)(A). Finally, since respondent relies only upon the autoimmune dysfunction, an "idiopathic" factor, it is clear that respondent cannot make a showing of "factor unrelated" under § 300aa-13(a)(1)(B). Petitioner, therefore, has qualified for a Program award in this case.

VI

ADDITIONAL DISCUSSION

A. Introduction

This final section of this Ruling will contain my own discussion of the legal issue raised by petitioner on review. Of course, there is no question that *the judge's* ruling upon this legal issue is the "law of the case," controlling this case on this remand. I have ruled upon the factual issue in the case, as set forth above, in conformity with that judge's ruling. Therefore, my own thoughts on this legal issue constitute pure *dicta*, not essential to my task on this remand. However, in the peculiar circumstances of this case, it may be appropriate that I set forth these thoughts, for several reasons. First, because petitioner's theory was never raised until after I filed my Decision in this case, it may be helpful to the ultimate resolution of this case that I explain the understanding of the law upon which I based that Decision. Second, petitioner's theory leads to an interpretation of the "actual causation" avenue of proof that is radically different from any that has been set forth in any published opinion during the Program's existence. In addition, this new interpretation comes at a time when the number of Program cases involving difficult, controversial "actual causation" questions seems likely to increase significantly.[(8)] Accordingly, since I have given considerable thought to petitioner's theory in the context of this remand proceeding, it seems appropriate that I lay out my thoughts on this issue for the benefit of those making any further legal rulings in this or other Program cases.

B. My prior assumption ("respondent's interpretation")

To begin with, I will briefly explain my assumption, upon which my original Decision in this case was based, as to the proper allocation of the burden of persuasion in "actual causation" cases. I start again by setting forth the controlling statutory provision, § 300aa-13(a)(1):

§ 300aa-13. Determination of eligibility and compensation

(a) General rule

(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 that 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.

Under this provision, as noted previously, to grant a Program award, a special master must reach two conclusions. First, under subsection (A), the special master must find that the petitioner has demonstrated the matters required in § 300aa-11(c)(1). Second, under subsection (B), the special master must conclude that there is *not* a preponderance of evidence in the record that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine."

In turn, § 300aa-11(c)(1) provides that a petitioner must make a number of individual showings. But in the area relevant here, subsection (C) explains the two alternative avenues for showing "causation" of the vaccinee's injury by the vaccination. Subsection (C)(i) provides the "Table Injury" route--*i.e.*, if an injury listed on the "Vaccine Injury Table," found at 42 U.S.C. § 300aa-14(a), occurred within the time period prescribed in that Table, then the injury will be *presumed* to qualify for compensation. Subsection (C)(ii) then provides the alternative, "actual causation" route; under this alternative, the petitioner simply must show that the injury was "caused by" the vaccine in question.

Looking at this overall scheme for demonstrating entitlement to a Program award, then, under § 300aa-13 (a)(1)(B) it doesn't matter whether the petitioner made the initial "causation" showing under the "Table Injury" route or the "actual causation" route--in either event, the special master still must then make the finding that the injury was *not* due to "factors unrelated to the ***vaccine." However, my view of that overall scheme has always been that when the "actual causation" route is successfully utilized by a petitioner, it would be by definition *impossible* for the respondent to then make a successful "factor unrelated" showing under § 300aa-13(a)(1)(B). That is, my view has been that for a petitioner to make the necessary "actual causation" showing, there must be a preponderance of *all the evidence in the record* indicating that the injury was vaccine-caused. And, of course, if this is true, then by definition there could *not* be a preponderance of evidence in the same record indicating causation by some factor other than the vaccination.

The key point, therefore, is that it was my assumption that for a petitioner to make his *initial showing* that his injury was "caused by" the vaccination under § 300aa-11(c)(1)(C)(ii), he must make the showing by a preponderance *of all the evidence in the record*, not by a preponderance of some restricted subset of evidence. The restriction against considering evidence as to "idiopathic" factors, in my view, applied only to an inquiry as to "factor unrelated," which inquiry would take place, if at all, only after a petitioner had already made his initial showing of either a "Table Injury" or "actual causation."

Now, in light of petitioner's argument made on review in this case, and the reviewing judge's conclusion that such argument has merit, it is evident that a different interpretation of the overall scheme can reasonably be proposed. Accordingly, in the following subsection, I will set forth my views as to the problems with each of the two opposing interpretations. In this discussion, I will refer to the interpretation urged by the petitioner and adopted by the judge in this case as "petitioner's interpretation." I will refer to the contrary interpretation set forth immediately above, which has been my own interpretation and also appears to be the respondent's interpretation, as the "respondent's interpretation."[(9)]

C. Difficulties with each of the two opposing interpretations

To begin with, I acknowledge the existence of a problem with respondent's interpretation of the statutory scheme, set forth immediately above. That is, under respondent's interpretation, if a petitioner's initial showing under § 300aa-11(c)(1)(C) is made under the "actual causation" rather than the "Table Injury" route, then the second inquiry under § 300aa-13(a)(1)(B), as to whether the respondent can show

causation by a "factor unrelated," becomes a formality, with the respondent precluded as a matter of logic from ever successfully making such a showing. This has always been a bit troubling. Why would Congress design a statutory scheme requiring such a redundant, formalistic inquiry? And does this apparent anomaly created by respondent's interpretation indicate that perhaps this interpretation is a faulty one?

My answer to these questions has been simply that Congress must have understood that the inquiry under § 300aa-13(a)(1)(B) would be important only in the cases where the showing under § 300aa--11(c)(1)(C) was made via the "Table Injury" route. Congress must have understood that, on the other hand, the § 300aa-13(a)(1)(B) inquiry would be redundant if, instead, "actual causation" had already been shown. But, merely for convenience of statutory drafting, it was easier to place the inquiry in a clause in the statute whereby the inquiry would apply nominally in both types of cases. Thus, the § 300aa-13(a)(1)(B) inquiry would be very important and relevant in "Table Injury" cases, while in the "actual causation" cases, where that inquiry would as a matter of logic be redundant, it would be a harmless redundancy, causing perhaps an extra sentence to be inserted in the factfinder's opinion, but not requiring any additional analysis.

At the same time, I also perceive a very serious problem with the competing statutory interpretation that the petitioner has advanced in this case. That is, petitioner's interpretation would mean that the "actual causation" issue in Program cases would become an issue *very different* from "actual causation" issues in non-Program tort proceedings. It would seem that the "actual causation" test would in effect be converted into a mere "plausibility" test. And it seems to me highly questionable whether Congress actually intended such a wholly new and radically different type of inquiry. I will elaborate upon this concern below.

I begin by noting that in a non-Program tort proceeding in which a plaintiff is alleging that his injury was caused by a vaccination, the plaintiff must prove "actual causation;" *i.e.*, it is the plaintiff's burden to demonstrate by a "preponderance of the evidence" that the vaccination actually caused the injury in question. *See, e.g., Hasler v. United States*, 718 F.2d 202, 204 (6th Cir. 1983), *cert. denied*, 469 U.S. 817 (1984); *Novak v. United States*, 865 F.2d 718, 725 (6th Cir. 1989). In such an inquiry, quite obviously, it is relevant whether there is evidence indicating that the injury was caused by some *factor other than* the vaccination; to the extent that such evidence exists, that evidence logically makes it *less* likely that the vaccination caused the injury. Indeed, under the "preponderance of the evidence" standard, the existence of the fact to be proved must be shown to be "more probable than not." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring). This means, in effect, that in a tort proceeding, a plaintiff must show that the likelihood that the vaccination caused the injury is greater than the likelihood that any other factors caused the injury. In other words, the evidence that the vaccination caused the injury must be weighed *directly against* any evidence indicating that any other factor caused the injury.

Under the petitioner's interpretation of the statute, however, the "actual causation" inquiry in Program proceedings would become a wholly different type of inquiry. First, pursuant to § 300aa-11(c)(1)(C)(ii), the petitioner would nominally be required to demonstrate that the vaccination "actually caused" the injury in question. But in this inquiry, the factfinder would *not* look to *all* of the evidence in the record; rather, the factfinder would be *forbidden* to consider any evidence relating to *any other potential cause* for the injury. Then, if the petitioner carries that burden, pursuant to § 300aa-13(a)(1)(B), the factfinder would next determine whether there exists a preponderance of the evidence indicating that the injury was due to "factors unrelated." In deciding that issue, the factfinder would then, of course, be able to consider certain evidence that had been disregarded in the initial inquiry--*i.e.*, evidence relating to potential *non-vaccine* causes. But even then, the factfinder would still be restricted to considering only evidence relating to *non-idiopathic* potential alternative causes; the factfinder would still be forbidden from considering evidence relating to *idiopathic* potential causes.

Thus, under petitioner's statutory interpretation, a Program "actual causation" inquiry would be an inquiry far different from a tort proceeding "actual causation" inquiry, because in the first stage of the inquiry, the factfinder would intentionally disregard evidence relating to potential non-vaccine causes. But, one must ask, what does it really mean to say that an "actual causation" determination must be made without regard to evidence of potential non-vaccine causes? How does one actually evaluate the question of whether the vaccination caused the injury, while intentionally disregarding evidence of other potential causes? In my view, by disregarding at this stage evidence of other potential causes, the "actual causation" inquiry is essentially converted into a "plausibility" test. That is, the petitioner would need to demonstrate, by scientific evidence, that the vaccine in question *can* cause the type of injury in question. The petitioner then would need to show that his own particular injury arose in circumstances making it *possible* that the vaccination could have caused the injury--for example, demonstrating that the *onset* of the injury's symptoms took place during the time frame after vaccination that would be expected for a vaccine-caused injury. By making these showings, a petitioner would then seem to have demonstrated it *plausible* that the vaccination caused the injury. In a tort proceeding, of course, the petitioner would then need to additionally quantitatively compare the likelihood of vaccine causation with the likelihood of other potential causes. But in the Program setting, under petitioner's statutory interpretation, this showing of "plausibility" would seem to be enough by itself to satisfy § 300aa-11(c)(1)(C)(ii).

To be sure, under petitioner's statutory interpretation, a petitioner's satisfaction of this "plausibility" test would not end the case. The respondent would then be entitled, pursuant to § 300aa-13(a)(1)(B), to attempt to demonstrate that the injury was more likely caused by some non-vaccine factor, *if* such factor was a *non-idiopathic* one (*i.e.*, if the *cause* of that factor was known). But my experience in Program proceedings has taught me that demonstrating a *non-idiopathic* "factor unrelated" can be an extremely difficult task. At this time, in many areas of medical science, researchers have been able to identify syndromes or disease patterns, without yet identifying the *cause thereof*. In many cases, therefore, the respondent may be able to demonstrate that an injury was part of a recognized syndrome that *predated* the vaccination in question, without being able to say what *caused* that syndrome. Such syndrome would therefore be an idiopathic factor, *not* qualifying as a "factor unrelated" in the inquiry under § 300aa-13(a)(1)(B).[(10)]

The question that troubles me concerning petitioner's proposed interpretation, then, is whether Congress could have actually intended that the "actual causation" inquiry in Program cases be so radically different from the "actual causation" inquiry in non-Program tort proceedings. It is true, of course, that in setting up the *Table Injury* categories, Congress clearly intended to provide a method for establishing causation that was new, distinct, and greatly simplified from the "actual causation" approach of tort proceedings. But at the same time, Congress set up the "actual causation" route as an *alternative* method for establishing causation. And I have found nothing in the legislative history indicating either that Congress intended the "actual causation" inquiry in Program cases to function in the same way that it does in tort cases, or that Congress intended a new and different type of "actual causation" inquiry. Given this dearth of legislative history, it seems to me to be highly questionable whether Congress, *in addition* to setting up the Table Injury method of proof, also intended to so fundamentally alter the "actual causation" inquiry. Had Congress intended also to fundamentally alter the "actual causation" inquiry, would not that intent have been noted in the legislative history? It seems more likely to me that Congress intended that, absent a Table Injury, the type of inquiry with respect to an "actual causation" claim would be *similar* to the inquiry that previously was made in tort cases.

D. Precedent

As explained above, as far as my research indicates, petitioner's statutory interpretation at issue here was never advanced in any Program case until petitioner advanced it on review in this case. Accordingly, it is

not surprising that there exists relatively little precedent relevant to this issue prior to the judge's opinion in this case. But there does exist *some* relevant case law, which would seem to support the respondent's interpretation.

1. *Federal Circuit opinions*

Several opinions of the United States Court of Appeals for the Federal Circuit are relevant. First, in *Munn v. Secretary of HHS*, 970 F.2d 863 (Fed. Cir. 1992), the court summarized the "actual causation" avenue of proof 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." *Id*. at 865 (emphasis added). In this sentence, the Federal Circuit arguably was indicating approval of the interpretation that I have labeled the "respondent's interpretation." That is, by including the clause emphasized above, the court indicated that it viewed the "actual causation" inquiry as a *single-stage* inquiry in which evidence as to *both* vaccine-causation and potential non-vaccine causation would be considered simultaneously, with the burden of persuasion on the *overall* issue resting upon the petitioner ("claimant must prove").

A case containing a similar indication is *Bunting v. HHS*, 931 F.2d 867 (Fed. Cir. 1991). In *Bunting*, the court stated that in an "actual causation" setting, "causation must be established by a preponderance of the evidence *as a whole*." *Id*. at 871 (emphasis added). By including the words "as a whole," the court arguably was indicating that in the "actual causation" inquiry, the factfinder should evaluate *all* of the evidence of record. This would be in contrast with petitioner's interpretation here, in which the factfinder is to initially disregard all evidence as to non-vaccine factors, and ultimately disregard all evidence as to idiopathic non-vaccine factors.

Next, the Federal Circuit pronouncement most clearly relevant here is found in *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992). In *Grant*, after reviewing the statute and legislative history relating to "actual causation" claims, the court stated as follows:

The [Vaccine] Act relaxes proof of causation for injuries satisfying the Table in § 300aa-14, but *does not relax proof of causation in fact for non-Table Injuries*.

Id. at 1148 (emphasis added). The *Grant* court, thus, in asserting that the Program statute "does not relax proof of causation in fact," obviously was comparing the Program standard for "actual causation" to the standard for "actual causation" in a *tort proceeding*. The court clearly, then, was interpretating the Program scheme *exactly as does the respondent here--i.e.*, the court understood that the "actual causation" (also known as "causation in fact") inquiry under the Program is to be *the same* (*i.e.*, "not relaxed") as in "actual causation" inquiries in tort proceedings.

Finally, another discussion of the "actual causation" avenue of proof was contained in *Jay v. Secretary of HHS*, 998 F.2d 979 (Fed. Cir. 1993). The Federal Circuit therein contrasted that method of proof to the "Table Injury" route, and noted that "causation in fact" in a Program case was "[a]nalogous to tort law." *Id*. at 984. Again, the implication is that the *Jay* court was assuming that the "actual causation" inquiry in Program proceedings was to be the same as in tort proceedings, as respondent argues here.

2. *Opinions of Court of Federal Claims Judges*

Similarly, several opinions of *judges* of this Court seem to indicate approval of the respondent's interpretation on the point revelant here. First, Judge Gibson's opinion in *Johnson* v. *Secretary of HHS*, 33 Fed. Cl. 712 (1995), *aff'd* 99 F.3d 1160 (Fed. Cir. 1996), is relevant here. In discussing the "actual causation" method of proof, the court observed:

In essence, then in non-Table cases, the relevant inquiry to be undertaken by the special master is collapsed into a *single determination*: *On the record as a whole, has the petitioner proven*, by a preponderance of the evidence, that her injury was in fact caused by the administration of a listed vaccine, rather than by some other superseding intervening cause?

Id. at 72 (emphasis added). Thus, in Judge Gibson's view, the factfinder is in effect to make a "single determination" based upon the "record as a whole," with the burden on the "petitioner." This view obviously supports the respondent's interpretation as to the statutory issue here.

Three other judges' opinions offer a similar view. In *Strother v. Secretary of HHS*, 21. Cl. Ct. 365 (1990), Judge Rader utilized the same language as did the Federal Circuit in *Grant*, above -- i.e., stating that "the [Vaccine] Act relaxes proof of causation for injuries satisfying the Table in §300aa-14, *but does not relax proof of causation in fact.*" *Id*. at 370 (emphasis added). Similarly, in *Shaw v. Secretary of HHS*, 18 Cl. Ct. 646 (1989), the same judge opined as follows:

The Act, in addition to providing compensation for injuries meeting the Table's legal standards for causation, also compensates individuals who can show that a vaccine in fact caused their injury. The traditional causation in fact standard governs vaccine tort cases in state and federal courts outside the Act. *See, e.g., Alvarez v. United States*, 495 F. Supp. 1188, 1206 (D. Col. 1980). These other state and federal vaccine tort cases are not subject to the compensation limits of the Act.

Id. at 650. This statement, as well, implies the understanding that the "actual causation" inquiry in a Program proceeding would be governed by the *same* "traditional causation in fact standard [that] governs vaccine tort cases *** outside the Act." *Id*.

Lastly, another opinion that directly supports the respondent's interpretation here is *Gurr* v. *Secretary of HHS*, 37 Fed. Cl. 314 (1997). In that case, Judge Robinson observed that in the context of the Program, "[p]roving causation-in-fact requires proof of actual causation *as in traditional tort law* ***." *Id*. at 319 (emphasis added).

3. *Opinions of Court of Federal Claims Special Masters*

Finally, I note that a number of published decisions of Program *special masters* have also expressed an interpretation of the statute in accord with respondent's interpretation here. For example, in *Samuels* v. *Secretary of HHS*, No. 91-127V, 1995 WL 809884 (Fed. Cl. Spec. Mstr. Aug. 1, 1995), Chief Special Master Golkiewicz stated that in a Program "actual causation" case--

the burden rests on petitioner to show that the vaccination in question more likely than not caused the specific injury using the *same methods that apply in traditional tort litigation*, including the preponderance of the evidence stardard.

Id. at *1, emphasis added. Similarly, in *Candelas* v. *Secretary HHS*, No 90-759, 1991 WL 1877316 (Cl. Ct. Spec. Mstr. Sept. 5, 1991), Special Master Baird stated that:

[t]he standards which apply in determining whether an illness, injury, or condition was actually caused by a vaccine listed on the Table are the *same standards which apply in traditional tort litigation*.

Id. at *4, emphasis added.

In *Einspahr* v. *Secretary of HHS*, No 90-923V, 1992 WL 336396, at *6 (Fed. Cl. Spec. Mstr. Oct. 28, 1992), Special Master Edwards stated succinctly that "[t]he same legal standards for actual causation which apply in traditional tort litigation apply in Program cases." Special Master Abell reached the same conclusion in *Guy* v. *Secretary of HHS*, No. 92-779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995), noting as follows:

The burden rests on the petitioner to show that the vaccination in question more likely than not caused the specific injury, under the *same standards which apply in traditional tort litigation*, in which the same "preponderance of the evidence" standard applies.

Id. at *1, emphasis added. And Special Master French concurred in *Bobbitt* v. *Secretary of HHS*, No. 90-1156V, 1992 WL 159524 (Fed. Cl. Spec. Mstr. June 10, 1992), stating:

[T]he standards which apply in determining whether an illness or condition was actually caused by a vaccine listed on the Table are the *same standards which apply in traditional tort litigation*.

Id. at *2, emphasis added.

Finally, I note also that in *Gherardi v. Secretary of HHS*, No. 90-1466V, 1997 WL 53449 (Fed. Cl. Spec. Mstr. Jan. 24, 1997), *aff'd* by unpublished order (Fed. Cl. Aug. 28, 1997), Chief Special Master Golkiewicz took note of the fact that the judge's opinion in this *Wagner* case seems to conflict with some of the earlier caselaw cited above. *Id*. at n. 16. The special master indicated that his own view was in line with the earlier precedent. *Id*.

In short, substantial case law under the Program supports the respondent's interpretation on the legal point at issue here, while I have found none (prior to the judge's opinion on review in this case) adopting petitioner's view.

E. Concern regarding "disproving" alternative causes

Another closely related but analytically distinct concern was raised in the judge's opinion in this case. The court observed that under the sixth criterion of my six-part test, set forth above, I required that the petitioner demonstrate that she had never received one of a series of specified diagnoses. As noted above, the judge found this requirement to be improper under the statute because it allowed consideration of "idiopathic" non-vaccine factors. The court was troubled also, however, by the possibility that this criterion --

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

37 Fed. Cl. at 139. In light of this expressed concern, it appears that some additional explanation of this sixth criterion of my test would be appropriate.

First, it should be kept in mind that these criteria were developed chiefly for the purpose of qualifying petitioners for awards, in appropriate cases, *without the need for an expert opinion specific to each case*. That is, if a petitioner's history met all of the criteria, then in effect the expert opinions taken in the Omnibus Proceeding would serve as the expert medical opinion for that petitioner,[(11)] qualifying the petitioner for an award. Thus, it was anticipated that in most cases, the sixth criterion would be satisfied

simply by the petitioner's own sworn representation that she had never received a diagnosis of one of the listed conditions (assuming that such representation was not contradicted by the records of her medical care). In these cases -- and there have been a great many that actually received an award in this fashion (*see* n. 4 *supra*) -- there would not even be a need for an expert opinion, much less the need for the petitioner to "affirmatively prove that an infinite number of potential causes were not at work" (37 Fed. Cl. at 139).

Further, it should also be stressed that even in cases that do not meet the criteria, an award is not necessarily foreclosed. Instead, as in this case, the petitioner is given an opportunity to offer expert testimony supporting the view that, nevertheless, the petitioner's particular condition was vaccine-caused. Indeed, precisely because this entire area is on the "frontier" of medical science--where the data is limited, no medical consensus exists, and better evidence could emerge at any time--I have stressed to each such petitioner that I am willing to listen to new medical opinion and evidence in any case, to supplement or even contradict the evidence taken during the Omnibus Proceeding.

Finally, in cases where the petitioner does offer a case-specific expert opinion, such as this one, I do not see it as a an inappropriate burden to require a petitioner to demonstrate that the likelihood that her condition was vaccine-caused is greater than the likelihood that it was caused by any non-vaccine factor. In my view, that is simply inherent in the "more probable than not" test. In other words, as a matter of logic, to show that it is "more probable *than not*" that factor *A* caused condition *B* means, in my view, that one must show that the probability that factor *A* was the cause is greater than the likelihood that the cause was *any other factor*. That is, in the phrase "more probable than not," the words "than not" should be viewed as the equivalent of "than any other factors."

But that does *not* mean that a petitioner's expert must "affirmatively prove that an infinite number of potential causes were not at work" (37 Fed. Cl. at 139), listing every possible cause and then specifically discussing each one. As a practical matter, a petitioner's expert usually states simply that he or she is familiar with the other potential causes of arthropathy, and is of the opinion that none of those causes explain the condition of the petitioner in question. This statement ordinarily will carry the petitioner's burden, unless the respondent's expert then points to a *particular* non-vaccine cause, and supplies evidence pointing to such cause in that particular case.

In short, the sixth criterion of my six-part test was not intended to place upon petitioners, and in my view has not in practice placed upon petitioners, a burden stricter than intended under the statute.

F. Conclusion

In sum, the legal question here, concerning which of the two differing interpretations of the "actual causation" method of proof is correct, is not a simple one. Reasonable minds can certainly differ on this issue. As demonstrated above, the respondent's interpretation seems to have been the one assumed by most (if not all) of the special masters and judges who have interpreted the provision, at least until the review motion in this case. But, on the other hand, the judge's opinion on review in this case demonstrates that a reasonable case for a contrary interpretation can be made. Based upon all of the considerations discussed above, my own opinion is that while the petitioner's interpretation has some appeal, the respondent's interpretation is the superior one. My chief reason is simply that the petitioner's approach would change the "actual causation" inquiry too radically from an "actual causation" inquiry in a tort case, without any indication in the legislative history that Congress intended that such a different test be applied. While it is *possible* that Congress intended such an alteration of the "actual causation" inquiry, on balance I do not think it *likely* that Congress so intended. Consequently, I would uphold respondent's interpretation.

VII

FURTHER PROCEDURE

In light of my conclusion stated in part V of this Ruling, above, the parties shall continue to work on the "damages" issue in this case, as directed in my order filed on May 19, 1997.

_____

George L. Hastings, Jr.

Special Master

1. The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq*. (1994 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (1994 ed.).

2. In 1995 and again in 1997, the Secretary of Health and Human Services promulgated administrative changes to the Table, adding "chronic arthritis" as a "Table Injury" for the rubella vaccine. These changes, however, apply only to Program cases filed on or after March 10, 1995. See 60 Fed. Reg. 7678 (1995); 62 Fed. Reg. 7685 (1997). Moreover, I note that even had these changes to the Table been in effect, the fact that petitioner has Sjogren's Syndrome might nevertheless still disqualify her from a Program award under the new regulatory language, which explicitly lists Sjogren's Syndrome as a disqualifying factor.

3. My prior decision in this case did not address the issue of whether petitioner has demonstrated that she incurred more than $1000 in unreimbursable expenses due to her joint symptoms. (See § 300aa-11(c)(1)(D)(i).) However, petitioner filed evidence concerning that issue in the form of Ex. 7, filed on March 16, 1993, and Ex. 8, para. 4, filed on August 16, 1993. At a status conference held on January 19, 1994, and again in my order filed on January 24, 1994, respondent was instructed to make a written filing by February 23, 1994, if she contended that the documentation contained at Ex. 7 failed to satisfy the "$1000 requirement." Respondent made no such filing. Accordingly, at that time, based upon my own review of Exs. 7 and 8, I concluded that petitioner had made the requisite showing concerning the "$1000 requirement" of § 300aa-11(c)(1)(D)(i).

4. In his opinion on review in this case, the judge indicated a potential concern about the propriety of my practice of applying the evidence gathered in the Omnibus Proceeding to cases that were not directly involved in that proceeding. *See* 37 Fed. Cl. at 138 n 4. Of course, this is a general concern that was considered fully within the Office of Special Masters even before the Omnibus Proceeding was initiated. The decision to pursue the Omnibus Proceeding resulted from the fact that a large number of Program cases appeared to involve resolution of a single medical/scientific issue, an issue that would require examination of a very large body of evidence. It seemed clear that it would be efficient as to both time and cost to conduct an initial comprehensive investigation into that issue, then apply the knowledge gained from that inquiry to the individual cases. But a concern was that, for obvious logistical reasons, it

would be impossible for every petitioner's counsel in every then-pending Program case that could potentially be affected by the Omnibus Proceeding (then already about 60 cases) to participate in the evidentiary hearing portion of that Proceeding. Thus, petitioners whose counsel did not participate in the evidentiary hearing portion of the Omnibus Proceeding (including, of course, petitioners such as the petitioner here, whose cases were not yet filed or assigned to a special master until after the Omnibus Proceeding) could potentially be affected by the evidence gained in that proceeding. Accordingly, the Chief Special Master and I considered whether it would be fair and appropriate for this evidence to affect the cases of petitioners who did not participate in the Omnibus Proceeding evidentiary hearings. After due consideration, we considered that it would be appropriate.

The chief reason is the very nature of the factfinding system set up under the Program. Congress assigned this factfinding task to a very small group of special masters, who would hear, without juries, a large number of cases involving a small number of vaccines. Congress gave these masters extremely broad discretion in deciding how to accept evidence and decide cases. (*See, e.g.*, § 300aa-12(d)(2).) Congress charged these masters to resolve such cases speedily and economically, with the minimum procedure necessary, and to avoid if possible the need for an evidentiary hearing in every case. *Id*; *see also* H.R. Rept. No. 99-660, at 16-17 (*reprinted in* 1986 U.S.C.C.A.N. 6344, 6357-58). Congress even specified that a master should be "vigorous and diligent in *investigating*" Program factual issues (H.R. Rept. 99-660, *supra* at 17 (emphasis added)), in an "inquisitorial" fashion (H.R. Rept. No. 101-247, at 513 (*reprinted in* 1989 U.S.C.C.A.N. 1906, 2239)), indicating that a master can and should actively seek out, on his own, evidence beyond that presented by the parties to a particular case. Given this factfinding system, it would appear quite likely that Congress intended that the special masters would gain expertise in factual issues, including "actual causation" issues, that would repeatedly arise in Program cases. It would appear that Congress *intended* that knowledge and information gained by the masters in the course of Program cases would be applied by the masters to other Program cases, when appropriate. A number of published opinions have recognized that this Congressional intent is implicit in the factfinding system devised by Congress. *See*, *e.g., Ultimo v. Secretary of HHS*, 28 Fed. Cl. 148, 152-53 (1993); *Loe v. Secretary of HHS*, 22 Cl. Ct. 430, 434 (1991). *See also Munn v. Secretary of HHS*, 970 F.2d 863, 873 (Fed. Cir. 1992) (appropriate for special master to rely upon written expert report introduced into evidence, even though petitioner had no opportunity to cross-examine the expert).

The idea of utilizing an "omnibus proceeding" to gather information applicable to a significant number of Program cases, therefore, would seem to fit clearly within this Congressional intent. This procedure not only allows a master to bring special expertise to particular cases, but also helps the Program to accomplish the Congressional goals of speedy and economical resolution of cases. This general procedure, therefore, has been utilized not only in the "rubella arthropathy" cases before me, but also for two other large groups of cases, *i.e.*, the "poliomyelitis" cases before Chief Special Master Golkiewicz (*see*, *e.g., Gherardi v. Secretary of HHS*, No. 90-1466V, 1997 W.L. 53449 (Fed. Cl. Spec. Mstr. Jan. 24, 1997)) and the "tuberous sclerosis" cases before Special Master Millman (*see, e.g., Costa v. Secretary of HHS*, 26 Cl. Ct. 866, 868 (1992)).

Of course, the masters managing these groups of cases have also taken care to ensure that the rights of individual petitioners to fair resolution of their cases is not lost in the efficiency of an "omnibus proceeding." For example, the procedure for taking evidence in my own Omnibus Proceeding with respect to the rubella arthropathy cases was devised in large part by *petitioners'* counsel--*i.e.*, two law firms that each represented many of the then-pending rubella arthropathy petitioners. (In fact, one of those two firms represents the petitioner in this case.) These law firms identified medical literature for my review, and selected half of the medical experts who testified during the Omnibus Proceeding evidentiary hearings. Moreover, before, during, and since the Omnibus Proceeding, I have stressed to petitioners' counsel in these rubella arthropathy cases that every individual petitioner has the right to offer additional relevant evidence and to challenge the validity of the evidence received during the Omnibus Proceeding.

The primary evidentiary materials utilized in the Omnibus Proceeding have always been available to every petitioner, and an opportunity for an additional evidentiary hearing has been afforded to every petitioner so requesting. (In this regard, I note that the "Notice" issued in this and other pending rubella arthropathy cases on February 7, 1997, was merely intended as a reminder to petitioners concerning information expressed repeatedly to petitioners on prior occasions, in status conferences and individual written orders in individual cases.)

Given the above-described Program factfinding system devised by Congress, accompanied by all the procedural safeguards described above, I have been satisfied that it is appropriate for me to utilize the evidence gained in the Omnibus Proceeding with respect to individual petitioners' cases. And I also note that, in general, the rubella arthropathy Omnibus Proceeding has been of great benefit to individual petitioners. Prior to this Ruling, in 61 such cases I have given written or informal oral rulings concerning the issue of whether a petitioner's chronic arthropathic symptoms were vaccine-caused. In 51 of those 61, I have found that the petitioner did in fact make the required "causation" showing. (*See, e.g., Long v. Secretary of HHS*, No. 94-310V, 1995 WL 470286 (Fed. Cl. Spec. Mstr. July 24, 1995).) In almost all of those cases, the petitioners gained awards based *exclusively* upon the medical evidence obtained in the Omnibus Proceeding, without the need to supply further evidence relating to the "causation" issue. Further, approximately 25 additional petitions remain pending before me at this time involving "rubella arthropathy" causation issues, with more such cases constantly being filed, so that many more petitioners may benefit from the Omnibus Proceeding.

In short, in my view the Omnibus Proceeding procedure has proved quite successful in fostering the Program goals of achieving accurate, inexpensive, and prompt resolution of Program claims, while still providing fair and appropriate consideration of each individual claim.

5. *See* discussion of this point at footnote 7 of my original Decision in this case.

6. As discussed at pp. 9-10 and n. 9 of my initial Decision in this case, it is *possible* that a "serum sickness" reaction to her Allopurinol treatment could explain petitioner's symptoms for a *few months* after December of 1987, but such a "serum sickness" could not explain her *chronic* arthritis.

7. *See, e.g.*, the letter of Dr. Borenstein filed with respondent's motion on March 7, 1997, in which he states that "the specific mechanism that initiates the autoimmune disorder is not known."

8. As noted above, administrative changes have been made recently to the "Vaccine Injury Table." (See citations at fn. 2, above.) These changes involve adding to the Table new vaccines for which *no* specific Table Injuries are listed, so that *all* cases with respect to such vaccines will involve allegations of "actual causation." Further, the Table Injury categories for the vaccines generating the most Program cases--*i.e.*, "DPT" and "MMR" vaccines--have been materially changed, eliminating "seizure disorder" entirely as a Table Injury and radically narrowing the scope of the "encephalopathy" category. Accordingly, many cases that would formerly have fit within these Table Injury categories, cases involving seizures or other serious neurologic symptoms manifested *very* soon after such vaccinations, may in the near future raise difficult questions of "actual causation."

9. As will be discussed *infra* (pp. 16-18), this theory has also been implicitly endorsed or explicitly adopted in a number of published decisions of judges and special masters, and *seems* to have been the working theory under which most or all the special masters and judges have addressed "actual causation" cases during the initial eight years of the existence of the Program.

10. This very case offers a good example. Here, the onset of petitioner's arthritis took place during a time period making it *plausible* that the arthritis was vaccine-caused. Therefore, petitioner's case passes the

§ 300aa-11(c)(1)(C)(ii) test under petitioner's statutory interpretation thereof, as adopted by the reviewing judge. The respondent then demonstrated to my satisfaction that it is likely that, despite the timing of the onset, petitioner's arthritis is more probably due to an underlying autoimmune dysfunction. But because we don't know what *caused* that dysfunction, it is an "idiopathic" factor not qualifying as a "factor unrelated" pursuant to § 300aa-13(a)(1)(B).

11. I note that it was a special goal in these "rubella arthropathy" cases to minimize the litigation costs that a petitioner would need to incur in a particular case. That is, because the "damages" awards in these cases are limited -- in many cases, the available "damages" consist only of an amount for "pain and suffering." And in cases involving vaccinations occurring prior to October 1, 1988, available "pain and suffering" awards are restricted by the "cap" provision of §300aa-15(b), which limits the *total* available for attorneys' fees, costs, lost wages, *and* "pain and suffering" to $30,000. Therefore, a goal of the Omnibus Proceeding was to develop a set of criteria which could quickly qualify some petitioners for awards, thereby minimizing attorneys fees and eliminating the need for a costly expert witness, and therefore making most of the $30,000 "cap" amount available for a "pain and suffering" award. As noted above (n. 4), the Omnibus Proceeding criteria have in fact served that goal, qualifying dozens of petitioners for awards with minimal proceedings and costs.