OFFICE OF SPECIAL MASTERS

No. 95-686V

(Filed: July 20, 1998)

* *		
SHEILA GARD-VALDEZ,	*	
Petitioner,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Bruce McGagin, Sacramento, California, appeared for petitioner.

Mark Rogers, Department of Justice, Washington, D.C., appeared for respondent.

DECISION

HASTINGS, *Special Master*.

This is an action seeking an award under the National Vaccine Injury Compensation Program[(1)] (hereinafter "the Program") . I conclude that petitioner is not entitled to such an award.

I

FACTUAL BACKGROUND

Sheila Gard-Valdez, the petitioner in this case, was born in 1956. Throughout the 1980's and early 1990's, petitioner often sought medical treatment for a number of different symptoms, including joint and muscle aches, fatigue, abdominal and bowel problems, poor sleep, panic attacks, anxiety, and depression. (*See, e.g.*, Ex. 9[(2)] at pp. 1-60.) On October 19, 1992, she received a rubella vaccination. Two weeks later, on November 2, 1992, petitioner visited a physician, Dr. Bush, and reported a rash. (Ex. 1, p. 5.) The following day, she returned to report that she was "aching all over." (*Id.* at 6.) On November 5, she again visited Dr. Bush, who examined her joints and noted "no dramatic swelling, but just a faint puffiness of the PIP joints in her fingers, and basically hurts all over, without major objective changes." (*Id.* at 7.) Dr. Bush recorded his "impression" at that visit as "[r]ubella, secondary to immunization with diffuse arthritis associated." (*Id.*)

Petitioner visited Dr. Bush again on November 11, 1992, and he recorded that her rash and arthritis were gone, with no joint swelling, but that she was still a "little achy" in the joints. (*Id.* at 8.) On November 18, she visited Dr. Bush and again reported joint aching, while he recorded that upon examination her joints were "perfectly normal." (*Id.* at 9.) On December 2, petitioner visited the same medical office, but this time saw Dr. Bush's partner Dr. Scalapino, who took a thorough history and performed his own detailed examination. (*Id.* at 10-12.) He recorded that petitioner reported generalized joint pain and was "tender" over certain finger joints, but that he could find "no hint of synovitis."[(3)] (*Id.* at 11.) Dr. Scalapino recorded his "impression" at that visit that petitioner had "[g]eneralized arthritis and arthralgias following rubella vaccination," but that he had assured her that the pain would likely resolve. (*Id.*) He added that she had a "hint of fibromyalgia."[(4)] (*Id.*)

Over the following years, petitioner has continued to routinely seek medical attention for chronic pain and various other symptoms. These reported symptoms have often included pain and tenderness in the joints of her hands and feet, but at most examinations no objective evidence of swelling or other joint changes has been observed by her physicians. No definitive cause for these joint symptoms or petitioner's additional chronic pain symptoms has been identified. A number of petitioner's physicians, however, have concluded that, as Dr. Scalapino first suggested in the notation above, petitioner suffers from the "fibromyalgia syndrome."

II

STATUTORY BACKGROUND

Under the Program, compensation awards are made to individuals who have suffered injuries after receiving certain vaccines listed in the statute. There are two separate means of establishing entitlement to compensation. First, if an injury specified in the "Vaccine Injury Table," originally established by statute at § 300aa-14(a) and since modified administratively (as will be discussed *infra*), occurred within the time period from vaccination prescribed in that Table, then that injury may be *presumed* to qualify for compensation. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a). If a person qualifies under this presumption, he or she is said to have suffered a "Table Injury." Alternatively, compensation may also be awarded for injuries not listed in the Table, but entitlement in such cases is dependent upon proof that the vaccine *actually caused* the injury. § 300aa-13(a)(1); § 300aa-11(c)(1)(C)(ii).

One of the vaccinations covered under the Program is the rubella vaccination. § 300aa-14(a)(II). In the Vaccine Injury Table as originally enacted, arthritis was *not* listed as a Table Injury for any vaccination. Therefore, an individual seeking compensation for arthritis had to demonstrate by evidence that his or her arthritis was *vaccine-caused*. However, the Table was administratively modified, effective as to Program petitions, such as this one, filed between March 10, 1995, and March 24, 1997. Under that modification, "chronic arthritis," if incurred under certain specified circumstances, was established as a "Table Injury" for the rubella vaccination. *See* 60 Fed. Reg. 7678 (1995); 42 C.F.R. § 100.3(a)(II.b)(A) and § 100.3(b)(6).[(5)]

III

ISSUES FOR DECISION

The primary issue in this case is whether petitioner has suffered a condition in her hands and feet qualifying as a "chronic arthritis" Table Injury under the above-described regulatory change to the Vaccine Injury Table. In addition, as an alternative argument, petitioner contends that her hand and foot symptoms since 1992 have been "actually caused" by her rubella vaccination.

The evidence introduced into this proceeding consists of numerous documentary exhibits introduced by both parties, plus oral testimony of petitioner, her expert witness, and respondent's expert witness at an evidentiary hearing held on May 28, 1997. After careful consideration of all the evidence of record, I must reject both arguments of petitioner, for the reasons that I will discuss in detail in parts IV and V of this Decision, below.

IV

"TABLE INJURY" ISSUE

A. Introduction

The first issue is whether petitioner has demonstrated[(6)] that it is "more probable than not" that she has suffered the Table Injury known as "chronic arthritis." The regulatory language that is applicable to this petition[(7)] defines the Table Injury "chronic arthritis" as follows:

(6) *Chronic Arthritis*. (i) For purposes of paragraph (a) of this section, chronic arthritis may be found in a person with no prior history of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred within 42 days after a rubella vaccination; and

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome or blood disorders.

(iii) Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of paragraph (a) of this section.

42 C.F.R. § 100.3(b)(6). Petitioner argues that the condition that she has reported in her hands and feet since November of 1992 qualifies under that Table Injury category of "chronic arthritis." Respondent disagrees. After careful consideration, I find that petitioner has failed to demonstrate that it is "more probable than not" that she suffered from "chronic arthritis" as defined in the Table language set forth above.

To begin with, I note that, in essence, the Table requires that a petitioner's case satisfy four distinct elements: (1) an absence of a pre-vaccination history of "arthropathy (joint disease);" (2) medical documentation of "objective signs of acute arthritis (joint swelling)" occurring within 42 days of vaccination; (3) medical documentation of the "persistence of objective signs of intermittent or continuous arthritis" for at least a six-month period; and (4) an absence of one of the diagnoses listed at part (ii) of 42 C.F.R. § 100.3(b)(6). Petitioner's case seems clearly to comply with the fourth element. As to the first two elements, there is no obvious answer as to whether petitioner's case complies. As to the first element, petitioner did have a significant history of pre-vaccination complaints of joint and muscular pain, but no history of actual *arthritis*. Does this constitute a history of prior "arthropathy (joint disease)?" The answer is unclear. As to the second element, petitioner on November 5, 1992, 16 days post-vaccination, was found by her physician to have "no dramatic swelling, but just a faint puffiness of the PIP joints in her fingers." (Ex. 1, p. 7.) Does that observation of "puffiness" constitute "medical documentation * * * of objective signs of acute arthritis (joint swelling)"? It probably does, especially because Dr. Bush added the impression of "diffuse *arthritis*." But again the answer is less than perfectly clear.

However, it is unnecessary for me to reach definite conclusions as to whether petitioner's case complies to those two initial elements. That is because I conclude that petitioner has *failed* to show that it is "more probable than not" that her case satisfies the *third* element, *i.e.*, "[m]edical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more the 6 months following vaccination." Even this issue is not wholly free from doubt; a rational argument can be made on petitioner's behalf. But in the final analysis, the evidence on this issue does not preponderate in petitioner's favor.

B. Summary of both parties' arguments

Petitioner's argument is that she has experienced chronic arthritis, meeting the requirement of this third element, in the joints of her hands and feet. She points to the above-mentioned "puffiness" observed in her fingers on November 5, 1992; the fact that since that time she has frequently reported pain in her joints; and the fact that at a number of physician visits it has been noted that she was "tender" at joint areas. In addition, petitioner relies upon the report of a visit she made on September 1, 1995, to the physician who has served as her expert witness in this case, Dr. M. Eric Gershwin, an expert in rheumatology. At that visit, it was recorded that petitioner had "mild swelling at [her right index] finger's MP and PIP joints." (Ex. 17, p. 25; see also Ex. 17, p. 5, which seems to be the actual office note of that visit.) At the evidentiary hearing in this case, Dr. Gershwin opined that in his view the history of the "puffiness" in petitioner's fingers observed by her physician on November 5, 1992, the "mild swelling" that he himself (Dr. Gershwin) observed in two finger joints on September 5, 1995, plus the frequent notations by physicians of pain and tenderness in petitioner's joints during the interim period, justify the conclusion that petitioner experienced intermittent arthritis over the three-year period after her rubella vaccination. As to the "medical documentation" required by the Table language with respect to the arthritis experienced since the initial acute episode in November of 1992, Dr. Gershwin points to his own observation of "mild swelling" in two finger joints on September 1, 1995, plus a number of physician notations that petitioner's joints were "tender" upon examination.

Respondent's expert Dr. Robert Simms, also a specialist in rheumatology, disagrees with Dr. Gershwin. Dr. Simms acknowledges that petitioner's symptoms reported in early November of 1992, including rash, pain in many joints, and perhaps the "puffiness" observed in her fingers on November 5, 1992, may have constituted a reaction to her rubella vaccination. But he does not view petitioner's history since that time as one of intermittent or continuous *arthritis*. He notes that in petitioner's extensive medical records of the period since November of 1992, there is no evidence of *swelling* in any joint, with the exception of the single observation by Dr. Gershwin on September 1, 1995. As to the petitioner's many complaints of joint pain and tenderness during that time period, Dr. Simms believes that these are attributable not to arthritis but to the syndrome known as "fibromyalgia syndrome," with which petitioner has been diagnosed.

Dr. Simms explained that, as illustrated in respondent's Exhibits C through I filed on April 22 and May 9, 1997, in recent years the medical profession has generally accepted the existence of a syndrome known as "fibromyalgia syndrome" (hereinafter sometimes "FMS"). In this syndrome, persons generally report pain in many different fibrous tissue areas of their bodies (*e.g.*, muscles, ligaments, tendons). To fit within the syndrome, multiple areas of the body must be involved--often the patients report that they "ache all over"--and the patients must be found to be especially sensitive to pressure at all or most of 18 specific "tender points" located at various fibrous tissue areas. Persons with FMS often, though not always, also report a number of other chronic or recurring symptoms, including pain in the joint areas, fatigue, sleep difficulty, "irritable bowel syndrome," headaches, non-cardiac chest pain, numbness and tingling in their extremities, the *feeling* of swollen extremities (but usually *without* any actual observable swelling), high stress, depression, and anxiety. As to the *cause* of FMS, there are a number of theories, but at this time, the cause is still not well-understood.

Dr. Simms points out that petitioner's medical history for many years *prior* to her rubella vaccination included not only joint complaints but a number of other symptoms that might indicate the early stages of FMS. He finds that her symptoms in recent years clearly indicate FMS, as some of petitioner's own treating physicians have concluded. He believes that petitioner's ongoing reports of pain and tenderness in her hand and foot joints are simply a part of her FMS, and do not indicate arthritis.

C. Discussion

*1. Scope of "objective signs of * * * arthritis"*

To begin with, the experts disagreed as to the appropriate interpretation of the phrase "objective signs of * * * arthritis" set forth in the Table. Dr. Gershwin initially seemed to indicate that if a person had in a joint *any* of five signs--*i.e.*, heat, redness, swelling, pain, or loss of function--that would constitute "objective signs of arthritis." (Tr. 64.) He then seemed to clarify that explanation by indicating that while a patient's own report of joint *pain* alone (*i.e.*, "arthralgia") would not necessarily indicate arthritis, if a physician examined the joint and found it "tender," meaning that the patient reported or exhibited pain when the physician squeezed the joint, then that finding of *tenderness* would constitute objective evidence of arthritis. (Tr. 65-66.)

Dr. Simms, on the other hand, seemed to take a much narrower view of what constitutes "objective signs of * * * arthritis." Dr. Simms took strong issue with Dr. Gershwin's suggestion that joint tenderness by itself would constitute an "objective sign" of arthritis. (*E.g.*, Tr. 97-98.) Dr. Simms also seemed to indicate that only a finding of "synovitis," which means inflammation of the synovial membrane, a particular part of the joint, would in his view constitute objective evidence of inflammatory arthritis. (Tr. 94-95, 123-27.)

After consideration of both parties' arguments on this point, I find that I cannot fully accept either party's interpretation of the phrase "objective signs of arthritis." Rather, the wording of the statute itself suggests a middle ground. In part (A) of 42 C.F.R. § 100.3(b)(6)(i), the word "arthritis" is immediately followed by the parenthetical "joint swelling." I conclude therefrom that "objective signs of arthritis," as used in the Table, means "objective signs of *joint swelling*." It is true, of course, that when the word "arthritis" is used again in part (B) of 42 C.F.R. § 100.3(b)(6)(i), it is not followed by any parenthetical. But it is my inference that the Table drafters intended this two-word "definition" of arthritis--*i.e.*, "joint swelling"-- to also apply to the word "arthritis" when it is used again in part (B).

In light of this statutory language, then, it appears that Dr. Simms' suggested interpretation of the phrase "objective signs of arthritis" is *too strict*. There need not necessarily be a finding of "synovitis"--*i.e.*, swelling of the synovium, a particular part of the joint. Any form of joint swelling would seem to be enough. But, on the other hand, Dr. Gershwin's view that a physician's report of joint "tenderness" qualifies as an "objective sign of arthritis" seems to be *too broad*. If a physician reports only tenderness, that means that the physician did not observe joint *swelling*. Moreover, it seems doubtful that a physician's notation of mere "tenderness" qualifies as an *objective* sign. Unlike swelling, which a physician can actually observe, "tenderness" means that the patient *reports* pain upon pressure, which would seem to put tenderness into the realm of a "subjective" sign, rather than an "objective" sign.[(8)]

Thus, I conclude that medical documentation of "objective signs of arthritis" *does* occur whenever upon *examination* (not upon the mere report of a patient) a physician recorded the observation of *joint swelling*.[(9)] It does not occur, however, when a physician merely notes *joint tenderness*.

2. Application to petitioner's case

Having made the above determinations as to the scope of the term "objective signs of arthritis," I must apply those determinations to petitioner's case. Pursuant to part (B) of 42 C.F.R. § 100.3(b)(6)(i), do petitioner's medical records contain medical documentation of the "persistence" of "intermittent or continuous" *joint swelling*? A close review shows that after the initial "puffiness" in petitioner's finger joints observed on November 5, 1992, the medical records of petitioner's physician visits over the next three years contain only one notation of joint swelling--*i.e.*, the notation of Dr. Gershwin on September 1, 1995, of "mild swelling" in two joints of a single finger. (Ex. 17, p. 25.) Many other records contain evidence of joint *pain or tenderness*, but none document *swelling*.

The question then becomes, does this single 1995 notation of mild swelling in two joints of one finger, in conjunction with the notation of "puffiness" on November 5, 1992 (which could also be interpreted as mild swelling), indicate a "persistence" of "intermittent or continuous" joint swelling? I conclude that it does not. There obviously was not "continuous" joint swelling throughout the nearly three-year period between November 5, 1992, and September 1, 1995. And, in my view, the words "persistence" and "intermittent," while certainly requiring much less than a "continuous" presence of objective symptoms, do require more than one observation of joint swelling over a three-year period. Those words imply that the joint swelling must be seen on multiple, separate occasions. That is simply not the case here.

In this regard, it should be noted that there exist records of many visits of petitioner to physicians at which joint pain was reported and a specific physical examination of petitioner was made, but *no joint swelling* was recorded. *See, e.g.*, records of visits on November 11, 1992 (Ex. 1, p. 8); November 18, 1992 (Ex. 1, p. 9); December 2, 1992 (Ex. 1, p. 11); January 15, 1993 (Ex. 3, p. 6); May 6, 1993 (Ex. 6, pp. 2-3); January 13, 1994 (Ex. 6, p. 5); February 16, 1994 (Ex. 11, p. 6); February 17, 1994 (Ex. 17, p. 15); April 21, 1994 (Ex. 7, p. 2); June 3, 1994 (Ex. 18, p. 21); June 15, 1994 (Ex. 15, pp. 3-4); June 17, 1994 (Ex. 16, p. 62); and October 19, 1994 (Ex. 16, p. 57). This circumstance refutes the suggestion of Dr. Gershwin that there might indeed have existed intermittent swelling episodes, but by chance those episodes simply never occurred on the days when petitioner visited her physicians. Given the number of these visits, Dr. Gershwin's suggestion simply seems unlikely. Moreover, I find this suggestion legally irrelevant in any event. That is, my interpretation of the Table Injury requirement of "medical documentation" of "objective signs" of the "persistence" of "intermittent" arthritis is that there must be multiple examples when a physician *did observe* actual swelling during the three-year post-vaccination period. And that simply did not happen, for whatever reason, in petitioner's case.

In short, for all the reasons discussed above, I conclude that petitioner has not demonstrated that she has experienced a case of "chronic arthritis" falling within the Vaccine Injury Table.

V

ISSUE OF "ACTUAL CAUSATION"

The second issue is whether petitioner has demonstrated that it is "more probable than not" that the pain symptoms in her hands and feet since 1992 were *actually caused* by her rubella vaccination. As to this contention of "actual causation," I will begin by setting forth, in Part A of this section of this Decision, a summary of information relating to this issue that I have received in prior Program cases. In Part B, I will discuss some legal points. Finally, in Parts C and D, I will discuss the factual specifics of this case.

A. 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, and, until 1995, no "chronic arthritis" Table Injury existed. Accordingly, upon assignment by the Chief Special Master, in 1992 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 70 Program cases on January 11, 1993, and will not be repeated here. *See Ahern et al. v. Secretary of HHS*, 1993 WL 179430 (Fed. Cl. Spec. Mstr. January 11, 1993). (I will hereinafter refer to that Order as the "Omnibus Order." Also, 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.") 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 arthritis or similar joint symptoms arose under a certain set of circumstances, it might reasonably be concluded--absent any additional evidence--that it is "more likely than not" that such symptoms were vaccine-caused. As explained in the Omnibus Order, this conclusion was based upon evidence showing that a large number of persons have experienced histories of joint symptoms 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 future Program cases*--attribute the chronic symptoms to the vaccination.

It has been questioned whether it is appropriate for me to apply evidence obtained during the Omnibus Proceeding to the individual cases of petitioners who did not themselves participate in that Proceeding. I have addressed this 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). Moreover, in their post-hearing briefs both parties to this case indicated their view that it *is* appropriate that I apply the Omnibus Proceeding information to

this case.[10] Accordingly, I have evaluated petitioner's case in light of the evidence received and the conclusions reached in the Omnibus Proceeding.

B. Legal considerations

It should be noted initially that in analyzing a contention of "actual causation," the presumptions available under the Vaccine Injury Table are, of course, inoperative. It is clear that the burden is on the petitioner to show that in fact the vaccination in question "more probably than not" caused the injury. *Hines v. Secretary of HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Carter v. Secretary of HHS*, 21 Cl. Ct. 651, 654 (1990); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd per curiam*, 950 F.2d 731 (1991); *Shaw v. Secretary of HHS*, 18 Cl. Ct. 646, 650-51 (1989). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." *Strother*, 21 Cl. Ct. at 370; *Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir. 1983), *cert. denied*, 469 U.S. 817 (1984); *Novak v. United States*, 865 F.2d 718, 724 (6th Cir. 1989). Temporal association alone is not sufficient. *Strother*, 21 Cl. Ct. at 370; *Shaw*, 18 Cl. Ct. at 650-51; *Carter*, 21 Cl. Ct. at 654. Moreover, simple "similarity of petitioner's injury to injuries listed on the Table does not show causation in fact. Encephalitis, seizure disorders, and other Table Injuries can have causes other than the administration of a vaccine." *Strother*, 21 Cl. Ct. at 370.

The briefs filed in this case, however, suggest that there is confusion as to the effect of the Omnibus Order, described above, on the petitioner's burden of showing that her problems were vaccine-caused. Petitioner's counsel seems to believe that there are two completely different, separate methods of demonstrating "actual causation"--*i.e.*, (1) actual causation under the approach detailed in my Omnibus Order, and (2) "traditional cause-in-fact"[11] analysis. (*See* petitioner's brief filed March 13, 1998, pp. 15, 18.) Respondent, on the other hand, suggests that "the analytical framework set forth in the omnibus order * * * does not require specific evidence of vaccine causation in a particular case." (*See* respondent's brief filed on March 6, 1998.) It seems appropriate, then, that I attempt here to resolve this confusion.

In fact, there is in my view no distinction whatsoever between the "traditional" approach to proving "actual causation" and the approach that I adopted in the Omnibus Order. In the Omnibus Order, I was merely outlining a *particular way* in which a petitioner could carry her "traditional" burden of showing "actual causation." I was explaining that if a petitioner could show that her history fit factually within a certain pattern, then that showing, *combined with the medical opinion evidence* that I heard in the Omnibus Proceeding, would (in the absence of additional medical opinion evidence) justify a conclusion that the petitioner's injury was vaccine-caused. In other words, I was merely providing a "short-cut" by which the *traditional* requirements of "actual causation" could be satisfied without the need for redundant medical expert testimony in every case; in effect, the expert testimony taken *in the Omnibus Proceeding* would serve as the expert opinion concerning the "actual causation" issue for the petitioner *in the particular case*.

Therefore, the petitioner in this case is erroneous in suggesting that there are two conceptually different methods of demonstrating "actual causation." At the same time, the respondent is wrong in her suggestion that the analytical framework of my Omnibus Order "does not require specific evidence of

vaccine causation in a particular case." To the contrary, my Omnibus Order framework *does* require "specific evidence of vaccine causation" in *every* case, as is plainly required under the statute. In each case, a petitioner must offer *specific factual evidence* that his or her medical history falls within a particular pattern. Then, applying the *medical opinion evidence* taken in the Omnibus Proceeding to the facts of the particular case, I may be able, in appropriate cases, to make a *specific finding* that there is evidence supporting the conclusion that it is "more probable than not" that *that particular petitioner's* condition was vaccine-caused.[(12)]

Thus, I have clarified above, I hope, my position as to how the approach set forth in the Omnibus Order fits squarely within the "traditional" legal approach to "actual causation." Next, I will address briefly a thornier legal topic--*i.e.*, the two different legal approaches to "actual causation" *under the Program* that emerged in the recent *Wagner* case. The two different approaches are explained in detail in *Wagner v. Secretary of HHS*, 37 Fed. Cl. 134 (Fed. Cl. 1997) (hereinafter *Wagner I*) and *Wagner v. Secretary of HHS*, No. 90-2208V, 1997 WL 617035 (Fed. Cl. Spec. Mstr. Sept. 22, 1997) (hereinafter *Wagner II*), and will not be repeated here. To summarize the divergence of analysis between the two opinions, in *Wagner II*, I set forth the view that in ruling upon a claim of "actual causation," a Program factfinder is authorized to consider *all* the evidence of record; in *Wagner I*, on the other hand, a judge of this court concluded that in ruling upon an "actual causation" claim the factfinder is *forbidden* to consider evidence concerning a possible non-vaccine cause of the injury if that possible cause constitutes an "idiopathic" factor"--*i.e.*, one of unknown cause.

In this case, respondent argues, among other things, that petitioner's chronic hand and foot complaints are symptoms of a condition called "fibromyalgia syndrome" (FMS), rather than being vaccine-caused. And it is essentially undisputed that FMS is a syndrome of unknown cause, so that under *Wagner I*, I would be precluded from considering evidence concerning FMS in resolving petitioner's "actual causation" claim in this case. Accordingly, I asked the parties to address in their post-hearing briefs the question of whether the outcome of this case depended upon whether I applied the approach of *Wagner I* or the approach of *Wagner II*.

In response, both parties to this case suggest that it is *not* necessary for me to choose between the two differing approaches, because the case should come out the same under either approach. Not surprisingly, each side argues that it should prevail regardless of which legal approach is applied. After careful consideration, I agree with the view that the issue of which *Wagner* opinion is correct is ultimately unimportant here, because I conclude that petitioner has *failed* in this case to demonstrate "actual causation" *whether I follow Wagner I or Wagner II*. That is, whether I disregard the evidence as to FMS or consider it, my ruling would be in respondent's favor.

I do note, however, that, because of the two differing analytical frameworks set forth in the two *Wagner* opinions, I will divide my discussion of the evidence relevant to the "actual causation" issue in this case into two general sections, below. Thus, in part C of this section of this opinion, I will analyze only that evidence that would be relevant under a *Wagner I* approach, disregarding the evidence with respect to FMS. Then, in part D, I will discuss the FMS evidence, demonstrating how consideration of that evidence would strengthen the conclusion that petitioner's joint complaints in recent years are probably *not* vaccine-caused.

C. Factual analysis of this case under Wagner I

1. Introduction

Turning to the particular facts of petitioner's case, I begin by observing that apparently the bulk of the energy of the petitioner's counsel and expert in this case must have been focused upon the Table Injury theory, because the record shows relatively little evidence with respect to the "actual causation" issue. To be sure, Dr. Gershwin clearly stated that he believes that petitioner's hand and foot pain since 1992 has been vaccine-caused. And he did explain in a very brief and summary fashion his theory in that regard--*i.e.*, that the rubella vaccination has affected petitioner's immune system in such a fashion that when she is exposed to various antigens, her own immune system reacts inappropriately and causes her joint pain. (See Tr. 73-76.) However, Dr. Gershwin did not really explain *why* he thought that the rubella vaccine could so effect petitioner's immune system. He did not cite any significant medical literature supporting his theory. He did cite to one article, which petitioner filed. (Ex. 24, filed on June 16, 1997.) That brief article, however, essentially presents only a *theory* that vaccines in general *might* trigger autoimmune disorders. There is no focus on the rubella vaccine in that article, and the article's conclusion itself stresses that the data summarized in the article merely "suggests" that some unnamed vaccines "may in rare cases" induce autoimmune disorders, and that "for the time being no conclusions can be drawn." (*Id.* at 3.)

In short, were the evidence for petitioner's "actual causation" argument in this case confined to the evidence actually presented by petitioner herself in this proceeding, I would have to reject her argument immediately, as wholly insubstantial and totally unpersuasive.

However, as explained above, this case was pursued in the understanding that the evidence gathered in the course of the Omnibus Proceeding *would be* applied to this case. And in the Omnibus Proceeding I was presented with evidence sufficient to indicate that cases of chronic joint symptoms which arose in *particular* circumstances, chiefly involving the *onset* of symptoms one to six weeks after a rubella vaccination, could be considered (in the absence of additional relevant facts) to be "more probably than not" vaccine-caused. Therefore, it is appropriate that I analyze whether the evidence introduced in this particular proceeding *combined with* the evidence received in the Omnibus Proceeding justifies a conclusion that petitioner's chronic hand and foot pain has been vaccine-caused. After a complete analysis[(13)] in that regard, I conclude that the combined evidence does *not* support such a conclusion.

2. Analysis under the Omnibus Order criteria

In the Omnibus Order, I stated that based upon the evidence taken in the Omnibus Proceeding, I could conclude that a petitioner's chronic joint symptoms were "more probably than not" caused by that petitioner's rubella vaccination if the petitioner's history met *all* of a specific set of criteria. The second of those criteria was as follows:

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.

Ahern, 1993 WL 179430 at *13.[(14)] Applying that criterion to this case, I find that petitioner's condition clearly is disqualified under that criterion. That is, petitioner's medical records demonstrate that in the years proceeding her rubella vaccination she *did* report joint complaints, including complaints concerning her hands and feet, to her physicians on a number of occasions.

For example, petitioner's medical records indicate that just three months prior to her rubella vaccination, on October 19, 1992, petitioner reported multiple joint complaints. On July 16, 1992, she reported tingling and pain in her left knee, right elbow, neck, and lower back, and, most important here, "constant numbness" in her right toes. (Ex. 10, p. 4.) Another history given by petitioner also states that at some unspecified time in 1992, petitioner had numbness in her right foot. (Ex. 3, p. 11.) A record dated July 9, 1992, reports shoulder and neck discomfort. (Ex. 1, p. 2.) And a record dated July 13, 1992, reports right foot numbness, extending to her ankle. (Ex. 1, p. 3.)

I have found no other reports of joint complaints within the *three years* immediately preceding petitioner's rubella vaccination, but going back only slightly more than three years shows a considerable history of joint complaints, again with some such notations relating specifically to the hands or feet. For example, on September 20, 1989, petitioner reported "vague stiffness." (Ex. 9, p. 51.) On May 26, 1989, she reported leg stiffness, as well as pain in "almost every place in her body." (Ex. 9, p. 48.) Another record also confirms that petitioner experienced "joint stiffness" and pain "almost every place" in May of 1989. (Ex. 3, p. 11.) On May 9, 1988, petitioner reported "cramps in the hands" and "pins and needles in the feet * * * and hands." (Ex. 9, p. 40.) Another report describes "pins and needles" in her "hands and feet" in 1987. (Ex. 3, p. 10.) On October 8, 1986, petitioner reported pain in her right wrist, along with her shoulders, neck, and right knee. (Ex. 9, p. 29.) Another record indicates that also in 1986, petitioner had an episode in which she thought that her knuckles were swollen. (Ex. 3, p. 10.) And, going back to even earlier medical records, there exist notations of back pain in 1983 (Ex. 1, p. 72; Ex. 9, p. 11), and "aches on occasion" in her "bones and joints" in 1982 (Ex. 9, p. 2).

This considerable history of pre-vaccination joint complaints means that petitioner fails the criterion #2 set forth above. To be sure, the experts who testified before me in the Omnibus Proceeding explained that this criterion would have to be applied to any particular case with an element of *judgment* as to the *extent and severity* of the pre-vaccine history. For example, one episode of a single swollen joint after trauma would not constitute a disqualifying factor. (*See*, *e.g.*, *Ahern*, 1993 WL 179430 at *18, fn.10.) But the history of the petitioner in this case, particularly the reports of *multiple* joint complaints *including the toes* in July of 1992, so recently prior to the vaccination in question, seems very significant. When those 1992 reports are *combined* with the extensive, repeated history of joint complaints from the late 1980's, there is clearly a history that casts doubt upon the theory that petitioner's post-vaccination joint complaints are a totally new phenomenon, related to the vaccination. That is, as the experts in the Omnibus Proceeding explained, the existence of significant pre-vaccination joint symptoms similar to the post-vaccination symptoms greatly reduces the likelihood that the post-vaccination symptoms were vaccine-caused. And those Omnibus Proceeding experts indicated that even joint symptoms predating the rubella vaccination by *more* than three years *could* be a disqualifying factor in a particular case. (*Id.*) In this case, Drs. Gershwin and Simms disagreed upon whether petitioner's pre-vaccination joint history cast doubt upon the theory that her recent joint pain is vaccine-caused. I found Dr. Simms to be vastly more persuasive on this point, in his argument that petitioner's pre-vaccination history *was* quite significant and *does* cast doubt upon the theory that her post-

vaccination joint symptoms were vaccine-caused.[(15)]

In short, evaluating petitioner's medical records based upon the testimony of Dr. Simms in this case and the experts who testified in the Omnibus Proceeding, I conclude that petitioner's pre-vaccination history is *not* sufficiently free from joint symptoms to qualify her under the criterion #2 set forth above.

This failure to satisfy criterion #2 is clearly enough *by itself* to mean that petitioner has failed under the Omnibus Order approach to show that her joint symptoms since 1992 have been a result of her rubella vaccination. That is, as stressed in the Omnibus Order, it must be kept in mind that even the basic theory that the rubella vaccine does cause *chronic* joint symptoms is a controversial one. That is, as conceded by even the experts who testified for petitioners in the Omnibus Proceeding, the evidence that the rubella vaccine causes chronic joint symptoms is limited. Even those petitioners' experts acknowledged that the causal connection is not "medically proven," because the type of extensive, repeated, "controlled" epidemiologic studies on the issue, which could "medically prove" the connection, have not been done. Thus, as I explained in the Omnibus Order, even when a particular petitioner's case seems to fall clearly within the general pattern of chronic rubella-associated arthropathy described in that Order, it can still only be said to be slightly more probable than not that the particular petitioner's symptoms were vaccine-caused. Therefore, to the extent that a particular petitioner's history deviates in any significant way from that general pattern, the probability that such person's symptoms were vaccine-caused therefore slips to less than 50%, or less than "more probable than not."

Moreover, there are other significant ways in which the petitioner's case deviates from the general pattern that would be most indicative of vaccine-caused joint symptoms. For example, in the classic post-vaccine joint symptom case as described in the Omnibus Proceeding, there is a record of *clear* arthritis--*i.e.*, quite *noticeable* swelling--in *multiple* joints, observed by a physician within the first several weeks post-vaccination. In petitioner's case, in contrast, the only physician observation during the acute stage described "no dramatic swelling, but just a faint puffiness" of a few finger joints. (Ex. 1, p. 7.) In addition, over the ensuing 5 1/2 years, there have been only two instances of a physician reporting swelling in petitioner's joints (in both cases in finger joints),[(16)] both by the physician who has served as petitioner's expert witness in this case. These circumstances are relevant because the experts who testified during the Omnibus Proceeding indicated that the more dramatic the swelling during the acute stage, the greater would be the chance for chronic symptoms to follow, and also that the more frequent and clear the actual swelling in the chronic stage, the stronger the inference that there truly is rubella-caused arthritis rather than discomfort caused by one of the legion of other potential sources of chronic joint pain. In this case, then, the marginal nature of the acute-stage "puffiness" and the almost total lack of swelling observations since that time are additional factors militating against a conclusion that petitioner's chronic symptoms are vaccine-caused.

A final point in this regard concerns the fact that petitioner points to a pair of physician's notations in petitioner's records and argues that such notations support petitioner's "actual causation" theory. See the notation of Dr. Bush on November 5, 1992, of "rubella, secondary to immunization" (Ex. 1, p. 7), and the notation of Dr. Macchello on April 15, 1993, that petitioner has "chronic arthritis/arthralgia most likely 2º [secondary to] rubella vaccine." (Ex. 3, p. 15.) Of course, I note that in this case as in all Program cases, I view the opinions of a petitioner's actual regular treating physicians with great respect. But after careful review, I conclude that these two opinions offer little support to petitioner's "actual causation" argument in this case.

First, Dr. Bush's notation is not really of any relevance to the issue here of whether petitioner's *chronic* joint pain has been vaccine-caused. Dr. Bush's comment was made only 17 days after her vaccination during petitioner's "acute" phase of rash and generalized aching, which, as even Dr. Simms acknowledges, probably did constitute a reaction to her vaccination.(17)

Dr. Macchello's notation, on the other hand, is of greater significance, since it was made some six months post-vaccination, long past the typical duration (one week to a few weeks) of an ordinary, transient rubella vaccine reaction. The fact that Dr. Macchello stated such an opinion as to causation is of evidentiary value. However, Dr. Macchello was obviously at a disadvantage compared to those physicians who treated petitioner at a later date, or those who have testified in this case. Dr. Macchello only had access to six months of petitioner's post-vaccination history, which is significant because the longer petitioner goes without observable swelling, the more questionable is the causal link to her vaccination. Moreover, it is unclear whether Dr. Macchello was aware of petitioner's history of *pre-vaccination* joint complaints.

Moreover, the brief opinions recorded by other physicians who treated petitioner at *later* times tend to support the *contrary* conclusion, that there likely was *no* causal relationship between petitioner's rubella vaccination and her chronic symptoms. For example, Dr. Dozier, a neurologist, wrote in February of 1994 that petitioner's problem seemed to be "myalgia [*muscle pain*] of unknown cause," and was *not* "typically arthritic." (Ex. 11, p. 7.) This opinion that petitioner's pain is muscular and not arthritic in nature obviously cuts against the notion that petitioner's symptoms are vaccine-caused. Also, Dr. Nagy, an internist, noted in April of 1994 the opinion that petitioner's condition is "not related to" her rubella immunization. (Ex. 16, p. 54.) Finally, Dr. White, a board-certified rheumatologist who evaluated petitioner's joint complaints regularly in 1993 and 1994, and then was asked to examine petitioner again in 1997, stated that he "cannot make a diagnosis of * * * rubella-associated arthritis." (Resp. Ex. K, filed on January 22, 1998, p. 1.)

In short, for all the reasons set forth above, even setting aside the evidence with respect to FMS, I find that petitioner clearly has failed to demonstrate that it is "more probable than not" that her chronic hand and foot pain since 1992 has been vaccine-caused.(18)

D. Additional factual analysis of evidence concerning fibromyalgia syndrome

Finally, I note that if the analysis of *Wagner II* is correct, and therefore I am authorized as factfinder to consider the evidence concerning the "fibromyalgia syndrome" (FMS), there would be even more reason for rejecting petitioner's "actual causation" argument.

1. Petitioner has FMS

The first issue in this regard is whether it can be fairly said that petitioner's condition fits within the fibromyalgia syndrome. I conclude that it can, for a number of reasons. First, a number of petitioner's

treating physicians so concluded. For example, as early as December 2, 1992, Dr. Scalapino analyzed petitioner's history and suggested that she had a "hint of fibromyalgia." (Ex. 1, p. 11.) Dr. White, the board-certified rheumatologist who evaluated petitioner at a number of visits in 1993 and 1994, reached at that time the conclusion that petitioner has FMS. (Ex. 6, pp. 2, 4, 5; Ex. 17, p. 14.) He reached the same conclusion after examining her again in 1997. (Resp. Ex. J filed Aug. 8, 1997, p. 2; Resp. Ex. K filed Jan. 22, 1998, p. 1.) In addition, another physician's note dated February 17, 1996--it is not clear who the physician was--indicates "fibromyalgia" as the physician's assessment (see notation at lower left-hand corner after the abbreviation "A/P," which likely stands for "assessment/plan"). (Ex. 17, p. 15.) And on February 1, 1994, Dr. Chang noted that petitioner "has a history of fibromyalgia syndrome." (Ex. 16, p. 44.)

In addition, I found respondent's expert in this proceeding, Dr. Simms, to be convincing in explaining why he agrees with those treating physicians that petitioner has FMS. I found persuasive, for example, the explanation that a diagnosis of FMS may be well-justified on the fact that an individual has particular tenderness at a *significant number* of the classic FMS "tender points," even if the number of tender points located falls short of the number 11 necessary for inclusion in formal FMS studies. (*See* Tr. 92-93, 101-102, 104-107, 121-123.) As Dr. Simms explained, a board-certified rheumatologist, such as Dr. White who treated petitioner, is qualified to make the diagnosis based upon the overall history of the individual along with a finding of tenderness at a reasonable number of the classic tender points. (*Id.*)

Moreover, after scrutinizing the articles concerning FMS filed by respondent at Exs. C through I, and then studying petitioner's medical records, I find that her history contains documented examples of many of the primary and secondary indicia of FMS. These include evidence of the classic, defining symptoms of FMS--*i.e.*, diffuse muscle pain, "aching all over," and special sensitivity at the "tender point" areas. See, for example, a report of pain "in almost every place in her body" on May 26, 1989 (Ex. 9, p. 48); diffuse muscle pain ("myalgia") on February 16, 1994 (Ex. 11, p. 7); Dr. White's enumeration of petitioner's tender points of May 6, 1993 (Ex. 6, p. 3, lower right-hand corner--see discussion of this notation at Tr. 44-45; 101-102; 104-107); and Dr. Scalapino's notation of "tender trigger points up and down the spine" on December 2, 1992 (Ex. 1, p. 11).

Petitioner's records also include many examples of the "secondary" symptoms that are not part of the definition of FMS but are very often experienced on a chronic basis by FMS patients, such as fatigue, sleep difficulties, "irritable bowel syndrome," non-cardiac chest pain, numbness and tingling, depression, anxiety, and panic attacks. For example, petitioner has reported sleep problems (Ex. 9, p. 28; Ex. 16, p. 57); fatigue (Ex. 6, p. 3; Ex. 9, pp. 17, 18, 20, 28; Ex. 17, p. 3); irritable bowel problems (Ex. 9, pp. 8, 9); non-cardiac chest pain (Ex. 9, pp. 18, 33); and numbness and tingling ("pins and needles," "parasthesias") (Ex. 1, p. 3; Ex. 3, pp. 3, 10, 11, 12; Ex. 9, p. 40; Ex. 10, p. 4). She also has experienced the type of psychological symptoms often associated with FMS, including reports of stress, anxiety, panic attacks, and depression. (Ex. 3, pp. 5, 10, 11, 12; Ex. 9, pp. 38, 40, 45, 51, 60.)

For all these reasons--the most important being the opinion of the board-certified rheumatologist Dr. White--I am persuaded that Dr. Simms is correct in asserting that it is reasonable to assign petitioner to the category of FMS patients.

2. Additional discussion

The fact that petitioner's case fits within the FMS category, thus, is additional reason to doubt that petitioner's difficulties with her hands and feet since 1992 have been vaccine-caused. It might be theoretically possible, of course, for a person to have both FMS *and* a chronic vaccine-caused joint condition. But the existence in petitioner of FMS, a very common syndrome, makes it much more difficult to determine the cause and even the nature of any joint symptoms that petitioner has. That is, as Dr. Simms testified and the medical literature filed in this case confirms, with FMS it is quite common for patients to have a "feeling" of swelling in the joints, or to have pain in fibrous tissues very close to the joints that is *mistaken* for joint pain itself. This makes it very difficult to distinguish between actual joint pain and FMS tissue pain close to the joints. In the total circumstances of this case, I am persuaded that it is more likely that petitioner's chronic joint complaints are a reflection of her FMS than that they are vaccine-caused.

One important point in this regard is that petitioner experienced many of her FMS-like symptoms, enumerated above at p. 17 of this Decision, during the years *prior* to her rubella vaccination. Thus, obviously, her FMS itself cannot be attributed to her vaccination. Moreover, one example stressed by Dr. Simms from petitioner's pre-vaccination history is particularly illuminating. That is, one medical record indicates that in 1986 petitioner went to a physician complaining of a swollen knuckle, but the physician found no swelling. (*See* Ex. 3, p. 10.) Dr. Simms indicated that this sort of incident--*i.e.*, to report a *feeling* of joint swelling and pain, but to have a physician find no objective evidence of injury--is typical not only of FMS patients in general, but also of *petitioner's own* post-vaccination history. (Tr. 87-88.) This point adds to the likelihood that petitioner's recent hand and foot complaints are symptoms of FMS rather than the result of her rubella vaccination.

In sum, the evidence as to FMS, if considered appropriate for consideration concerning the "actual causation" issue, would add even more weight to the conclusion that petitioner has *not* made a successful "actual causation" showing in this case.[(19)]

VI

CONCLUSION

It is, of course, very unfortunate that petitioner suffers from chronic ailments, including the pain in her hands and feet. She is certainly deserving of sympathy for those symptoms. As the above discussion indicates, however, I must conclude that petitioner does *not* qualify for a Program award, under either of

her two theories. Absent a timely motion for review of this Decision, the Clerk of this court shall enter judgment accordingly.

_____

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, all "§" references not otherwise designated will be to 42 U.S.C. (1994 ed.).

2. Petitioner filed records divided into exhibits 1 through 7 with the petition, and Exhibits 8 through 20 on September 13, 1996. "Ex. __" references, unless otherwise noted, will be to those exhibits.

3. "Synovitis" is defined as inflammation of the synovial membrane, which is a part of a joint. Dorland's Illustrated Medical Dictionary (27th ed. 1988), p. 1649. See also Tr. 123-125.

4. "Fibromyalgia syndrome," as will be discussed at length in the pages to come, is a relatively common syndrome, of unknown cause, in which a person reports pain in multiple areas of the body, and often other related symptoms, but no objective evidence of injury is detectable by the physician.

5. "C.F.R." references in this opinion are to the 1996 edition of the C.F.R.

6. Petitioner bears the burden of demonstrating the facts necessary for entitlement to a Program 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).

7. It may be noted that another administrative revision to the Vaccine Injury Table was promulgated in 1997. *See* 62 Fed. Reg. 7685, 7688 (1997) (to be codified at 42 C.F.R.). That revision did make some minor changes to the Table definition of "chronic arthritis," but those changes are not applicable to this case, since such changes only apply to Program petitions filed after March 24, 1997. Moreover, it does not appear that those minor changes would change the result in this case in any event.

8. Moreover, I note that part (iii) of 42 C.F.R. § 100.3(b)(6) *specifies* that "[a]rthralgia (joint pain) * * * without joint swelling shall not be viewed as chronic arthritis." And, as noted above, a report of joint "tenderness" means merely that the patient reports *joint pain* upon pressure.

9. Could there be other possible "objective signs of arthritis" in addition to specific physician observations of "joint swelling"? Bone scan evidence, for example? It is unnecessary for me to reach that question in this case. It is necessary only for me to conclude that physician reports of "joint tenderness" do *not* qualify as "objective signs of arthritis."

10. Further, while I have included this part V(A) in this opinion 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 joint symptoms caused by a rubella vaccination, have been fully or partially resolved. In 66 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 14 of those 66, I found that the petitioner 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 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).)

11. I understand the terms "actual causation" and "causation-in-fact" to be synonyms. They both refer to the method of proof by which a petitioner shows *by scientific evidence* that vaccination A caused injury B, as permitted under § 300aa-11(c)(1)(C)(ii). This method, of course, is the alternative to proof of causation via the Table Injury route.

12. Of course, I recognize that certain medical studies published since I issued the Omnibus Order have added to the available evidence on the issue of whether the rubella vaccine causes chronic arthritis. *See Bilotti v. Secretary of HHS*, No. 92-429V, 1998 WL 78717, at *4 (Fed. Cl. Spec. Mstr. Jan. 20, 1998). There has been no need for me to consider in this case the two studies discussed in *Bilotti*, since, as will be seen, I must reject petitioner's case as failing even under the criteria originally set up in my Omnibus Order. However, in future cases I will, of course, continue to evaluate the evidence submitted in the Omnibus Proceeding in light of any *additional* evidence submitted by the parties.

13. In this particular analysis, in compliance with *Wagner I*, I am *excluding and disregarding* evidence with respect to FMS.

14. In any analysis under *Wagner I*, of course, I would *not* apply the *sixth* criterion set forth in my Omnibus Order, which *Wagner I* found to be improperly restrictive.

15. It is worthy of note that Dr. Gershwin first seemed to argue that petitioner's pre-vaccination history was more or less typical of the ordinary aches and pains that most people experience. (*See, e.g.*, Tr. 11, 34-35.) But I found this suggestion to seem preposterous on its face, and Dr. Simms took strong issue with it. Eventually, Dr. Gershwin was forced to back off from that assertion and to acknowledge that petitioner's pre-vaccination history is typical not of an "average" individual, but of the type of patient who is routinely seen by a rheumatologist. (Tr. 35-37.)

16. I have already described above the fact that Dr. Gershwin's note of September 1, 1995, reported mild swelling in two finger joints. In addition, during the hearing held on June 20, 1997, Dr. Gershwin was present with petitioner, and stated that on that day he observed swelling in two of the petitioner's fingers. (Tr. 79.) (Because Drs. Gershwin and Simms were both testifying by telephonic conference call, Dr. Simms could not also view petitioner's fingers on that day.) I note that based upon this representation of Dr. Gershwin at the hearing, at the conclusion of the hearing I asked the parties to jointly select a rheumatologist to examine petitioner again, to determine whether she was experiencing actual joint swelling. They picked Dr. White, who examined petitioner on July 8, 1997, and found no joint swelling.

17. As explained in the Omnibus Order (1993 WL 179430 at *4), it is well accepted that the rubella vaccine causes *transient short-lived* episodes of arthritis in perhaps 15% of adult vaccinees. The controversial question, rather, is whether that vaccine causes *chronic* arthritis. It should be noted, moreover, that the *acute* reaction of the petitioner in this case, though in fact probably vaccine-caused, does *not* qualify petitioner for a Program award, because there is no good evidence that the effects of this problem lasted for at least *six months*. *See* § 300aa-11(c)(1)(D)(i).

18. In this regard, I note that I have closely considered Dr. Gershwin's testimony concerning petitioner's positive antinuclear antibody (ANA) test. However, I found the testimony of Dr. Simms, who asserted that this result was not significant to the issue of vaccine-causation (*see, e.g.*, Tr. 95-97), to be substantially more persuasive.

19. I note that in two other cases in which the petitioners had FMS, I declined to find that the petitioners had chronic vaccine-caused joint symptoms. *See Johnson v. Secretary of HHS*, No.

92-478V, 1995 WL 61536 (Fed. Cl. Spec. Mstr. Jan. 31, 1995), *aff'd* 33 Fed. Cl. 712 (1995), *aff'd* 99 F.3d 1160 (Fed. Cir. Oct. 30, 1996); *Awad v. Secretary of HHS*, No. 92-79V, 1995 WL 366013 (Fed. Cl. Spec. Mstr. June 5, 1995).