**OFFICE OF SPECIAL MASTERS**

**No. 94-444V**

**(Filed: November 25, 1997)**

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| BETTY GRAVES, | * | |
| Petitioner, | * | **TO BE PUBLISHED** |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |

***Edward Spence, III, Pittsfield, Massachusetts, for petitioner.***

***Aristia Karas, Department of Justice, Washington, D.C., for respondent.***

**DECISION**

**HASTINGS, Special Master.**

This is an action seeking an award under the National Vaccine Injury Compensation Program (hereinafter "the Program"[(1)]). For the reasons stated below, the undersigned special master concludes that petitioner is not entitled to such an award.

**I**

**STATUTORY BACKGROUND**

Under the National Vaccine Injury Compensation Program (hereinafter "the Program"), compensation awards are made to individuals who have suffered injuries after receiving certain vaccines. The primary requirement for obtaining an award is that the petitioner must establish a *causal link* between a vaccination and his or her injury. There are two separate means of establishing that causal link. First, if an injury listed on the "Vaccine Injury Table," found at § 300aa-14(a), occurred within a time period after vaccination specified 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 the arthritic condition from which she has suffered over the last several years was caused by the rubella component of the measles, mumps, and rubella ("MMR") vaccination that she received on July 18, 1991. That "MMR" vaccination is one listed in the Vaccine Injury Table, but petitioner does not allege that she suffered any of the specific injuries listed in the Table for that vaccination, so this case does not involve an allegation of a "Table Injury."[(2)] Instead, the issue here[(3)] is whether petitioner has successfully demonstrated that her condition was "more probably than not"[(4)] *caused by* that vaccination.

## II

## PETITIONER'S CONDITION

The petitioner, Betty Graves, was 52 years of age on July 18, 1991, when she received a measles, mumps, and rubella (MMR) inoculation. Prior to that date, petitioner apparently had not consulted any medical personnel concerning any chronic symptoms of an arthritic nature. On August 12, 1991, petitioner called her physician, Dr. Patricia Lehmann, to report that she was suffering joint pains. (Ex. 3[(5)], p. 24.) She visited Dr. Lehmann on August 20, reporting at that time

that her pain had begun, in her hand, knee, and hip joints, about August 8, three weeks after her inoculation. (*Id*.) She also reported, however, that she had experienced "stiffness" in the morning "for months prior" to her MMR inoculation. (*Id*.) At that time, Dr. Lehmann apparently found one index finger joint to be swollen, noting the absence of any other observable ("objective") evidence of arthritis. (*Id*.)

In phone calls on August 30 and September 9, 1991, petitioner again reported to Dr. Lehmann that she was experiencing joint pain. (Ex. 3, p. 33.) Dr. Lehmann then referred petitioner to a rheumatologist, Dr. Philip Volastro, who saw petitioner on October 21, 1991. Petitioner reported to Dr. Volastro on that date that she had experienced pain, swelling, and/or stiffness in her hands, feet, knees, ankles, and shoulders. (Ex. 4, pp. 34-35.) On examination of her joints, Dr. Volastro found swelling in a number of hand and foot joints, though none in her knees or hips. (*Id*. at 35.)

In his initial written comments about petitioner's case, on October 21, 1991, Dr. Volastro found the three-week interval between petitioner's MMR vaccination and the onset of significant joint pain to be "highly suggestive" of a reaction to the vaccine. (*Id*.) He also noted, however, that he was quite concerned about the possibility of "rheumatoid arthritis." (*Id*.)

Petitioner continued to visit Dr. Volastro over the next several years, for treatment of pain and swelling in her joints. In his office notations concerning a number of those visits, Dr. Volastro recorded that it was

his "impression" or his "diagnosis" that petitioner was suffering from "rheumatoid arthritis." (Ex. 4, pp. 8, 9, 11, 12, 13, 14, 16, 18, 19, 20, 22, 23, 25.)

In 1992, petitioner sought another opinion concerning her arthritis. After evaluating petitioner on May 14, 1992, Dr. William DeMarco concluded that petitioner had "apparent reactive arthritis," with a "[q]uestion of underlying rheumatoid arthritis." (Ex. 5 at 3.)

The records of petitioner's visits to Dr. Volastro show that petitioner experienced joint pain and swelling throughout the rest of 1991, 1992, 1993, and into January of 1994. (Ex. 4 at pp. 5-25.) According to the testimony of two experts at the evidentiary hearing in this case (held on January 7, 1997), she had X-rays done on her hands and feet in 1994, which showed some reduced bone mass ("periarticular osteopenia") and erosions in her joints. Petitioner apparently continues to experience arthritis in multiple joints.

## III

## MEDICAL BACKGROUND: THE GENERAL ISSUE OF

## THE RELATIONSHIP BETWEEN THE RUBELLA

## VACCINE AND CHRONIC JOINT SYMPTOMS

The issue here--*i.e.*, whether a person'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* medical/scientific issue of whether rubella vaccinations can cause persistent joint pain and related joint symptoms, and, if so, in what circumstances. That inquiry involved extensive research into the relevant medical literature, as well as evidentiary hearings in which I heard the testimony of a number of medical experts. The history of that inquiry was set forth in an Order filed in 70 Program cases on January 11, 1993, and will not be repeated here. (That Order was electronically published under the caption *Ahern et al. v. Secretary of HHS*,

No. 90-1435V, 1993 WL 179430 (Fed. Cl. Spec. Mstr. January 11, 1993); it was placed into the record of this case by my Order dated July 25, 1994. I will hereinafter refer to that Order as the "Omnibus Order.") 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--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, but still later by a recurrence or persistence of more swelling, or simply 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 in the particular case*--attribute the chronic symptoms to the vaccination.

As will be seen in the pages that follow, the petitioner here argues that her history of symptoms falls within the general pattern described to me by the experts and the documentary evidence described above. The respondent points out, however, significant ways in which the petitioner's history diverges from that pattern.

I also note that in the pages to come, I will at times 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."[(6)] 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, and "arthritis," defined as *objective findings* in a joint of swelling, redness, heat, and/or limitation of motion. The chief distinction between the key terms of "arthralgia" and "arthritis" is that only the latter involves objective findings observable by a physician. "Arthralgia," by definition, means that the patient reports joint pain, but no objective findings are observable. In addition, I will utilize the terms "chronic" and "acute" to distinguish between two different stages of arthropathic symptoms in a vaccinated individual. The stage following soon after the inoculation, usually starting one to six weeks thereafter and lasting from one week to several weeks, will be designated as the "acute" stage. Any symptoms that occur thereafter, on an ongoing basis, will be deemed the "chronic" stage.[(7)]

## IV

## DISCUSSION

### *A. Summary of expert testimony*

It may be helpful to begin by summarizing the views of each of the two experts who testified in this proceeding, at an evidentiary hearing held on January 7, 1997. Dr. Philip Volastro, who has been petitioner's regular treating rheumatologist, testified that his view is that petitioner's history is largely typical of the pattern of chronic arthropathy following rubella vaccination described above in part III of this opinion. Dr. Volastro is heavily influenced by the fact that petitioner's reports of polyarticular arthropathy began just one month following her MMR vaccination containing the rubella vaccine. Based upon that chronology, Dr. Volastro opined, it seems probable that petitioner's chronic arthritis was vaccine-caused. Further, while Dr. Volastro acknowledges that during much of the time period during which he was treating the petitioner he used the term "rheumatoid arthritis" as his "working definition" of petitioner's condition (Tr. 25), he now doubts that her condition falls within that category.

Respondent's expert, rheumatologist Dr. Alan Brenner, disagrees with Dr. Volastro. Dr. Brenner opined that petitioner's history differs greatly from the typical pattern of chronic post-rubella arthropathy, described in the Omnibus Order, in that she apparently had morning stiffness in her joints for several months *predating* the vaccination. He also believes that petitioner does in fact have rheumatoid arthritis, a type of arthritis which, Dr. Brenner asserts, has not been shown to be vaccine-caused. Dr. Brenner testified further that the physical changes that have been observed in petitioner's joints, while common in rheumatoid arthritis, are not typical of chronic post-rubella arthropathy, or of virally-caused arthritis in general, casting further doubt on the theory that petitioner's arthritis was vaccine-caused.

### *B. Analysis*

I have carefully considered the evidence submitted in this case, including the opinions of both of the well-qualified experts. Both sides made important points, and ultimately the issue is not completely free from doubt. But in the final analysis I conclude that petitioner has failed to show that it is "more probable than not" that her chronic arthritis was caused by the rubella vaccination.

***1. Pre-existing symptoms***

One important aspect of this case is the evidence indicating that prior to the onset of her observable arthritis in August of 1991, petitioner had a months-long history of arthropathic symptoms that *predated* the vaccination in question. The most crucial record consists of the notes recorded by Dr. Lehman on August 20, 1991. (Ex. 3, p. 24.) There, after first describing the hip, hand, and knee symptoms that petitioner had reported as occurring since August 8, Dr. Lehman added the following line: "AM stiffness for months prior to MMR." (*Id*.) In addition, other records indicate that in November of 1990 petitioner experienced swelling of either one or both ankles. That is, petitioner told Dr. Lehman on August 20, 1991, that on or about November 29, 1990, she had "Rt. ankle swelling." (Ex. 3, p. 24.) On October 21, 1991, she told Dr. Volastro himself that "last October [she] had swelling of her ankles for no apparent reason. Aching crept up into her calves * * *." (*Id*. at 34.) Further, Dr. Volastro's notes made on October 21, 1991, also indicate that petitioner reported that "[m]orning stiffness has been quite significant lasting 3-4 hours." (*Id*.)

To be sure, these few notations in the medical records do not provide much detail as to the nature and extent of petitioner's pre-vaccination joint symptoms. For example, with respect to the reports of ankle swelling in late 1990, the most contemporaneous medical record is a record of an emergency room visit by petitioner on November 29, 1990, which notes only pain in the left *calf*. (Ex. 3, pp. 21-22.) But it also clear that in 1991 petitioner reported to *both* Dr. Lehman (Ex. 3, p. 24) and Dr. Volastro (Ex. 3, p. 34) that she had *ankle swelling* in late 1990. To Dr. Volastro, she added that the ankle swelling then "crept up into her calves." (Ex. 3, p. 34.) Thus, although ankle swelling is not mentioned in the emergency room record made on November 29, 1990, it seems to me extremely likely that petitioner *did* have some ankle swelling in late 1990, sometime during the weeks prior to the emergency room visit.

Similarly, the two notations concerning the "morning stiffness" are certainly less than precisely clear. Indeed, if one looks only at Dr. Volastro's note (Ex. 3, p. 34), the placement of the sentence about "morning stiffness," directly after a sentence dealing with neck pain, might suggest that the "morning stiffness" being described there was only in petitioner's neck area, and thus might be something totally separate from the polyarthritic symptoms that petitioner clearly exhibited after August of 1991. However, in Dr. Lehman's note (Ex. 3, p. 24), the report of "AM stiffness" follows after the notation of "joint pain" and specific mention of hip, hand, and knee symptoms, suggesting that the reported stiffness was a general joint phenomenon.

Dr. Brenner testified that the fact that petitioner reported "AM stiffness" in her joints "for months prior to" her MMR immunization (Ex. 3, p. 24) is important evidence for the proposition that her arthritic history since 1991 was *not* vaccine-caused. (See, *e.g.*, Tr. 42.) The logic behind that testimony seems straightforward. That is, one common symptom of arthritis is "morning stiffness," meaning that the joints are *especially* stiff during the minutes or hours directly after the person wakes up in the morning. And petitioner, of course, began experiencing *observable* arthritis beginning in August of 1991. Therefore, since petitioner had "morning stiffness" in her joints for months *soon followed by* the onset of observable arthritis, it seems distinctly possible that the two phenomena are part of the same condition or disease process. And if they are part of the same condition, since the "morning stiffness" *predated* the MMR vaccination, then that condition obviously could not have been vaccine-caused.

Indeed, that reasoning seems particularly strong in light of one additional aspect of petitioner's case. That is, as will be discussed in detail in the next section of this Decision, petitioner's arthritis fits within the formal diagnostic criteria for the form of arthritis known as "rheumatoid arthritis." And Dr. Brenner explained that rheumatoid arthritis commonly *begins* subtly, with episodes of morning stiffness predating observable arthritis. (Tr. 42.[(8)]) Petitioner's case seems to perfectly fit that pattern, adding to the reason

for concluding that the pre-vaccination morning stiffness was likely related to her subsequent full-scale arthritic course, and that therefore that overall condition could *not* have been vaccine-caused.[(9)]

I also note one further point concerning the issue of these pre-vaccination symptoms--that it is questionable whether Dr. Volastro has realistically taken them into account in reaching and adhering to his opinion of vaccine-causation in this case. First, at the evidentiary hearing, when confronted with Dr. Lehmann's notation that petitioner had "AM stiffness for months prior to MMR" (Ex. 3, p. 24), Dr. Volastro seemed a bit surprised, responding that-- "well, it would be of interest. I did not have that history when I had seen her." (Tr. 26.) To be sure, Dr. Volastro then added that the history of pre-existing stiffness would not be enough to change his opinion (*id.)*, but he really never explained that statement or gave an explanation for the pre-vaccination symptoms.

Further, Dr. Volastro's post-hearing letter contained the following statement:

It should be made clear that Mrs. Graves did not have stiffness for months prior to 8/21/91. The only stiffness that she had was reported in the Hillcrest Hospital record dated 11/29/90. Those records showed that she had pain in her calf. Calf pain is not a symptom or sign of rheumatoid arthritis.

(See letter filed on May 27, 1997.) This statement seems to indicate that when Dr. Volastro wrote his post-hearing letter, he fundamentally misunderstood the facts of petitioner's case. The statement totally ignored the incontrovertible fact of Dr. Lehmann's note, quoted above. It also ignores the above-described notations concerning ankle-swelling in both Dr. Lehmann's and Dr. Volastro's own notes.

The fact that Dr. Volastro made such a demonstrably wrong statement in his letter of May 1997 certainly makes it appear that Dr. Volastro has never truly taken into account petitioner's pre-vaccination morning stiffness symptoms. Indeed, it calls into question the credibility of his entire opinion in this case.

***2. Rheumatoid arthritis***

As described above, one dispute between the two experts was whether petitioner's arthritis is accurately characterized as "rheumatoid arthritis." A discussion of this point, therefore, is in order. "Rheumatoid arthritis" (hereinafter "RA") is a term used to describe chronic arthritis that fits within a certain set of defined criteria. Specifically, a person with chronic arthritis will be diagnosed with RA if the case fulfills at least four of seven criteria set forth by the American College of Rheumatology, *and* the case does not fit within any of the other recognized categories of arthritis. (Tr. 26-27, 63-66; see also William N. Kelley et al., *Textbook of Rheumatology*, pp. 898-99, 902-03[(10)] (5th ed. 1997). The cause of RA is unknown. (Tr. 63; *see also* Kelley et al., *supra*, at 852--"[T]he etiology of RA remains a mystery * * *.") It seems likely that there are a number of different causes, which simply have not yet been identified. (*See* Tr. 63-64.)

It is relevant to determine whether petitioner's case is one of RA because, as Dr. Brenner argued, the evidence that the rubella vaccine can cause *RA*, as opposed to non-rheumatoid arthritis, is slim. For example, in the course of the hearings held during the Omnibus Proceeding, all three of the experts who addressed this issue indicated that the evidence for vaccine-causation would be far less strong if the arthritis constituted RA rather than non-rheumatoid arthritis. The two experts for the respondent testified that if an individual had RA, vaccine causation was unlikely, even assuming the onset of symptoms shortly after a rubella vaccination. (*See* 1-Omn. Tr.[(11)] 117; 2-Omn. Tr. 380-81.) Even the petitioners' expert who addressed the issue, Dr. Aubrey Tingle, a leading researcher and advocate for the view that the rubella vaccine causes chronic arthritis, candidly acknowledged that the evidence for vaccine-causation would be far less strong in the case of RA. (1-Omn. Tr. 41-42; 57-59.) Indeed, when asked

whether he could say that a case of RA that arose within the appropriate post-vaccination period was "more probably than not" vaccine-caused, Dr. Tingle declined to do so, indicating that even with such a temporal relationship the overall weight of the evidence concerning the causation issue would be virtually evenly balanced ("a toss-up"). (1-Omn. Tr. at 58.) And the reason for this distinction between RA and non-rheumatoid arthritis, made by all three of those Omnibus Proceeding experts, seemed to be simply that the data connecting RA, as opposed to non-rheumatoid arthritis, to the rubella vaccine was extremely scant.[(12)] (See, *e.g.*, 1-Omn. Tr. 117.)

With respect to the petitioner here, the two experts in this case agreed that petitioner's arthritis does meet at least four of the seven criteria for RA.[(13)] (Tr. 27-30, 48-49.) But Dr. Volastro nevertheless argued that petitioner's case should *not* be considered to be RA. Dr. Volastro's argument, as I understood him, is that a diagnosis of RA is appropriate only when at least four of the criteria are met *and a cause for the arthritis cannot be determined*. (*See*, *e.g.*, Tr. 63-66.) Dr. Volastro argues that petitioner's arthritis should be viewed as caused by the rubella vaccination, and therefore *by definition* should not be considered to be RA.

While this argument of Dr. Volastro has some initial appeal, ultimately I must reject it as logically flawed. This argument in essence is an exercise in semantics rather than logic. The first important point is that, apparently, of the cases of chronic arthropathy with onset shortly after rubella vaccination studied by Dr. Tingle's group and other researchers, very few (if any) have *fallen within the diagnostic criteria for RA*.[(14)] Therefore, even if a few of the observed post-vaccine cases did fall within the RA criteria,[(15)] that number would be far too small upon which to reasonably base a conclusion that the rubella vaccine can cause RA. Any such isolated cases falling within the RA criteria could easily have had their onset after vaccination solely by chance, as the testimony of Dr. Tingle and the other Omnibus Proceeding experts acknowledged.

Logically, then, the key point here, as Dr. Brenner argued, is that petitioner's case *falls within the basis diagnostic criteria for RA*, a circumstance which is *extremely untypical* of the cases of chronic arthropathy that have been observed after rubella vaccination and have been suspected to be vaccine-caused. It matters little whether the label "RA" has been or should be formally applied to petitioner's case.[(16)] As a matter of logic, what is important is whether petitioner's case *meets the basic criteria* for RA--which, of course, it does.

In sum, then, the important fact that petitioner's case *does meet the diagnostic criteria for RA* makes petitioner's case untypical of the observed cases of chronic post-rubella arthropathy. And this deviation is another important factor arguing against a conclusion that petitioner's arthritis is vaccine-caused.

***3. Erosive joint changes***

Another important factor in this case, which is closely related to the issue of RA, is the fact that radiographic images show that petitioner has suffered erosive changes in her hand and wrist joints--*i.e.*, joint erosions. The two experts agree that this is the case. (*See*, *e.g.*, Tr. 19-20, 28, 44, 48-49.)
Dr. Brenner argued that the existence of joint erosions, while typical of RA, is quite untypical of chronic post-rubella arthropathy. (Tr. 41, 76.) He also pointed out that even in arthritis caused by other types of viruses (the rubella vaccine contains a weakened form of the rubella virus), erosive joint changes would be unknown or exceedingly rare. (Tr. 41.) Dr. Volastro acknowledged that Dr. Brenner was generally correct, in that erosive changes are *not* usually seen with post-rubella arthropathy. (Tr. 19.) He stated, however, that he found it possible that if a case of chronic rubella-caused arthritis lasted long enough, it would result in joint erosions. (Tr. 19, 31, 36, 71.)

At the hearing, Dr. Volastro explained that while he believed that chronic post-rubella arthropathy could cause joint erosions, he was unsure whether any medical literature existed to support that theory. (Tr. 31-32.) Accordingly, at the conclusion of the evidentiary hearing, I suggested that Dr. Volastro examine the literature and see if he could find any evidence to that effect. (Tr. 90-92.) Petitioner did indeed file some medical literature, in the form of 16 post-trial exhibits filed on February 6, 1997. However, after carefully examining the literature and post-trial written comments submitted by both Dr. Brenner (*see* Ex. C filed April 4, 1997, and Ex. D filed on July 1, 1997) and Dr. Volastro (*see* letter filed on May 27, 1997), I find that it tends to support Dr. Brenner's argument, rather than that of Dr. Volastro. Specifically, Dr. Volastro's literature search did not produce a single case in which a person with chronic post-rubella arthropathy had erosive joint changes. To the contrary, as Dr. Brenner pointed out (Ex. C, p. 1), the articles submitted concerning persons with chronic post-rubella arthropathy (post-trial Exs. 5, 6, 7, and 16) do not report any erosive changes.

To be sure, Dr. Volastro did submit two articles[(17)] relevant to Dr. Brenner's general point that joint erosions are not typically seen with arthritis caused by *any virus*. First, Dr. Volastro submitted an article identifying a single individual, with arthritis thought to be caused by a *parvovirus*, who had joint erosions. (Post-trial Ex. 1.) But Dr. Brenner responded with a discussion explaining that there is a good chance that this single case was mere coincidence. (Ex. C, p. 2.) Dr. Volastro also submitted an article showing that joint erosions are seen in persons with "HIV," the human immunodeficiency virus. (Post-trial Ex. 2.) But Dr. Brenner explained persuasively that the arthritis in HIV patients is not a direct result of that virus. (Ex. C, pp. 1-2; Ex. D.) In short, Dr. Brenner's *general* point that *virally-caused arthritis* usually does not result in joint erosion has not been substantially weakened, in my view, by the post-trial literature submitted by petitioner. And certainly Dr. Brenner's more *specific* point that joint erosions have not been documented in *post-rubella* arthritis remains unchallenged. Accordingly, I find that the fact that the petitioner in this case does have joint erosions is another significant piece of evidence weighing against the view that her chronic arthritis was vaccine-caused.

***4. Summary***

Based chiefly upon a combination of the facts that (1) petitioner had "morning stiffness" that predated her vaccination, (2) petitioner's condition falls within the criteria for RA, a condition untypical of chronic post-rubella arthropathy, and (3) petitioner has experienced point erosions, which also[(18)] are not typical of chronic-post rubella arthropathy, I conclude it is *not* "more probable than not" that petitioner's chronic arthritis was vaccine-caused.

## V

## CONCLUSION

After considering her case, it is impossible not to feel sympathy for petitioner's arthritic condition. However, for reasons set forth above, I have found petitioner's theory of proof in this case to be unsupported by the overall record. Thus, in this case, the evidence simply does not

support a causal link between any aspect of petitioner's condition and her vaccination. I therefore decide that petitioner does not qualify for a Program award in this case.

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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 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. Those 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); 42 CFR § 100.3. Moreover, I note that even had those changes to the Table been in effect, the fact that petitioner's chronic arthritis fits within the diagnostic criteria for "rheumatoid arthritis" would likely still disqualify her from a Program award under the new regulatory language, which explicitly lists rheumatoid arthritis as a disqualifying factor. *See* 42 CFR § 100.3(b)(6)(ii).

3. There may also be a dispute concerning whether petitioner has demonstrated that she incurred more than $1000 in unreimbursable expenses due to her arthritis. Due to my resolution of petitioner's "causation" claim, however, there is no need for me to reach that issue.

4. Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than not." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

5. Petitioner filed eight numbered exhibits with her petition on July 11, 1994. Hereinafter, "Ex. __" references will be to those exhibits.

6. It has been questioned whether it is appropriate that I apply evidence obtained during the Omnibus Proceeding to the individual cases of petitioners who did not themselves participate in that Proceeding. I have addressed that issue at length in *Wagner v. Secretary of HHS*, No. 90-2208V, 1997 WL 617035, at *17 n.4 (Fed. Cl. Spec. Mstr. Sept. 22, 1997). I also note that in this case, after I placed the Omnibus Order into the record on July 25, 1994, the fact that I would rely upon the evidence gathered during the Omnibus Proceeding was discussed at the first status conference, held on December 21, 1994. See also my orders dated July 25, 1994, February 7, 1997, and April 10, 1997.

7. It may be noted that as a result of the "Omnibus Proceeding" and subsequent proceedings in individual cases, thus far a significant number of cases, each involving allegations of arthropathy caused by a rubella vaccination, have been fully or partially resolved. In 61 cases, prior to this case, I have given written or informal oral rulings concerning the issue of whether a petitioner's chronic arthropathic symptoms were vaccine-caused. In 10 of those, I have found that the petitioner has failed to make the required "causation" showing. (See, *e.g.*, *Awad v. Secretary of HHS*, 1995 W.L. 366013, No. 92-79V (Fed. Cl. Spec. Mstr. June 5, 1995.) In the other 51, I have concluded that the requisite showing of causation *was* made. (See, *e.g.*, *Long v. Secretary of HHS*, 1995 W.L. 470286, No. 94-310V (Fed. Cl. Spec. Mstr. July 24, 1995).)

8. The fact that rheumatoid arthritis often begins with morning stiffness is confirmed at William N. Kelley et al., *Textbook of Rheumatology* 900 (5th ed. 1997).

9. I also note, concerning the topic of evidence of possible *pre-vaccination* joint disease, that Dr. Brenner pointed out that X-rays of petitioner taken in 1991 showed slight joint-space narrowing in petitioner's hands. (Tr. 49-50.) The two experts agreed that *if* that narrowing was the result of an inflammatory process, such process would necessarily have predated the vaccination here in question. (Tr. 34, 50.) Dr. Brenner indicated the view that the narrowing quite possibly was the result of a pre-vaccination inflammatory process, further indicating that petitioner's arthritis predated her vaccination. (Tr. 49-50.) At the hearing, Dr. Volastro expressed disagreement with Dr. Brenner on this latter point, indicating that the narrowing was slight and not a particularly unusual finding, and was probably unconnected to the arthritis that petitioner has manifested since August of 1991. (Tr. 32-35.) However, it is noteworthy that in 1991, Dr. Volastro wrote that the narrowing was suggestive of "early degenerative disease of her hands." (Ex. 4, p. 1.)

In the final analysis, I do not place any weight on this point, since Dr. Brenner ultimately acknowledged that he was not as qualified as a radiologist to evaluate the significance of the narrowing seen on the 1991 X-rays. (Tr. 77.) I note the existence of the 1991 X-rays simply as *possible additional* evidence of a pre-vaccination joint disease process.

10. At p. 903, the textbook adds that "[O]ther diseases must be excluded before the diagnosis of RA is made," then begins a list of the other forms of arthritis that must be excluded.

11. I refer to the transcript of the evidentiary hearings held during the Omnibus Proceeding. "1-Omn. Tr." will refer to the hearing held on November 12, 1992; "2-Omn. Tr." will refer to the hearing held on November 13, 1992. The specific pages of that transcript to which I refer above were placed into the record of this case by my Order filed on April 10, 1997. *See also* my Order dated Feb. 7, 1997, in which I explained the availability of these transcripts to the parties in this case.

12. The fact that these three Omnibus Proceeding experts were unwilling to say that the rubella vaccine can cause RA seems likely to be fairly representative of the medical community. For example, even the petitioner's expert in this case, Dr. Volastro, acknowledged in his hearing testimony that "no one's willing to say that vaccines can cause RA." (Tr. 64.)

13. Dr. Brenner believes that petitioner meets a fifth criterion as well--see Tr. 49.

14. In contrast, a much larger number of cases of *non-rheumatoid* arthritis have been observed with onset soon after rubella vaccination, enough to justify the general conclusion that it is *probable* that the rubella vaccine can cause chronic *non-rheumatoid* arthritis.

15. I also note that I invited Dr. Volastro to submit post-trial medical literature in this case (*see* Tr. 90-92), and he did so in the form of 16 post-trial exhibits filed on February 6, 1997. It is noteworthy that this literature seems generally to confirm the point that the vast majority of cases of chronic post-rubella arthropathy have *not* involved RA. That is, in the several articles dealing with chronic post-rubella arthropathy, only *one* individual is noted to have fallen within the RA criteria. (*See* post-trial Ex. 5, p. 608.) And while that individual had the presence of rheumatoid factor, the individual apparently did not have the erosive joint changes suffered by the petitioner here. (*Id.*)

16. It is noteworthy, however, that in the course of actually treating petitioner, Dr. Volastro, in his office notations concerning many of petitioner's visits, indeed recorded that it was his "impression" or his "diagnosis" that petitioner was suffering from "rheumatoid arthritis." (Ex. 4, pp. 8, 9, 11, 12, 13, 14, 16, 18, 19, 20, 22, 23, 25; note that Dr. Volastro often used the abbreviations "RA" for "rheumatoid arthritis" and "Dx" for "diagnosis.")

17. Dr. Volastro has also suggested that post-trial Exhibits 3, 4, and 5 show that "viral infections can cause erosion." (See his letter filed on May 27, 1997, p. 1.) But I can find no mention of joint erosion in Ex. 5. And Exs. 3 and 4 relate to Lyme disease, which, as Dr. Brenner pointed out (Ex. D), is apparently *not* virally-caused.

18. Of course, it is in fact the existence of petitioner's *joint erosions* that provides the crucial fourth criterion, putting petitioner's case within the diagnostic criteria for RA. Therefore, I am well aware that, in effect, points 2 and 3 above are in fact virtually two different ways of making a *single* point.