OFFICE OF SPECIAL MASTERS
No. 92-429V
(Filed: January 20, 1998)

ALECIA BILOTTI,	
Petitioner,	**TO BE PUBLISHED**
v.	
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Respondent.	

James B. Ford, Kalamazoo, Michigan, for petitioner.

Catharine Reeves, 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.[(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 thought to be caused by certain vaccines. There are two separate 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 be awarded for injuries not listed on the Table, if the petitioner demonstrates 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 other symptoms that she has reported over the last several years were caused by a rubella vaccination that she received on June 30, 1989. The rubella 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 vaccination, so this case does not involve an allegation of a "Table Injury."(2) Instead, the issue here is whether petitioner has successfully demonstrated that her symptoms were "more probably than not"(3) *caused by* that vaccination.

II

PETITIONER'S CONDITION

The following facts are essentially undisputed, and I so find. The petitioner, Alecia Bilotti, is an unfortunate woman who has had a complicated medical history in recent years. While petitioner was born in 1963, the record in this case relates chiefly to events occurring since the mid-1980's. Petitioner was involved in an automobile accident in 1985 or 1986, after which she suffered low back pain. (1-Tr. at 16-17.(4)) In November of 1987, she suffered a spontaneous abortion. (Ex. 1, p. 1.(5)) In late 1988, she again became pregnant. (*Id.*) On January 31, 1989, in the course of her prenatal care, petitioner reported that she had a history of "dizziness and headaches [HA's] since prior pregnancy." (Ex. 5, p. 1.)

On June 29, 1989, petitioner delivered her child, and on the following day, June 30, she received a rubella vaccination. (Ex. 2, p. 29.) On July 3, 1989, at about 8:00 a.m., a few hours before she was discharged from the hospital, she complained of a headache. (Ex. 2, pp. 30, 49.) On July 6, 1989, petitioner went to a hospital emergency room, reporting a slight fever and a headache that lasted all day. (Ex. 4, p. 2.)

Petitioner's medical records do not show any further trips to medical personnel with respect to headaches or other pain symptoms in 1989, after the July 6 visit. On January 24, 1990, however, petitioner visited Dr. Dunne, a neurologist, and reported that she had been suffering from headaches and dizziness since the birth of her child. (Ex. 6, p. 1.) On January 26, 1990, petitioner watched an episode of the television program "20/20," which discussed the issue of whether the rubella vaccine can cause chronic viral-type symptoms, especially chronic joint pain, muscle pain, swollen lymph nodes, and fatigue. (1-Tr. 21; *see also* Resp. Ex. E, filed on March 31, 1995.) On February 23, 1990, she returned to see Dr. Dunne, bringing along a transcript of that television program, and reporting that she was "firmly of the belief" that her "problems began with the vaccine." (Ex. 6, p. 3.) On March 28 and April 4, 1990, she again visited hospital emergency rooms, again, reporting headaches. (Exs. 7, 8.)

Sometime prior to June 7, 1990, petitioner wrote letters to Dr. Aubrey Tingle and Dr. Janet Chantler, both of whom had appeared in the "20/20" episode. (Ex. 20, pp. 4-5, 13-15.(6)) With the letter to Dr. Tingle, she filled out a "Data Collection Form" (Ex. 20, pp. 6-13), which indicated that about *four days* after her rubella inoculation, she had the onset of pain in her whole body (*id.* at 8). In her letter to Dr. Chantler, she indicated that she had the onset of "whole body" pain on July 6, 1989, along with a headache. (*Id*. at 13.)

On May 1, 1990, petitioner visited Dr. Mark Leohrke. Again petitioner's chief complaint was headaches, but at this visit she also reported that she had been experiencing enlarged lymph nodes, body aches including her joints, dizziness, and fatigue. (Ex. 21, p. 2.) She also stated that the symptoms had existed

intermittently since "about a week" after her rubella vaccination, when she had the "abrupt onset" of severe headaches, body aches, and fevers. (*Id*.)

Since the summer of 1990, petitioner has reported similar symptoms to a number of physicians, often relating that such symptoms began about a week after her rubella vaccination. (*E.g.*, Ex. 22, p. 3; Ex. 23, p. 1.) Her physicians, however, apparently, have not detected any *objective* evidence of abnormality in the joints. (*E.g.*, Ex. 23, p. 2--"Physical Examination" notes "no erythema or swelling in joints;" Ex. 24, p. 2--"no swelling or erythema of the 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 qualified medical experts. The history of that inquiry was set forth in an Order filed in this case and 69 other Program cases on January 11, 1993, and will not be repeated here. (I will hereinafter refer to that Order as the "Omnibus Order."[(7)]) 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 which 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 at this point 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."[(8)] 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, then, 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.

IV

DISCUSSION

A. Summary of respective expert theories

It may be helpful to begin by summarizing the views of each of the two experts who testified in this proceeding.(9) Dr. Daniel Braun, a specialist in infectious diseases, testified that in his view the petitioner's history was in some respects typical of the pattern of chronic arthropathy following rubella vaccination described in the Omnibus Proceeding (see part III of this opinion). In this respect, Dr. Braun was relying upon petitioner's representations that her current chronic symptoms had their onset abruptly in the few days following her rubella vaccination. (1-Tr. 56-57, 97-98.) Assuming that chronology, and with no evidence of any other cause for petitioner's condition, Dr. Braun opined, it seems probable that petitioner's chronic symptoms since 1989--*i.e.*, headache, muscle ache, joint ache, and fever--have been vaccine-caused.

Respondent's expert, rheumatologist Dr. Alan Brenner, however, disagreed with Dr. Braun. Dr. Brenner opined that the petitioner's history differs significantly from the typical pattern of chronic post-rubella arthropathy described in the Omnibus Proceeding. First, in light of the absence of contemporary documentation, Dr. Brenner questioned the accuracy of petitioner's report that her *joint pain and muscle pain* had an onset about a week after her rubella vaccination. He further noted that, even generally accepting petitioner's reports, her report of headaches as the *chief* symptom for many months is not typical of the post-rubella pattern. Dr. Brenner noted also that no objective arthritis--*i.e.*, joint swelling observable by a physician--has ever been noted in petitioner, and pointed to the fact that petitioner had a significant history of headaches *predating* her vaccination.

Based upon all these deviations of petitioner's case from the general pattern of cases described in the Omnibus Proceeding, Dr. Brenner finds it unreasonable to conclude that petitioner's chronic complaints have been vaccine-caused.

B. My analysis

1. Overview

I have carefully considered the evidence submitted in this case, included the opinions of both of the experts described above. I found both of those physicians to be well-qualified and honest, and both made important points. But in the final analysis I conclude that petitioner has clearly failed to show it "more probable than not" that her chronic symptoms have been caused by her rubella vaccination. There are a number of reasons for this conclusion, which I will discuss separately below.

2. Recent studies relating to the general issue of whether the

rubella vaccine causes chronic arthropathy

Before turning to the evidence relating specifically to petitioner's condition, I note that, in this case, the respondent introduced important evidence concerning the *general* issue discussed above in part III of this opinion concerning whether the rubella vaccine causes chronic arthropathy. Specifically, respondent on October 8, 1997, filed copies of two articles published in medical journals in recent months. Respondent's Ex. I is an article entitled *Randomized Double-blind Placebo-controlled Study on Adverse Effects of Rubella Immunizations in Seronegative Women*, by Dr. Aubrey Tingle[(10)] and colleagues. (*Lancet* 1997, Vol. 349, pp. 1277-81--hereinafter the "Tingle article.") Respondent's Ex. J is an article entitled *Risk of Chronic Arthropathy Among Women After Rubella Vaccination*, by Dr. Paula Ray and colleagues. (*JAMA*, August 20, 1997, Vol. 278, No. 7, pp. 551-56--hereinafter the "Ray article.")

The Tingle article details a *prospective* medical study of approximately 550 women, half of whom were administered a rubella vaccination and half of whom were injected only with an inactive "placebo." The subjects were then followed over the ensuing year. The study found that, as expected, the number of women experiencing an *acute, transient* arthropathic reaction several weeks after the injection was "significantly" greater in the vaccinated group as compared to the placebo group. However, as to *chronic* (recurrent) arthropathy over the following year, the frequency of arthropathy was only "marginally" greater[(11)] in the vaccinated group. Specifically, 22% of the vaccinated group, as opposed to 15% of the placebo group, were found to have experienced "new- onset" chronic arthropathy not associated with other causes.

The Ray article, on the other hand, was not a *prospective* but a *retrospective* medical study. Ray and colleagues reviewed medical records of 971 women who received rubella vaccinations and 3,345 women who had not, checking for reports of arthropathy over the one-year post-vaccination period for the vaccinees and a one-year period for the non-vaccinees. The study found that the vaccinees were no more likely than the nonvaccinees to report chronic arthropathic symptoms during the one-year period reviewed.

At the second evidentiary hearing in this case, Drs. Braun and Brenner discussed these two articles. The two experts generally agreed that the two articles show that chronic arthropathy caused by a rubella vaccination is not a common phenomenon, if it exists at all. They disagreed, however, as to the significance of the Tingle article.

Dr. Braun pointed out that the *prospective* study format used in the Tingle study is generally a better form of study for determining causal relationships of the type at issue here. He believes that the Tingle study's finding, of at least a *marginally* greater occurrence of chronic arthropathy in the vaccinated group, supports the general view that it is *probable*, though not scientifically certain, that in some cases the rubella vaccine causes chronic arthropathy.

Dr. Brenner, on the other hand, argued that the Tingle study is not reliable because, he believes, it is significantly flawed. He pointed to the fact that even in Tingle's placebo group 15% of all individuals were found to have new-onset chronic arthropathy during the year in question, a figure that Dr. Brenner found to be preposterously high in light of consistent previous studies showing that adults generally have about a 2% chance of developing new-onset chronic arthropathy during a given year.[(12)]

However, Dr. Brenner did not argue that these two new studies, when added to the previously-existing studies concerning this topic, mean that one should conclude that no causal relationship exists between the rubella vaccine and chronic arthropathy. Dr. Brenner explained that in a hypothetical case where the timing of the onset of chronic arthropathy was well-documented and followed a rubella vaccination in

the expected time period, and no other cause was indicated, he could still envision finding it at least *probable* that the chronic arthropathy was vaccine-caused.

After considering the two articles and the discussion of them by Drs. Braun and Brenner, I conclude that, at this time, the articles do not warrant any significant changes in the general approach to these arthropathy cases set forth in my Omnibus Order. The overall state of the evidence still seems to justify the conclusion that *if* a particular case of arthropathy meets all of the criteria set forth in that order, then it is at least "more probable than not" that such person's chronic arthropathy was vaccine-caused.

However, the articles reinforce the fact that the causal connection between rubella vaccination and chronic arthropathy is far from well-established. Instead, at best it can be said that the rubella vaccination *probably* does cause some cases of chronic arthropathy, on a relatively *infrequent* basis. Therefore, in my view, only when a petitioner's case clearly meets all aspects of the criteria set forth in my Omnibus Order, and does not differ in any significant way from the general pattern of chronic post-rubella arthropathy cases described in the Omnibus Proceeding, can one conclude that it is "more probable than not" that the petitioner's arthropathy was vaccine-caused. If there is any significant deviation from the pattern, or any significant doubt about any of the individual criteria, then the degree of confidence in the overall conclusion of "vaccine-causation" will drop to below 50%.

Applying this principle to petitioner's case, then, means that the petitioner's claim must be denied. That is, for reasons that will be detailed in the pages to come, there is significant doubt concerning the accuracy of the symptom history provided by petitioner, and a number of ways in which her case significantly deviates from the general pattern of chronic post-rubella arthropathy. Based on these deviations, it cannot be said that it is "more probable than not" that petitioner's chronic symptoms have been vaccine-caused.

3. Doubt concerning the accuracy of the history of joint and muscle aches

As should be clear from the discussion above in part III of this opinion, the most crucial factor in determining whether a person's arthropathic symptoms were caused by a rubella vaccination is the timing of the onset of symptoms. The experts who testified during the Omnibus Proceeding were unanimous in opining that only if the symptoms had their *onset* during the time period from one to six weeks post-vaccination is it plausible that such symptoms were vaccine-caused. In this case, Dr. Braun explained that in reaching his opinion concerning petitioner's condition, he was relying in substantial part upon the accuracy of petitioner's testimony that she had the abrupt onset of not only headaches, but also joint and muscle pain, a few days after her rubella inoculation of June 30, 1997. (See, *e.g.*, 1-Tr. 56-57, 97-98.)

There is reason, however, to have doubt about the accuracy of this history given by the petitioner, as pointed out by Dr. Brenner. First, although petitioner now contends that her whole body ached on July 6, 1989, the only symptoms noted in the medical record made on that date are headache and fever, despite the fact that an "objective" physical examination of petitioner was conducted at the emergency room. (Ex. 4, pp. 1-2.) Second, notes of four obstetrician- gynecologist visits by petitioner in July, August, and September of 1989 include no mention of any aching. (Ex. 5, p. 2.) Third, when petitioner visited Dr. Dunne on January 24, 1990, and complained of *headaches* since the previous July, again no mention of body aching or joint symptoms is recorded. (Ex. 6, pp. 1-2.)

The fact is that apparently no mention of muscle aching, joint pain, or lymph node abnormality was made by petitioner to *any* physician until after January 26, 1990, when petitioner watched the "20/20" episode. That episode mentioned muscle aching, joint pain, arthritis, and enlarged lymph nodes as

possible symptoms of a chronic reaction to the rubella vaccine. (Resp. Ex. E.) Only *after* witnessing that episode, and going so far as to obtain a transcript thereof, did petitioner begin to relate to physicians that she had joint and muscle pain and enlarged lymph nodes.[(13)]

This circumstance of the lack of any mention of these symptoms by petitioner until after she viewed the "20/20" episode, combined with the fact that *objective* signs of arthritis have *not* been identified in petitioner, certainly casts at least some doubt upon the accuracy of petitioner's story.

On the other hand, it is true, as Dr. Braun emphasized, that petitioner did report a headache at the emergency room on July 6, 1989, and did report to Dr. Dunne on January 24, 1990, *before* watching the "20/20" episode, that her chronic headaches dated to the time of vaccination. (Ex. 6, p. 1.) This is certainly a point in petitioner's favor concerning this issue.

Ultimately, I need not reach a definite conclusion as to whether petitioner did have the onset of joint pain and muscle aches about a week after her vaccination. That is because even if I *assumed* that she did, I would still find her overall evidence on this causation issue to be lacking. I simply note that this is one additional point of doubt concerning petitioner's case.

4. Pre-vaccination symptoms

Another important aspect of this case is the evidence indicating that *prior* to petitioner's rubella vaccination, she had a significant history of recurrent headaches. For example, on January 31, 1989, she told her obstetrician-gynecologist, Dr. Triplett, that she had a history ("hx") of "dizziness and headaches [HA's] since prior pregnancy." (Ex. 5, p. 1; note that petitioner's prior pregnancy ended in November of 1987 (Ex. 1, p. 1).) See also a medical record made on February 7, 1989, nothing that petitioner had complained that she was "very tense" and had increased ("") headaches. (Ex. 1, p. 7, second line.) Indeed, in her testimony in this proceeding, petitioner acknowledged that prior to the vaccination she had headaches about once or twice a month. (1-Tr. 9.)

Of course, it is not unusual for even a generally healthy person to have occasional headaches. But in this case, the issue of headaches is particularly significant, since petitioner's *primary symptoms* for many months *after* her vaccination seem to have been her headaches. And despite attempts by petitioner since her vaccination to downplay the importance of her pre-vaccination headaches, those pre-vaccination headaches apparently were significant enough that she reported them to medical personnel on at least two occasions. (Ex. 1, p. 7; Ex. 5, p. 1.) Moreover, her report to Dr. Triplett concerning a "history" ("hx") of headaches "since [her] prior pregnancy" (Ex. 5, p. 1) indicates that for *well over a year*, petitioner had been having headaches the strength and/or frequency of which seemed to the petitioner to be greater than the petitioner's prior experience.

Dr. Brenner testified that the fact that petitioner reported an ongoing history of headaches for lengthy period prior to her rubella immunization is important evidence for the proposition that her history of pain symptoms since that vaccination was *not* vaccine-caused. The logic behind that testimony seems straightforward. That is, if petitioner had chronic and unusual headaches for well over a year, then was plagued primarily by *more headaches* in the first few months after her rubella vaccination, it seems distinctly possible that the two phenomena are part of the same condition. And if they are part of the same condition, since the chronic headaches *predated* the rubella vaccination, then that condition obviously could not have been vaccine-caused.

In short, the fact that petitioner had complaints of chronic headaches *prior* to her vaccination in this case is another reason to doubt that her post-vaccination symptoms were vaccine-caused.

5. Onset of headaches on July 3, 1989

Petitioner in this proceeding has asserted that the onset of her allegedly new condition, which at first was dominated by the symptom of headaches, took place on July 6, 1989, six days after her rubella vaccination. But Dr. Brenner pointed out that at about 8:00 a.m., on July 3, petitioner complained of a headache. (Ex. 2, pp. 30, 49.) And Dr. Braun acknowledged that he viewed the July 3 headache as the onset of petitioner's vaccine-caused condition. (1-Tr. 107-08.)

The fact that this first post-vaccination headache took place on July 3 rather than July 6, however, poses another problem for petitioner. That is, Dr. Brenner pointed out that the morning of July 3 was no more than three days after the administration of the rubella vaccination, and argued that that would be too soon for the rubella virus to be producing strong symptoms in petitioner's system. He explained that it takes a number of days--at least a week, and usually about two weeks--for the rubella virus to replicate sufficiently within the human body to cause noticeable systemic symptoms.

Dr. Braun expressed disagreement on this point. He admitted that the case would be stronger if petitioner's onset had come between one and four weeks post-vaccination, but stated that he does not believe that three days would necessarily be too soon. But he did not explain his reasoning on this point in much detail. And I note that Dr. Brenner's general viewpoint on this issue was supported by *all* of the experts--petitioner's as well as respondent's--during the Omnibus Proceeding hearings. (*See* Omnibus Order at pp. 9-10.)

After analyzing this point, I need not, and do not, conclude that a condition that had its onset within three days of a rubella vaccination could *never* be vaccine-caused. However, the testimony of Dr. Brenner in this case (buttressed by the testimony of the Omnibus Proceeding experts) persuades me that when post-vaccination symptoms have their onset less than a week post-vaccination, the sooner after vaccination the onset, the less likely that the symptoms were vaccine-caused. Accordingly, in this case, the fact that petitioner's post-vaccination headaches had their onset no more than three-days post-vaccination is another factor *against* petitioner's causation claim in this case.

6. Other ways in which petitioner's case is not typical of chronic post-rubella arthropathy

I have already highlighted above two very important ways in which petitioner's history is not typical of the pattern of chronic post-rubella arthropathy highlighted during the Omnibus Proceeding--*i.e.*, petitioner's pre-vaccination symptoms and the onset of post-vaccination symptoms only three days later. But Dr. Brenner has also pointed out additional ways in which petitioner's case is not typical of that pattern.

First, even *assuming* the accuracy of petitioner's own testimony, her dominant symptoms during the first few months of her condition were headaches. (*See*, *e.g.*, 1-Tr. 13.) But while headaches certainly are sometimes associated with viral reactions, they have not been frequently mentioned as part of the pattern of chronic post-rubella arthropathy. Moreover, it certainly is not typical of that pattern, as even Dr. Braun acknowledged, to have a person complain primarily of headaches in the beginning, then only months later have muscle and joint pains become predominant. (1-Tr. 119-20, 129-30.)

Second, there is no evidence that petitioner has *ever* had "frank arthritis"--*i.e.*, definite joint swelling observable by a physician. Recorded examinations of her joints have not shown arthritis.[(14)] (See, *e.g.*, Ex. 24, p. 2; Ex. 23, p. 2; Ex. 21, p. 3--"extremities" normal; see also the records of three more physical or "objective" examinations of petitioner in early 1990, all of which do not indicate any joint swelling--Ex. 4, p. 2; Ex. 7, p. 2; Ex. 8, p. 2.) Moreover, even the petitioner cannot say whether she had actual

joint swelling during the initial episode on July 6, 1989. (1-Tr. 16.) The absence of any objective arthritis at any time is a problem because in the typical pattern, actual arthritis is usually observable in at least the initial "acute" stage of the illness. (*See, e.g.*, Omnibus Order at p. 15.)

In sum, the fact that petitioner's history, even fully accepting her testimony, diverges in these additional significant ways from the generally-observed pattern of chronic post-rubella arthropathy gives further reason to doubt that her condition is vaccine-caused.

7. Additional discussion

Several other points are worthy of at least a brief discussion. First, I note that Dr. Braun stated that one of his reasons for reaching his conclusion in this case was that he could see no other obvious cause for petitioner's chronic symptoms. But Dr. Brenner pointed out that persons with chronic muscle and/or joint pain syndromes of unexplained cause are *extremely* common. (Dr. Brenner said that he sees such a case practically every day in his practice.) It seems likely to me that Dr. Brenner, a rheumatologist, might be more keenly aware of this fact than Dr. Braun, an infectious disease specialist, and thus that Dr. Braun may be placing too much emphasis on the lack of another obvious cause.

Secondly, even Dr. Braun acknowledged that among the chronic arthropathy cases that he has seen that he suspects were vaccine-caused, petitioner's case offers a relatively *weak* causal link between the vaccination and the symptoms. (See, *e.g.*, 1-Tr. 117, 123.)

Third, Dr. Braun relied in part upon the fact that immunologic testing showed that petitioner has a relatively poor response to the peptide known as BCH-178. (See, *e.g.*, 1-Tr. 66-73.) At the second hearing, he explained that in a study published in 1996 by Drs. Tingle, Mitchell, and colleagues, a poor response to that peptide seemed to correlate with susceptibility to the rubella virus. However, during further discussion of that topic at the hearing, Dr. Braun also acknowledged that in a recent telephone conversation Dr. Tingle indicated that more recent experimental work in this area, with some of the women who are actually thought to have chronic rubella-caused arthropathy, does *not* seem to bear out the existence of such a correlation. Therefore, in the final analysis, I could not conclude that the finding of this poor response by petitioner to that peptide was a very significant factor.

In addition, Dr. Braun relied upon the fact that some tests on petitioner seem to indicate that she has undergone some kind of chronic or intermittent systemic inflammatory process. (See, *e.g.*, 1-Tr. 65.) However, as Dr. Brenner pointed out and Dr. Braun did not disagree, those tests are extremely non-specific and do not even indicate an inflammatory process in the *joints*, much less that such process was rubella-caused. Thus, although these test results were a point *consistent* with Dr. Braun's theory, I did not find them to be particularly strong evidence that petitioner has a vaccine-caused condition.

Next, I note that in addition to Dr. Braun's testimony, petitioner has also filed an affidavit of Dr. Aubrey Tingle, a leading researcher in the area of the possible connection between the rubella vaccine and chronic arthropathy (the same Dr. Tingle mentioned above). (Ex. 13.) Dr. Tingle's brief affidavit stated that, based upon the materials provided to him, he would conclude that petitioner's "chronic arthritis" was vaccine-caused. (*Id.* at para. 7.)

I have studied much of Dr. Tingle's published work, and heard his testimony during the Omnibus Proceeding as well as during a number of subsequent case-specific Program proceedings. As I have noted in prior opinions, I conclude that he is a distinguished medical scientist and an honest witness. The

fact that he was willing to afford such a written opinion in this case, therefore, is a factor that might be entitled to some weight. However, it is not clear what materials of petitioner's medical history Dr. Tingle had available to him when he provided his affidavit. Moreover, he seems to have been provided with a history of petitioner's ailment that was incomplete, and in some respects clearly erroneous. For example, Dr. Tingle mentioned "severe arthritis" (para. 2), but petitioner has never been found to have *any* actual arthritis. Further, his history of petitioner's acute symptoms (para. 2) seems to imply the understanding that petitioner actually reported arthralgias, muscle aching, and lymph node swelling on July 6, 1989, but the record (Ex. 4) shows that she did not. Moreover, there is no indication that Dr. Tingle was told that petitioner's chief early post-vaccination symptoms were headaches, that she had chronic headaches pre-vaccination, or that her post-vaccination headaches actually began on July 3, 1989, not July 6.

Dr. Tingle did not testify in this case and thus has not been able to explain his reasoning or to tell us whether his opinion might change based upon a more accurate history of petitioner's condition. For all these reasons, and in the absence of the opportunity to hear how Dr. Tingle might refute the specific and cogent points made by Dr. Brenner, I certainly cannot adopt his opinion over that of Dr. Brenner.

Finally, I note that several documents from the records of one of petitioner's medical providers seem to indicate a conclusion that petitioner's chronic symptoms have been vaccine-caused. That is, records of Dr. J.S. Todd, a doctor of osteopathy, indicate diagnosis of "chronic rubella viremia" (Ex. 9, p. 1) and "rubella arthritis" (Ex. 18, p. 1). Dr. Todd also supplied an affidavit stating the view that petitioner has "rubella-associated arthritis." (Ex. 27.)

Of course, in every Program case I have great respect for, and give strong attention to, the opinions of the actual treating physicians of a petitioner, such as Dr. Todd here. However, Dr. Todd, like Dr. Tingle, did not testify in this case. Moreover, Dr. Brenner commented on these brief, unexplained statements of diagnosis appearing in Dr. Todd's records, explaining that the rest of Dr. Todd's records offer no support or documentation whatsoever for the conclusions either that petitioner has a rubella-caused condition or even that she has actual "arthritis." I found Dr. Brenner's comments to be persuasive on this point as well, and thus in the final analysis I can afford little weight to these unexplained notations of Dr. Todd.

8. Summary

Based upon a combination of all of the factors discussed above, I do not find it "more probable than not" that petitioner's chronic symptoms have been vaccine-caused.

V

CONCLUSION

After considering her case, it is impossible not to feel sympathy for the symptoms that have plagued Alecia Bilotti in recent years. However, for reasons set forth above, I have found her theory of proof in this case to be unsupported by the overall record. The evidence in this case simply does not support a causal link between any aspect of petitioner's condition and her vaccination. I thus decide that petitioner does not qualify for a Program award in this case.

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 this change to the Table been in effect, the petitioner here would still seem to be disqualified from a Program award under the new regulatory language, since there clearly does *not* exist "medical documentation, recorded within 30 days after the onset," of actual *arthritis* occurring in the six-week period post-vaccination. (*See* 42 C.F.R. § 100.3(b)(6)(A) (1996).)

3. 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).

4. "1-Tr." references are to the transcript of the hearing held on March 30, 1995, while "2-Tr." references are to the transcript of the hearing held on October 29, 1997.

5. Petitioner filed Exs. 1 through 13 with her petition; Exs. 14 through 17 on July 8, 1993; and Exs. 18 through 27 on September 26, 1994. "Ex." references will be to those exhibits. (I also note that on July 8, 1993, petitioner filed supplements to Exs. 9, 10, and 13; those pages, however, were eventually refiled with different exhibit numbers. References to Exs. 9, 10, and 13, therefore, will be to the exhibits filed with the petition.)

6. Dr. Tingle's office seems to have date-stamped the letter from petitioner as having been opened on June 7, 1990. (Ex. 20, p. 4.) That letter also mentions that petitioner had already corresponded with Dr. Chantler. (*Id*.)

7. The Omnibus Order was also electronically published under the caption *Ahern et al. v. Secretary of HHS*, 1993 WL 179430 (Fed. Cl. Spec. Mstr. January 11, 1993).

8. 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 *3, footnote 4 (Fed. Cl. Spec. Mstr. Sept. 22, 1997). Further, while I have included this part III in my opinion here in the interest of thoroughness, in order to make it clear that the evidence in this case was evaluated in light of my experience gained in the course of the Omnibus Proceeding, I also note that even had I based my ruling in this case *strictly* upon *the evidence introduced in this proceeding alone*, my ruling would have been the same.

It may be also 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 64 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 12 of those 64, I have found that the petitioner has failed to make the required "causation" showing. (See, *e.g., Awad v. Secretary of HHS*, 1995 WL 366013, No. 92-79V (Fed. Cl. Spec. Mstr. June 5, 1995).) In the other 52, I have concluded that the requisite showing of causation *was* made. (See, *e.g., Long v. Secretary of HHS*, 1995 WL 470286, No. 94-310V (Fed. Cl. Spec. Mstr. July 24, 1995).)

9. Petitioner also presented written opinions of two other physicians who, did not testify. I will discuss those opinions at part IV(B)(7) of this Decision.

10. This is the same Dr. Tingle who appeared in the "20/20" episode mentioned above. Dr. Tingle also was one of the experts who testified during the Omnibus Proceeding.

11. When study results are said to identify a "significant" difference in outcome between two groups, it means that the differences observed between the groups are so great that it is extremely unlikely that the differences are due merely to chance. When a study finds a "marginal" difference between two groups, it means that due to the size of the difference and the total sample size, the possibility that the difference was due to chance cannot be ruled out.

12. Dr. Braun acknowledged (as did the Tingle study's own authors) that the overall rate of chronic arthropathy found in the Tingle study was surprisingly high. But Dr. Braun argued that the Tingle study should not be disregarded for this reason. He suggested that the unusual finding was likely the result of the study's format of actively contacting the subjects *asking* if they had joint symptoms, in contrast to the Ray study's more typical methodology of counting only those persons who actively sought medical attention for a joint condition.

13. It is also noteworthy that after hearing the "20/20" description of enlarged lymph nodes, petitioner reported to her physicians that she felt such enlarged nodes, but her physicians did not detect them. For example, on May 1, 1990, petitioner reported lymph node enlargement to Dr. Leohrke, at a particular location, but that physician could not find any enlargement himself. (*See* Ex. 21, p. 3--"patient was convinced that she felt a nodule along the occipital ridge, but I could not really palpate this myself.") Note also the specific lack of any lymphadenopathy noted on April 4, 1990, on October 1, 1993, or even in Dr. Braun's own exam of petitioner in 1994. (Ex. 8, p. 2; Ex. 23, p. 2; 1-Tr. 103.) Note further that at the emergency room on July 6, 1989, Dr. Doster did an "objective" examination of petitioner, and did not remark upon any swollen lymph nodes. (Ex. 4, p. 2.)

14. In his testimony, Dr. Brenner noted that in a few records (*e.g.*, Ex. 19, Ex. 18, Ex. 15) there are notations indicating that petitioner has "arthritis" or even "rheumatoid arthritis." Dr. Brenner pointed out, however, that these notations were not made by rheumatologists, and were not accompanied by any notations of any examinations indicating that petitioner in fact had actual arthritis. (The only rheumatologist to examine petitioner, Dr. Moore, did *not* find arthritis.) Dr. Brenner found these notations to be of no value at all, and I found his testimony persuasive on this point.