OFFICE OF SPECIAL MASTERS

No. 94-58V
(Filed: May 6, 2005)

E. BARBARA SNYDER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	**TO BE PUBLISHED**

Ronald Homer, Boston, Massachusetts, appeared for petitioner.
Linda Renzi, U.S. Department of Justice, Washington, D.C., appeared for respondent.

DECISION[1]

HASTINGS, ***Special Master***.

This is an action in which the petitioner seeks an award under the National Vaccine Injury Compensation Program (hereinafter "the Program--see 42 U.S.C. § 300aa-10 *et seq*.[2]). For the reasons set forth below, I conclude that she is not entitled to such an award.

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[1]This document constitutes my final "decision" in this case, pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Unless a motion for review of this decision is filed within 30 days, the Clerk of this Court shall enter judgment in accord with this decision.

Also, the petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Rule 18(b)(2) of the Vaccine Rules of this Court, this decision will be made available to the public unless petitioner files, within fourteen days, an objection to the disclosure of any material in this decision that would constitute "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy."

[2]The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq*. (2000 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2000 ed.). I will also sometimes refer to the Act of Congress that created the Program as the "Vaccine Act."

I

THE APPLICABLE STATUTORY SCHEME AND CASE LAW

Under the National Vaccine Injury Compensation Program (hereinafter the "Program"), compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showings that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious long-lasting injury; and has received no previous award or settlement on account of the injury. Finally--and the key question in most cases under the Program--the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table" corresponding to the vaccination in question, within an applicable time period from the vaccination also specified in the Table.[3] If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury not of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists of demonstrating entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. It is clear that the burden is on the petitioner to *prove* that in fact the vaccination caused the injury in question. See, e.g., *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*, 950 F. 2d 731 (Fed. Cir. 1991); *Shaw v. Secretary of HHS*, 18 Cl. Ct. 646, 650-1 (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; *Shaw*, 18 Cl. Ct. at 650-651; *Carter*, 21 Cl. Ct. at 654. Further, the showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A). Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring). The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Secretary of HHS*, 165 F. 3d 1344, 1352 (Fed. Cir. 1999).

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[3]The original version of the Vaccine Injury Table was contained in the statute, at § 300aa-14(a). As will be detailed below, however, the Table has been administratively amended.

II

BACKGROUND FACTS

The petitioner, E. Barbara Snyder, was born in 1946. The records of this case do not indicate any unusual medical history for petitioner prior to February of 1992.

On February 10, 1992, at age 45, petitioner received an "MMR"--*i.e.*, measles, mumps, rubella--vaccination. (Ex. 2[4].) Eighteen days later, on February 28, petitioner visited Dr. Michele Anthony, where she reported that since the vaccination she had experienced the onset of a rash, slight fever, "thick throat," lymph nodes, and joint pains. (Ex. 3, p. 2.) The rash was gone by that February 28 examination, but petitioner on that date apparently indicated that she was still experiencing pain in some joints, including hips, knees, and wrists. (Ex. 3, p. 2; Tr. 88.) Dr. Anthony wrote, as one of her "impressions" at that visit, "[a]cute rubella 2º [secondary] to vaccine" (Ex. 3, p. 3), apparently indicating the physician's view that petitioner's above-mentioned symptoms were part of a case of rubella caused by the rubella portion of her MMR vaccination.

Petitioner returned to see Dr. Anthony on both March 5 and March 10, 1992. On March 5, the physician wrote that petitioner continued to suffer from "diffuse arthralgia.[5]" (Ex. 3, p. 6.) On March 10, Dr. Anthony recorded in her notes that petitioner was reporting "increased arthralgia." (Ex. 3, p. 10.) The physician wrote that upon examination, she found "synovial thickening[6] and bogginess" of petitioner's right wrist. (*Id*.) Dr. Anthony also wrote a note on that date indicating that petitioner had "frank arthritis of the right wrist and diffuse arthralgia;" she concluded that petitioner was still "suffering from acute rubella syndrome secondary to vaccination." (Ex. 3, p. 7.)

Petitioner visited Dr. Ana Cilurso, a rheumatologist, on March 16, 1992. Dr. Cilurso's records of that visit record the onset of petitioner's joint pain as occurring two weeks after her vaccination, and state that in light of that "temporal association," the symptoms "most likely" represented a reaction to the rubella portion of the vaccination. (Ex. 4, pp. 1-2.) Dr. Cilurso's examination on that day found "no evidence of acute synovitis." (Ex. 4, p. 1.)

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[4]Petitioner filed Exhibits numbered 1 through 14 with the petition, and additional, sequentially-numbered exhibits on many occasions since then. Respondent has filed exhibits designated by letters on several occasions. "Ex." references will be to those exhibits. "Tr." references will be to the pages of the transcript of the evidentiary hearing held on September 28, 2004.

[5]"Arthralgia" means joint pain. *Dorland's Illustrated Medical Dictionary*, 27th ed. 1988 (W.B. Saunders Co.), p. 147.

[6]"Synovial thickening" would appear to mean a thickening of the "synovia," a fluid contained in joints. "Synovitis" refers to swelling of the synovial membranes of the joints. *Dorland's Illustrated Medical Dictionary*, 27th ed. 1988 (W.B. Saunders Co.), pp. 1648-49. A notation by a physician of an absence of "synovitis" means that the physician examined a joint, or a number of joints, and observed no swelling.

Petitioner visited Dr. Cilurso again on March 23, April 2, April 15, and April 17, 1992, reporting continued joint pain and some muscle pain. (Ex. 4, pp. 3, 5, 7, 10, 11.) The notes of those visits contain no indication that Dr. Cilurso ever found any objective evidence of joint swelling; to the contrary, the physician specifically wrote "no synovitis" on several occasions. (Ex. 4, pp. 3, 5, 7.) In the notes of the visit of April 8, Dr. Cilurso wrote that the post-rubella reaction "may be entering a resolution phase." (Ex. 4, p. 7.) She also wrote that she found "[m]ultiple tender points," and concluded that petitioner's condition fit within the diagnosis of "fibromyalgia." (*Id*.)

During the ensuing years, petitioner has visited many physicians, continuing to repeatedly report joint pain, muscle pain, and a number of other symptoms. As will be detailed below, a number of those physicians made notations in their records seeming to indicate that those physicians viewed petitioner's ongoing symptoms as resulting from her MMR vaccination of February 10, 1992. Some of petitioner's physicians, on the other hand, made notations indicating their doubt about the possibility of such a causal connection. In addition, a number of physicians, beginning with Dr. Cilurso on April 8, 1992 (Ex. 4, p. 7), reached the conclusion that petitioner is suffering from the condition known as "fibromyalgia syndrome."

Petitioner's condition has deteriorated over the ensuing years. She continues to report constant pain in multiple areas of her body. She has not been employed for many years. She ambulates only with a walker, and uses a motorized scooter when she leaves her residence. She utilizes a nurse's aid to help her with certain aspects of daily living. (See, *e.g.*, Ex. 41, pp. 2-3.)

III

PROCEDURAL HISTORY AND STATEMENT OF ISSUE

A. Procedural history

Petitioner filed her Program petition, via attorney Boyd McDowell, on January 31, 1994. Petitioner's case, thus, became at that time one of a large number of pending Program cases in which a petitioner alleged that his or her chronic joint pain was caused by a rubella vaccination. In that context, respondent's representatives at that time considered whether petitioner's chronic joint pain appeared to satisfy the "causation criteria" set forth in an opinion that I had filed on January 11, 1993, in 70 such cases. In that opinion, to be discussed in detail below, I had stated that if a petitioner's chronic joint pain arose under certain circumstances after a rubella vaccination, I would likely find such joint pain to be vaccine-caused. Respondent conceded, in the "Respondent's Report" filed on May 2, 1994, that petitioner's chronic joint pain met those "causation criteria;" accordingly, respondent indicated that respondent would not contest that petitioner's chronic *joint pain* was vaccine-caused. The parties then attempted to reach agreement on an appropriate amount of compensation for petitioner's chronic joint pain.

After discussion between the parties, however, it became clear that petitioner desired compensation for *other* symptoms, in addition to joint pain, and the parties agreed that petitioner would need to obtain expert opinion supporting her claim that her *other* symptoms were vaccine-caused. Thereafter, petitioner and her then-counsel continued for years to seek such an expert opinion, without ever filing an expert report.

In the meantime, as will also be detailed below, more evidence became available concerning the *general issue* of whether the rubella vaccine causes chronic joint problems. I reviewed a number of recent studies on the issue, and an extensive evidentiary hearing was held to explore the importance of those studies on March 26 and 27, 2001. I kept petitioner informed concerning my process of taking and evaluating that additional evidence. (See, *e.g.*, my Orders filed in this case on February 6, July 18, October 3, and November 26, 2001.)

After the hearing on the general causation issue took place in March of 2001, counsel for respondent and counsel for a number of the other petitioners with related cases expressed interest in attempting to settle individual cases in light of the testimony at the hearing. These counsel requested that I refrain from issuing my written analysis of the evidence taken at the hearing until their settlement efforts were finalized. After considerable efforts by counsel, a significant number of cases were, in fact, settled. Judgment was entered in the last of those settled cases in May of 2002. Accordingly, after those settlements were finalized, I issued my written analysis of the general causation issue on December 13, 2002, in a document filed in this and several other then-pending cases. In that opinion, I concluded that the available evidence supported a causal link between the rubella vaccination and chronic joint symptoms, *if* the claimant's history fit within a particular set of circumstances.

During the meantime, petitioner changed counsel. In early 2002, Mr. McDowell informed petitioner and myself that he would soon be leaving his law practice, and petitioner was notified, during a status conference on January 24, 2002, in which she participated along with Mr. McDowell, that she could retain new counsel or represent herself. She chose to represent herself. (See my Order dated February 26, 2002.)

On March 5, 2003, petitioner filed papers indicating that she had retained a new attorney, Ronald C. Homer, and on March 10, 2003, I conducted the first of a new series of unrecorded telephonic status conferences (as the record reflects), in order to move the case. Petitioner's counsel and respondent's counsel entered into negotiations in an attempt to settle the case. Those settlement efforts continued until March 4, 2004, when petitioner's counsel informed me during a status conference that settlement efforts had reached an impasse, and that petitioner would soon be filing a motion seeking an immediate ruling on her claim.

On March 8, 2004, petitioner filed her motion, entitled a "Motion for Judgment on the Pleadings." In the motion, petitioner explained that she would *not* be filing any expert report in support of her claim that a whole range of symptoms, in addition to her chronic joint pain, was vaccine-caused. Instead, petitioner requested that I file forthwith a *final decision* concerning petitioner's petition, granting her compensation, *without* allowing the respondent to file any evidence in the case. Both parties filed additional briefs concerning that motion. I denied the motion in a written ruling filed on June 14, 2004.

In her motion, petitioner relied chiefly on the extraordinary fact that this petition has been pending for more than ten years. Petitioner blamed this delay on the respondent, and suggested that because of this delay I should immediately proceed to a final decision, based exclusively on the evidence already in the record, without conducting any further procedures or giving respondent a chance to address the factual questions that petitioner was then, for the first time, asking me to resolve.

In denying the motion, I concluded that such an immediate decision would not be appropriate. I noted that to begin with, the delay in the processing of this case has been almost completely the result of *petitioner's own choices*. As noted above, the respondent's initial report concerning the case indicated that respondent would not contest at that time, based upon the medical evidence then available, that petitioner's chronic *joint pain* was vaccine-caused. However, petitioner then elected to seek compensation for *other* symptoms in addition to joint pain, and, accordingly, sought to obtain an expert opinion supporting her claim that her *other* symptoms were also vaccine-caused. Our plan for the case was that once petitioner supplied an expert opinion, respondent would then file an expert opinion if respondent did not agree with petitioner's expert. Petitioner spent nearly ten years asking me to give her more time in which to obtain such an expert opinion. Not until March of 2004 did petitioner ask me for a *ruling* concerning which of her symptoms, if any, was vaccine-caused. She had previously taken the position that I should *delay* any such ruling until she could obtain an expert report.

Therefore, I concluded, it was not reasonable for petitioner to suddenly argue that I should make an *immediate* and final ruling on her claim, without giving respondent a chance to provide evidence concerning the very complex factual issues raised by that claim, based on the faulty premise that respondent had somehow caused the delay in her case. As indicated above, respondent did *not* cause the delay, so that to deny the respondent a chance to make an evidentiary response to petitioner's claim would be unfair.

In that opinion denying her motion, however, I noted that since petitioner was now for the first time seeking my ruling on her contention that she suffers from vaccine-caused symptoms, I would give her a *reasonably prompt* ruling on that contention, after first giving respondent a reasonable a chance to respond. As indicated by my orders dated April 13 and May 12, 2004, respondent desired to present the report of an expert witness, Dr. Alan Brenner, concerning petitioner's causation contentions. That expert report was filed on June 15, 2004. At status conferences held on July 7 and 14, 2004, I encouraged petitioner's counsel to present, if possible, her own expert testimony in response to Dr. Brenner. Petitioner's counsel, however, elected to proceed without offering an expert witness of petitioner's own.

I scheduled a hearing for September 28, 2004, to hear the oral testimony of Dr. Brenner, and to give petitioner's counsel an opportunity to cross-examine that expert. At the conclusion of that hearing, petitioner's counsel requested the opportunity for a post-trial briefing process. Petitioner's final brief in that process was filed on February 1, 2005, at which time the dispute became ripe for my ruling.

B. Issue to be decided

In this case, petitioner does not allege that she suffered a "Table Injury."[7] Instead, she alleges[8] that her chronic joint pain, as well as all other aspects of her condition known as "fibromyalgia syndrome," was "caused-in-fact" by her 1992 rubella vaccination. I will deal with that claim in parts IV through VII of this Ruling.

IV

"CAUSATION-IN-FACT" ISSUE: INTRODUCTION

As noted above, the petitioner's contention in this proceeding is that her chronic joint pain, along with additional symptoms, was "caused-in-fact" by her rubella vaccination of February 10, 1992. This case, thus, is one of many Program cases in which petitioners have alleged that rubella vaccinations have caused chronic joint pain and/or arthritis. I have described these cases as the "rubella/arthropathy" cases, since the term "arthropathy" encompasses both *joint pain*, also known as "arthralgia," and *joint swelling*, also known as arthritis. The general history of these "rubella/arthropathy" cases is relevant to the resolution of this case.

That general history is, in fact, *crucial* to the resolution of this case, because in this case, as noted above, the petitioner has *not* presented the oral testimony of an expert witness specifically supporting her claim that her joint pain was vaccine-caused. Instead, the petitioner relies, in part, on the fact that in the course of the above-described "rubella/arthropathy" cases, all decided by myself as special master, in published opinions I have developed a set of "causation criteria," stating that if a particular petitioner's case falls within those criteria, *and* there is no substantial evidence introduced in that particular case casting doubt on a "causation" finding, I would be inclined to infer a causal relationship between the vaccination and the petitioner's chronic arthropathy. Petitioner asserts that her own case fits within my published "causation criteria," and that, on that basis, without need for any case-specific expert testimony, I should conclude that *petitioner's* chronic joint pain was vaccine-caused.

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[7]Effective in March of 1995, "chronic arthritis" was added as a Table Injury for vaccinations containing the rubella vaccine. *See* 60 Fed. Reg. 7678 (1995). However, because the petitioner in this case filed her petition in this case prior to the March 1995 effective date of that new Table Injury, the Table Injury was *not* applicable to her case. (See 42 C.F.R. § 100.3(c) (10-1-96 edition of C.F.R.).) Petitioner has never contended that her case could qualify under that "chronic arthritis" category or any other Table Injury category. Moreover, it appears to me that petitioner's case, in any event, would *not* satisfy the "chronic arthritis" Table Injury criteria, since petitioner has not been found by medical professionals to suffer from *actual arthritis* since Mach 10, 1992.

[8]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).

Respondent, on the other hand, argues that petitioner has *not* demonstrated that her chronic arthropathy was vaccine-caused. First, respondent disagrees generally with the view that chronic joint pain falling within my "causation criteria" can reasonably be deemed to be vaccine-caused. Second, respondent argues that, in any event, petitioner's case fails to meet several of my criteria. Finally, respondent, unlike petitioner, has presented the testimony of an expert witness specifically addressing petitioner's case in detail. Respondent urges that the testimony of that witness, Dr. Brenner, supports a conclusion that petitioner's chronic joint pain has *not* been vaccine-caused.

In considering these arguments of both parties, I will analyze and rule upon petitioner's causation claim based on the available record. In doing so, I will, as both parties agree that I should, analyze not only the evidence introduced in this case, but also the evidence on the *general* "rubella/arthropathy" causation issue that I have developed in the above-mentioned "rubella/arthropathy" cases.

Therefore, in order to analyze this aspect of the petitioner's "causation-in-fact" claim, I will, in Part V of this Decision, set forth the history of the "rubella/arthropathy" cases, explaining the "causation criteria" that I have developed in the course of those cases. Then, in Part VI, I will deal with petitioner's argument that application of those "causation criteria" to *petitioner's* case demonstrates that petitioner's chronic *joint pain* was vaccine-caused. I will explain why I must reject that argument.

The petitioner in this case, however, does *not* rely *exclusively* on the theory that her case meets my "causation criteria." She also advances an additional line of argument. That is, petitioner argues that other symptoms, in addition to her chronic joint pain, have been vaccine-caused. Petitioner has been diagnosed with a condition known as "fibromyalgia syndrome," and she contends that this syndrome was indirectly caused by her rubella vaccination. She argues that the vaccine caused her joint pain ("arthropathy"), and that such joint pain in turn resulted in her "fibromyalgia syndrome." I will deal with this argument of petitioner in part VII of this Decision.

V

HISTORY OF THE "RUBELLA/ARTHROPATHY" CASES

A. Proceedings in early 1990's concerning the general causation issue

A version of the "Vaccine Injury Table" was set forth in the statute establishing the Program, at § 300aa-14(a). That statutory version of the Table was applicable to petitions filed during the first several years of the Program's experience. That version of the Table, however, contained no provision concerning arthropathy, arthritis, or similar symptoms following any vaccination. Thus, from the beginning of the Program through early 1995, a petitioner suffering from arthropathy or a similar condition after a rubella vaccination had the burden of proving that the vaccination "caused-in-fact" the condition.

During the early 1990's, various petitioners filed a large number of Program cases involving allegations that rubella vaccinations caused chronic arthropathy. Accordingly, in order to most efficiently resolve all of those cases, the undersigned special master was assigned by the Chief Special Master to undertake an inquiry into the *general issue* of whether the rubella vaccine can cause chronic arthropathy, with the hope that information and conclusions concerning that *general* causation issue, developed from the general inquiry, could be applied to each *individual* case.

Toward that goal, I initiated a series of meetings, involving counsel who each represented a large number of petitioners in Program cases involving claims of this type, and counsel on behalf of respondent. Those counsel developed evidence to put before me concerning the general causation issue. They supplied a series of written reports from medical experts.[9] I also conducted an extensive search of relevant medical literature, based upon both bibliographies supplied by the aforementioned counsel and my own research. Then, in November of 1992, I conducted a three-day evidentiary hearing in which six medical experts, three sponsored by petitioners' counsel and three by respondent, testified concerning the general causation issue.[10]

B. My analysis in the "1993 Order"

Based upon the medical evidence and expert testimony discussed above, I concluded, in a published opinion filed on January 11, 1993, that the evidence was sufficient to support a determination that it is "more probable than not" that the rubella vaccine does cause some cases of chronic arthropathy. (I will refer to that document as the "1993 Order;" it was published as *Ahern et al. v. Secretary of HHS*, 1993 WL 179430 (Fed. Cl. Spec. Mstr. Jan. 11, 1993).) A copy of that "1993 Order" was filed into the record of this case as an attachment to my order filed on March 25, 2004. In that "1993 Order," I concluded that a petitioner "more probably than not" has suffered a condition "caused-in-fact" by a rubella vaccination, and is thus entitled to a Program award, if that petitioner's case meets *all* of the following criteria:

1. The petitioner received a rubella vaccination at a time when the petitioner was 18 years of age or older.

2. The petitioner had a history, over a period of at least three years prior to the vaccination, of freedom from any sort of persistent or recurring polyarticular joint symptoms.

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[9]I have established a special file in the office of the Clerk of this court known as the "Rubella Omnibus File." In that file I have placed copies of all the evidentiary items upon which I have relied in my rulings concerning the possible causal relationship between the rubella vaccine and chronic arthropathy. That file is open for inspection or copying by any interested person. A summary of the contents of that file appears as the Appendix to this Ruling.

I hereby incorporate that entire "Rubella Omnibus File" into the record of this case by this reference. For convenience, I will not physically place a copy of that entire voluminous File into the record of this case, but it shall be considered an integral part of the record of this case. I note that counsel for both parties in this particular case are thoroughly familiar with the contents of that File. See also footnote 13, below.

[10]The transcript of that 1992 hearing, entitled "Omnibus Hearing *Re*: Rubella/Chronic Arthropathy Issue," is contained in the Rubella Omnibus File as part C.

Further, I note that I will hereinafter sometimes refer to both the 1992 inquiry and the subsequent 2001 inquiry, concerning the general rubella/arthropathy causation issue, as the "omnibus proceedings" or "omnibus hearings."

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

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

5. Polyarticular arthropathic symptoms continued for at least six months after the onset; or, if symptoms remitted after the acute stage, polyarticular arthropathic symptoms recurred within one year of such remission.

6. There is an absence of another good explanation for the arthropathy; the petitioner has not received a confirmed diagnosis of rheumatoid arthritis, nor a diagnosis of any of a series of specific conditions (see list at p. 10 of the 1993 Order).

Ahern, 1993 WL 179430 at *13.

In reaching that conclusion, I noted that all six of the experts who testified at the 1992 hearing, including those who testified for respondent, agreed that at least in cases in which the vaccinee experienced acute polyarticular *actual arthritis* (*i.e.*, joint *swelling*), as opposed to *arthralgia* (*i.e.*, joint *pain* without swelling), during the expected time period after vaccination, any chronic arthritis suffered by that vaccinee thereafter could reasonably be attributed to the rubella vaccination. The respondent's experts differed with the petitioners' experts, rather, chiefly as to a single issue, concerning those cases that fit the diagnostic criteria set forth above, but in which in either or both of the acute and chronic stages of the condition the individual had only *arthralgia*, without any measurable *arthritis*. In such cases the petitioners' experts opined that the chronic arthralgia was likely vaccine-caused; the respondent's experts would not make such a finding. On that point of dispute, I found the petitioners' experts to be more persuasive, for reasons that I explained in the "1993 Order."

Accordingly, I concluded in the "1993 Order" that when a petitioner's case met the six criteria listed above, and there was no substantial case-specific evidence in that case pointing to some other explanation for the arthropathy, the evidence would support a conclusion that the petitioner's chronic arthropathy, whether it be chronic arthritis or arthralgia, was likely caused by the rubella vaccination.

C. Developments after the "1993 Order"

After I issued the above-described "1993 Order," several developments relevant to the general causation issue occurred, which I will briefly describe.

1. Resolution of cases

As a result of the above-described proceedings that I conducted in 1992 concerning the general causation issue, culminating in my "1993 Order," a significant number of cases, each involving an allegation that joint symptoms were caused by a rubella vaccination, were resolved. In 71 cases decided during the years 1993 through 2001, either I concluded that the requisite showing of causation was made, or the parties agreed upon an award based on the similarities between the petitioner's case and the criteria set forth in that "1993 Order." (See, e.g., *Long v. Secretary of HHS*, No. 94-310, 1995 WL 470286 (Fed. Cl. Spec. Mstr. July 24, 1995).) In 19 cases, 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 15, 1995).) I dismissed four cases on procedural grounds. Finally, in 52 additional cases, the petitioner either voluntarily dismissed or simply abandoned prosecution of his or her case, apparently in light of the fact that the case plainly did not seem to fit within the criteria set forth in the "1993 Order."

2. Table Injury designation

As noted above, the Vaccine Act provides that the Secretary of Health and Human Services may administratively amend the Vaccine Injury Table. Thus, the Table was administratively modified in 1995, with the addition of "chronic arthritis," if incurred under certain specified circumstances, as a "Table Injury" for vaccinations that include the rubella vaccine. *See* 60 Fed. Reg. 7678 (1995). A second administrative revision to the Vaccine Injury Table was promulgated in 1997, retaining "chronic arthritis" as a Table Injury for rubella vaccinations, while slightly modifying the definition of that term for Table purposes. *See* 62 Fed. Reg. 7685, 7688 (1997). [11] Those Table revisions adopted criteria for the new "chronic arthritis" Table Injury which are similar, but not identical, to the criteria that I set forth for "causation-in-fact" in my "1993 Order." The chief difference is that to qualify under the new Table Injury category, a petitioner must, as noted above, establish that he or she suffered "objective evidence * * * of acute *arthritis* (joint swelling)." (42 C.F.R. § 100.3(b)(6)(A) (1997 ed.), emphasis added.) That is, it must be demonstrated that a physician observed actual *arthritis* (joint *swelling*), not merely *arthralgia* (joint *pain*), in both the acute stage and the chronic stage of the vaccinee's illness. (42 C.F.R. § 100.3(b)(6)(A) and (B) (1997 ed.).) This requirement is more strict than the criteria that I adopted in my "1993 Order," in which I concluded that "causation-in-fact" of an arthropathic condition might be established even where, during the acute stage and/or the chronic stage, only *arthralgia* was reported.

Since 1995, five Program petitioners have successfully established that they have suffered compensable injuries under the new "chronic arthritis" Table Injury category. A number of other pending cases, however, have involved situations in which, as in this case, a petitioner has suffered chronic arthropathy, but not under circumstances which correspond precisely to those set forth in the "chronic arthritis" Table Injury's regulatory definition. In each of these cases, the petitioner has sought a finding of "causation-in-fact."

3. Additional inquiry in 2001-2002

During the late 1990's, several medical studies relevant to the general causation issue were completed, and the results of those studies were published. Accordingly, I determined that I should re-analyze the general causation issue in light of the new studies. Again, attorneys representing the

[11] As noted above (fn. 7), these two administrative revisions do not apply to petitioner's case, since her petition was filed before the effective date of these provisions.

petitioners and respondent submitted expert reports, and a hearing, at which six such experts testified, was held in 2001.[12]

After that hearing, I reviewed the general causation issue again, in light of the 1990's studies and the recent expert reports and hearing testimony. On December 13, 2002, I published a document entitled "Analysis of Recent Evidence Concerning General Rubella/Arthropathy Causation Issue." (I will refer to that document as the "2002 Analysis;" it was published as *Snyder et al v. Secretary of HHS*, 2002 WL 3196572 (Fed. Cl. Spec. Mstr. Dec. 13, 2002) (hereinafter "*Snyder I*"). A copy of that "2002 Analysis" was filed into the record of this case on December 13, 2002.) In that "2002 Analysis," I concluded that while the overall argument for the general proposition that the rubella vaccine causes chronic arthropathy had been somewhat weakened, nevertheless a sufficient "causation-in-fact" case could still conceivably be made in an individual case. Considering all the evidence available, I concluded that the criteria set forth at pp. 9-10 above are still quite relevant to my analysis of any individual case. I modified those criteria in the two areas suggested by the more recent evidence. That is, (1) the vaccinee need only have been *past puberty* (not 18 years of age) at the time of vaccination; and (2) the onset of polyarticular symptoms must have taken place between *seven and 21 days* after vaccination (rather than between one and six weeks post-vaccination). Therefore, the newly-modified criteria stood as follows:

1. The petitioner received a rubella vaccination at a time when the petitioner was past puberty.

2. The petitioner had a history, over a period of at least three years prior to the vaccination, of freedom from any sort of persistent or recurring polyarticular joint symptoms.

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

4. The petitioner experienced the onset of polyarticular (*i.e.*, in *multiple* joints) joint symptoms during the period between seven and 21 days after the vaccination.

5. Polyarticular joint symptoms continued for at least six months after the onset; or, if symptoms remitted after the acute stage, polyarticular joint symptoms recurred within one year of such remission.

6. There is an absence of another good explanation for the joint symptoms.

Snyder I, 2002 WL 3196574 at *8, *20. Further, I stated that if any individual case falls squarely within those modified criteria, *and* there are no special circumstances of the case that cast doubt on a causal relationship, *and* there is no additional medical evidence submitted in that case that alters my view of the general causation issue, then I would be likely to find "causation-in-fact" in that case. *Id*. at *20. In other words, considering all the evidence that I had reviewed up until that point in time, I found the evidence sufficient to support a finding of causation in a particular case, *if* that case falls within those modified criteria, in the absence of countervailing evidence.

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[12] A collection of the expert reports submitted in preparation for the 2001 hearing is contained at part D of the "Rubella Omnibus File." The transcript of the 2001 hearing constitutes part E of that File.

VI

APPLICATION OF THE "CAUSATION CRITERIA" SET FORTH IN MY "2002 ANALYSIS" DOES NOT DEMONSTRATE THAT PETITIONER'S CHRONIC JOINT PAIN WAS VACCINE-CAUSED

A. Introduction

As noted above, petitioner's first argument in this case is that petitioner's case meets the six "causation criteria" set forth in my "2002 Analysis," and that, therefore, her chronic joint pain should be considered to have been vaccine-caused. After careful consideration, however, I must reject this argument. I will explain my reasoning below. First, however, I note that in reaching this conclusion, I have considered all of the evidence concerning the *general causation issue* that I heard during both the early 1990's

proceedings and the 2001-2002 proceedings described above, as contained in the Rubella Omnibus File;[13]

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[13]I note that counsel for both parties have been well aware that I would utilize the evidence contained in the Rubella Omnibus File, and the knowledge concerning the general rubella/arthropathy causation issue that I have gained in the course of the above-described general proceedings concerning that issue, in resolving this case. Indeed, the entire idea of the proceedings on the general issue was that information gained in those proceedings *would be applied to individual cases*. Moreover, petitioner's entire "causation-in-fact" argument *in this case* is that I *should* apply to her case the causation criteria developed in the proceedings concerning the general issue.

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

The idea of utilizing an "omnibus proceeding" to gather information applicable to a significant number of Program cases, therefore, would seem to fit clearly within this Congressional intent. This procedure not only allows a special master to bring special expertise to particular cases, but also helps the Program to accomplish the Congressional goals of speedy and economical resolution of cases. This general procedure, therefore, has been utilized not only in the "rubella arthropathy" cases before me, but also for two other large groups of cases, *i.e.*, the "poliomyelitis" cases before Chief Special Master Golkiewicz (see, e.g., *Gherardi v. Secretary of HHS*, No. 90-1466V, 1997 WL 53449 (Fed. Cl. Spec. Mstr. Jan. 24, 1997)) and the "tuberous sclerosis" cases before Special Master Millman (see, e.g., *Costa v. Secretary of HHS*, 26 Cl. Ct. 866, 868 (1992)). This general procedure is also currently being utilized, at the request of the petitioners, in the "thimerosal/autism" cases currently pending before myself (see the *Autism General Order #1*, 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002)).

Of course, the special masters managing these groups of cases have also taken care to ensure that

(continued...)

I have also considered, of course, the evidence specific to petitioner's own case.

Petitioner's argument seems simple at first glance, but the analysis of petitioner's argument is, in fact, quite complex. I start by pointing out that in my "2002 Analysis" I did *not* state that if a petitioner's case meets all of my six stated criteria, I would *automatically* conclude that such petitioner's chronic joint pain was vaccine-caused. Rather, I stated as follows:

> I will state that if any individual case falls squarely within those modified criteria, *and there are no particular circumstances of the case that cast doubt on a causal relationship*, and there is no additional medical evidence submitted in that case that alters my view of the general causation issue, then I would be likely to find causation in that case. In other words, considering all the evidence that I have reviewed at this point in time, I find the evidence sufficient to support a finding of causation in a particular case if that case falls within those modified criteria, *in the absence of countervailing evidence*.

Snyder I, 2002 WL 31965742, at *20, emphasis added. As is made clear by the language emphasized above, I did not state that fulfillment of the six criteria would *automatically* result in a finding of entitlement. Rather, I indicated the possibility that even if the criteria were met, "particular circumstances of the case that cast doubt on a causal relationship" might nevertheless cause me to reject a causal relationship.

This qualifying language concerning use of my "causation criteria," of course, conforms to the statute itself, which states that I must evaluate "the record as a whole" when making a finding concerning whether a particular petitioner is entitled to an award. § 300aa-13(a)(1). Clearly, I am obligated to consider *all* evidence of record that relates to the "causation-in-fact" issue in a case, whether or not such evidence happens to fit into any of my criteria categories. Further, while I believe that it is highly appropriate for a special master to state an analysis of a general causation issue, as I did in my "1993 Order" and my "2002 Analysis," it should be clear that a special master should *not* thereafter apply such an analysis to particular cases in a *mechanistic* fashion. For example, in *Pafford v. Secretary of HHS*, 64 Fed. Cl. 19, 31 (2005), Judge Block approved of a special master's practice of setting forth a list of factors to be utilized in Program "causation-in-fact" analyses, but stressed that in *applying* those factors to an *individual case*, there is "no hard and fast rule" for applying such factors; instead, the master must utilize a "rule * * * of reason, in which the Special Master gives greater weight to certain factors in certain cases depending on the facts of that particular case." Accordingly, when I apply my rubella/arthropathy "causation criteria" to

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[13](...continued)
the rights of *individual petitioners* to fair resolution of their cases is not lost in the efficiency of an "omnibus proceeding." For example, before, during, and after the general proceedings that I have conducted concerning this rubella/arthropathy causation issue, I have stressed to all counsel in the rubella/arthropathy cases that each party in each individual case has the right to offer additional relevant evidence, and to challenge the validity of the evidence received during the "omnibus proceeding."

Given the above-described Program factfinding system devised by Congress, accompanied by the procedural safeguards for individual cases described above, I am satisfied that it is appropriate for me to utilize the evidence gained in the "omnibus proceeding" in resolving *individual* petitioners' cases. Neither the respondent, nor any petitioner in any individual Program case, has ever argued otherwise.

an individual case, I do not apply them in a mechanistic fashion. I consider, for example, not only whether the case fits a particular criterion, but also whether there is a "strong fit" or a "weak fit" as to criteria such as Criteria 4 and 5--the stronger the fit, the stronger the support for a "vaccine-causation" conclusion.[14] And I will consider any and all evidence in the particular case that does not happen to fall neatly within any one of my criteria.

In this case, then, I must consider petitioner's case in light of my criteria set forth in my "2002 Analysis," but *also* consider *all aspects* of the record in this case, in determining whether petitioner has demonstrated that her chronic joint pain was "caused-in-fact" by her rubella vaccination of February 10, 1992. I have done so. I will divide my discussion into three parts below. In part B, I will explain why I conclude that petitioner's case generally does fit within my Criteria 1 through 5. In part C, I will explain why I conclude that petitioner's case does *not* meet Criterion 6. And in part D I will explain my view that *one particular aspect* of petitioner's case convinces me that my application of my criteria to petitioner's case *cannot* reasonably result in a conclusion that petitioner's chronic joint pain was vaccine-caused.

B. Criteria 1 through 5

It is undisputed that petitioner's case meets *some* of the six "causation criteria" of my "2002 Analysis" set forth above at p. 12--namely, Criteria 1, 2, and 3. Petitioner received a rubella vaccination at the age of 45 years. (Criterion 1.) Nothing in the record indicates that she had any sort of persistent or recurring polyarticular joint symptoms prior to that vaccination. (Criterion 2.) And after that vaccination, she developed an antibody response to the rubella virus. (Criterion 3.)

Further, although respondent has raised issues as to Criteria 4 and 5, I conclude that petitioner's case seems to generally to meet those two criteria as well.

Criterion 4 requires that the petitioner have experienced the *onset* of polyarticular joint symptoms between seven and 21 days after vaccination. As to that issue, the contemporaneous medical records indicate that sometime between her February 10 vaccination and her visit to Dr. Michele Anthony on February 28, petitioner experienced the onset of a rash, joint pain, and other symptoms. (Ex. 3, p. 2.) The rash was gone by that February 28 examination, but petitioner on that date apparently indicated that she was still experiencing pain in certain joints. (Ex. 3, p. 2; Tr. 88.) Dr. Anthony wrote, as one of her "impressions" at that visit, "[a]cute rubella 2º to vaccine" (Ex. 3, p. 3), apparently indicating the physician's view that petitioner's above-mentioned symptoms were part of a case of rubella caused by the rubella portion of her MMR vaccination.

The records of that first visit to Dr. Anthony do not specify *exactly when* the joint pain and the other symptoms occurred, except that the onset obviously occurred between February 10 and 28.

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[14]This is in contrast to the form of analysis that I would utilize if a *Table Injury* was involved. That is, if a petitioner's case fits within each element of a Table Injury, the presumption of causation *automatically* arises. There would be no distinction between a "strong fit" and a "weak fit." In a "causation-in-fact" analysis, on the other hand, as noted in *Pafford*, the analytical factors cannot be applied mechanistically, but must be weighed carefully in the context of the individual case.

However, on March 16, 1992, petitioner's rheumatologist, Dr. Ana Cilurso, wrote that the arthralgias developed "two weeks after" the rubella vaccination. (Ex. 4, p. 1.)

Accordingly, I conclude that petitioner's case *does* meet Criterion 4.

As to Criterion 5, that criterion requires that the polyarticular joint symptoms must have continued or repeatedly recurred over a period of more than six months after onset. And petitioner's medical records make it clear that since her onset of joint complaints in February of 1992, petitioner has consistently and repeatedly reported to physicians that she has experienced pain in multiple joints. So it appears that petitioner's case meets Criterion 5 as well.

I do note, however, that as to Criteria 4 and 5, petitioner's case is certainly not the "strongest fit" possible to the classic pattern of chronic arthritis after rubella vaccine that the experts described during the 1992 and 2001 "omnibus hearings" described above. That is, the strongest case would be one in which the patient had an observable, "frank" arthritis in multiple joints during the acute reaction about two weeks post-vaccination, then went on to experience frank arthritis continuously or intermittently thereafter, in the same joints. Also fairly strong would be cases in which the patient had frank polyarthritis in the acute stage, then *arthralgia only* in the same joints intermittently thereafter. In petitioner's case, however, no frank arthritis in any joints was noted in the records of her first two physician visits after rubella vaccination on February 28 and March 5, 1992. (Ex. 3, pp. 2, 6.) The only indication of frank arthritis in any of petitioner's records is a notation on March 10, 1992, of arthritis in one joint only, her right wrist. (Ex. 3, pp. 7, 8.) No swelling in that wrist or any other joints, however, was observed on March 16, 1992 (Ex. 4, p.1), or thereafter. Thus, while petitioner's case is within the parameters of my Criteria 4 and 5, her case is not a particularly "strong fit" in either of these categories.[15]

C. Criterion 6

Criterion 6 is the most problematic criterion for petitioner. In my "2002 Analysis," I listed Criterion 6 as follows:

6. There is an absence of another good explanation for the arthropathy * * *.

Snyder I, 2002 WL 3196574 at *8. In this case, respondent argues that there *does exist* another good explanation for petitioner's continuing complaints of pain in her joint areas--*i.e.*, the fact that she has been diagnosed as suffering from the "fibromyalgia syndrome," respondent argues, is the explanation for those continuing complaints.

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[15]I add this discussion, about the "strength of the fit" as to Criteria 4 and 5, only for purposes of completeness. The lack of a "strong fit" in these categories is *not* of crucial importance in my ultimate analysis in *this* particular case. What is important is that petitioner's cases *fails* Criterion 6, and also the circumstance discussed at part D of this Section VI of this Decision.

I begin my discussion of this issue with some general background concerning the fibromyalgia syndrome, to which I will hereinafter often refer as "FMS."[16] In recent years, the medical profession has generally accepted the existence of a syndrome known as fibromyalgia syndrome (though it has previously been known by other names, such as "fibrositis" or "fibromyositis"). In this syndrome, persons generally report pain in many different fibrous tissue areas of their bodies (*e.g.*, muscles, ligaments, tendons). Upon examination, however, no particular physical cause for the pain--*i.e.*, no identified tissue damage, infection, disease, traumatic injury, etc.--is identified. To fit within the syndrome, multiple areas of the body must be involved, and often the patients report that they "ache all over." Further, persons diagnosed with the syndrome are found to be especially sensitive or "tender" to pressure at 18 specific points located at various fibrous tissue areas. Generally, to fit within the syndrome a person must be found to be sensitive, upon physician examination, at 11 or more of these "tender points" or "trigger points."

With FMS, it is extremely common for the patient to complain of pain and the *feeling* of swelling in joint areas, but upon examination a physician finds no swelling or identifiable physical cause for the joint pain. (Ex. D, p. 690; Tr. 107.) (This has been the case with respect to petitioner.[17])

In this case, both sides agree that petitioner is accurately diagnosed as suffering from FMS. Respondent, as noted above, argues that the chronic pain that the petitioner has reported in her joint areas is simply a symptom of her FMS, and, therefore, should not be considered to be vaccine-caused. Petitioner responded to this argument at pp. 9-11 of her reply brief filed on February 1, 2005. In this response, petitioner did *not* contest that petitioner's chronic joint-area pain is part of her FMS. Petitioner merely asserted the argument that I will discuss below in part VII of this Decision--*i.e.*, the argument that the petitioner's *joint symptoms* were caused by her MMR vaccination, and that those joint symptoms then resulted in her *FMS*.

After fully considering this issue, I conclude that petitioner's case fails to meet Criterion 6. Both parties agree that petitioner's pain in her joint areas *is* a part of her FMS. Therefore, FMS is indeed, at some level, an "explanation" for those pain reports. To be sure, it is not accurate to say that FMS is the "cause" of her joint pain. To say that a person has FMS is not really to say what "caused" the FMS symptoms. To say that a person has FMS, rather, is merely to say that a person *has a set of symptoms* that are commonly seen together. It does not tell us what is the "cause" of that symptom set.

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[16]Respondent's Exs. C through F, filed on September 23, 2004, provide a description of the fibromyalgia syndrome.

[17]The records of many of petitioner's physician visits indicate that the physician found "no synovitis," or a similar notation that no joint swelling was found. The one exception is the notation of arthritis of the right wrist on March 10, 1992. (Ex. 3, p.10.)

In this regard, it is true that on March 16, 1992, Dr. Cilursu found "mild swelling * * * along the medial aspect of the ankles" (Ex. 4, p. 1.) However, Dr. Brenner explained that this finding did *not* constitute joint swelling. (Tr. 42-43.) Dr. Brenner seems to be correct in that regard, because Dr. Cilursu also wrote, in that same paragraph, "no evidence of acute synovitis." (Ex. 4, p. 1.)

However, the term "explanation," as I used it in the "2002 Analysis," is not the same as "cause." With respect to the question of *why* petitioner is experiencing pain in her joint areas, the fact that she has FMS is an "explanation," though it does not provide a "cause" in the medical sense. And in the context of the logic of my "causation criteria" analysis, it makes sense that only an "explanation," not a "cause," is necessary to cast doubt on the theory of a causal connection between vaccine and chronic arthropathy. That is, the logic of the "causation criteria" approach is that if a person's chronic polyarticular joint pain arose according to my first five criteria, and there is no other explanation for that chronic pain, then those circumstances *plus* that lack of any other reasonable explanation gives us just enough reason to conclude that the chronic pain was probably vaccine-caused. However, if there exists another reasonable *explanation* for the chronic pain, even if that explanation does not rise to the level of a "cause" in the medical sense, then that factor diminishes our confidence that there exists a causal relationship between the vaccination and the chronic pain.

To explain this reasoning process in another way, I note that, as I stressed in the "2002 Analysis," the evidence that the rubella vaccine *can* cause chronic arthropathy *in general* is certainly not overwhelmingly strong. It is a *very* close question whether the available evidence justifies a conclusion that the rubella vaccine *ever* causes chronic arthropathy. Therefore, even when a person's chronic arthropathy *precisely* fits within the "classic" pattern of arthropathy after vaccination described in my two omnibus rulings, it still can be said only that it is *slightly* "more probable than not" that the petitioner's chronic arthropathy was vaccine-caused. Accordingly, when a person's history substantially *differs* from the pattern described in my omnibus rulings, by the fact that the joint pain is clearly part of a larger, relatively common syndrome, then that factor makes the case look *less* like the classic pattern, and therefore less likely to have been vaccine-caused.

In petitioner's case, petitioner has been diagnosed to be suffering from FMS, which is a *very common syndrome*,[18] in which patients very often do report pain in multiple joint areas. And in many if not most cases of FMS, no cause for the syndrome is ever identified.[19] Thus, we *cannot* say that the only possible "explanation" for petitioner's chronic joint pain suggested by the record is that the vaccination caused it. To the contrary, one other very possible explanation is that petitioner is simply one of the *very many* unfortunate people who develop FMS for no known reason.

Further, I note that only one expert witness in this case has directly and fully addressed the question of whether FMS is an alternative explanation for petitioner's chronic joint pain. And that expert, Dr. Brenner, has opined that FMS *is* a reasonable alternative explanation. Dr. Brenner's view is that petitioner is simply one of the large number of unfortunate people who develop FMS for no known reason.

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[18]It is estimated that perhaps 2 to 4% of the population have FMS. (Ex. D, p. 687; Ex. E, p. 563.)

[19]See the article about FMS that I placed into the record on April 6, 2005, in which, of 127 patients with FMS, in only 29 cases (23%) did the patient report having trauma, surgery, or a medical illness before the onset of FMS.

In sum, for the reasons set forth above, I find FMS to be an alternative "explanation" for petitioner's chronic joint pain. Therfore, I conclude that petitioner's case does not fulfill Criterion 6.[20]

D. Additional discussion

As set forth above, I conclude that petitioner's case does not fall within my six criteria because it does not meet Criterion 6. But actually there is *another* important reason for concluding that petitioner's case cannot qualify for an award under the "causation criteria" approach. That is the fact that petitioner's chronic joint complaints are, as all agree, *a part of her overall FMS condition*. When I developed my "causation criteria," I assumed that they would apply to situations in which a person's chronic arthropathy was a "stand-alone" condition. I certainly never considered that the criteria would be applied to a situation in which a person's chronic joint pain is only a *part* of a *larger syndrome.* That is, it seems to me that as a matter of basic logic, if a person has a recognized, common syndrome, with several different symptoms that are generally thought to be part of a single disorder, it makes little sense to isolate one *part* of that syndrome and try to determine the cause of that one part. It makes more sense to try to determine, if possible, the cause of the *overall syndrome.*

Therefore, in this case it really does not matter whether petitioner's case technically meets all of my six "causation criteria" or not. As explained above (p. 15), in the "2002 Analysis" I stated that the criteria can be applied to reach a "vaccine causation" conclusion only if there are no "particular circumstances of the case" that point against a conclusion of causation by the vaccine. In this case, the relevant "particular circumstance" is that petitioner's chronic joint pain is clearly only a *part* of her overall FMS condition. That circumstance means that I must reject any attempt to utilize the "causation criteria" to support a conclusion that petitioner's chronic *joint pain*, isolated from her other FMS symptoms, was vaccine-caused. The real question to be answered in this case, rather, is whether the petitioner can demonstrate that her *overall FMS* was vaccine-caused. That is the question that I will address in Section VII of this Decision.[21]

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[20]I note that there exist two different legal approaches to "causation-in-fact" under the Program, a dichotomy which emerged in another "rubella/arthropathy" 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*, 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 "causation-in-fact," 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 a "causation- in-fact" 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, I have followed the *Wagner II*, approach, which I believe to be the correct legal approach, for the reasons set forth in *Wagner II*. Therefore, I have considered evidence concerning FMS, even though FMS may possibly be considered to be a syndrome of "unknown cause."

[21]Of course, I am saying only that if a person has a recognized syndrome, as a *general matter* it makes sense to look for the cause of the overall syndrome. It is *possible* that in a particular case a

(continued...)

In this regard, I note that the existence of petitioner's other symptoms, in addition to her joint symptoms, creates another problem for the theory that a causal link exists between the vaccination and petitioner's chronic joint pain. That is, the basic theory of causation of the petitioners' experts in the 1992 omnibus proceeding was that the rubella virus itself penetrates each joint after the vaccination, and *remains active in the joint* thereafter, *directly causing* the ongoing symptoms of chronic joint pain.[22] But in this case petitioner does *not* seem to argue that the rubella virus also remains active in the *fibrous tissues* of the body, directly causing FMS pain *in muscles* as well as joints. Rather, petitioner's theory seems to be that the vaccine *directly* caused[23] only the petitioner's chronic *joint pain* ("arthropathy" is the term petitioner uses), then that joint pain, in turn, caused petitioner to develop her *FMS*. (See, *e.g.*, Pet. Post-Hearing Br. p. 20.) It seems odd, however, in the context of a syndrome defined by pain in many different areas of the victim's body, to theorize that in this petitioner these two types of pain--*i.e.*, joint pain vs. muscle pain--are so different in origin. This is another way, therefore, in which petitioner's overall theory simply seems unlikely.

E. Notations of petitioner's physicians

In support of her contention that her chronic joint pain has been vaccine-caused, the petitioner, in addition to urging that her case fits within my "causation criteria," also relies upon the notations of a number of physicians in petitioner's medical records, which appear to indicate that those physicians considered petitioner's joint symptoms to be possibly or likely vaccine-caused. (See petitioner's Post-Hearing Brief, filed December 3, 2004, pp. 11-12; petitioner's Reply, filed February 1, 2005, pp. 16-18.)

These statements certainly do supply some support for the proposition that petitioner's chronic joint pain has been vaccine-caused. I do in this case, as in all Program cases, view with great respect the opinions of physicians who have actually treated the petitioner. But, as explained above, the issue of whether a rubella vaccination can cause chronic arthropathy is an extremely complicated area on the "frontier" of medical knowledge, where even the few specialist physicians who have closely studied the area admit that their understanding is very limited. My impression, from spending much time during the last 13 years studying this issue, is that very few general practice physicians or even rheumatologists have done any particular study of the issue of whether the rubella vaccine can cause chronic joint pain. And it is unclear

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[21](...continued)
petitioner might be able to demonstrate that *a certain portion* of a syndrome was vaccine-caused, or that a vaccination was a *substantial factor* in causing part or all of the syndrome, if not the sole cause. However, in this particular case the petitioner has not so demonstrated.

[22]The rubella vaccine contains a weakened, but live, form of the rubella virus. The theory is that such virus replicates itself in the vaccinee's body, then remains active in the joint thereafter. See the transcript of the omnibus hearing held on November 12 and 13, 1992, pp. 24-25, 320-326.

[23]Similarly, in the two other cases in which a petitioner diagnosed with FMS has claimed that all or part of her FMS symptoms were caused by a rubella vaccine, those petitioners' experts also did not claim that the rubella virus *actively invaded* those petitioners' fibrous tissues. See *Johnson v. Secretary of HHS*, No. 92-478, 1995 WL 61536 (Fed. Cl. Spec. Mstr. Jan. 31, 1995); *Awad v. Secretary of HHS*, No. 92-79V, 1995 WL 366013 (Fed. Cl. Spec. Mstr. June 5, 1995).

whether petitioner's treating physicians, whose notations are cited by petitioner, have any more knowledge in this area than the typical physician. As Dr. Brenner suggested, some of these physicians, upon first seeing petitioner, may have noted an association between petitioner's arthropathy and her vaccination in their notes, simply based upon *petitioner's own assertion* of such a causal connection. (Tr. 11-12, 112-114.) In any event, in none of the cited notations do the physicians explain *why* they reach their apparent conclusion. And none of those physicians has apparently been willing to *explain* their notations orally to me in the course of this proceeding.

In these circumstances, I simply must view with considerable caution the unexplained notations in the medical records suggesting a possible causal link between petitioner's vaccination and joint pain. And ultimately, as to the very specialized and complicated issue of the causation of petitioner's symptoms, I find more persuasive the opinion of Dr. Brenner, a specialist who routinely treats persons with joint complaints, who has spent a great deal of time studying the issue of the possible causation of joint complaints by rubella vaccination, and who has been willing to *explain and defend* his opinion of petitioner's case in both a detailed written report and oral testimony in this case.

Moreover, as indicated at pp. 20-21 above, one important point in analyzing petitioner's first argument is that it seems to make little sense as a matter of logic to separate out petitioner's *joint pain* from her other symptoms of FMS, for purposes of determining causation. And most of the notations in question seem to refer simply to petitioner's joint complaints, not her overall FMS.[24] If any of these physicians has a good reason for concluding that it makes sense to attribute petitioner's joint pain, apart from her other FMS symptoms, to her vaccination, such good reason simply does not appear in the medical records, so these record notations simply are of limited probative value.

Finally, I note that there are also some notations in petitioner's medical records indicating that certain of petitioner's physicians were *skeptical* of the theory that her chronic joint pain was vaccine-caused. For example, Dr. Sagransky wrote on July 7, 1992, that while he believed that petitioner did suffer an *acute* reaction to the vaccine, he thought that by June 15 of that same year her symptoms did *not* fit the pattern of a *chronic* post-vaccine arthritis.[25] (Ex. 5, pp. 2-3.) In addition, on February 3, 1997, an infectious disease specialist, Dr. Marshall Williams,[26] wrote about petitioner that:

> I certainly can't say she has pain due to Rubella. * * * The diagnosis of chronic arthritis due to vaccination is not an acceptable diagnosis. * * * All of this could be due to some

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[24]Three of those notations did seem to implicate the vaccination as a cause of the *overall FMS*. I will discuss those notations below at pp. 23-24.

[25]I recognize that Dr. Sagransky apparently evaluated petitioner on behalf of the insurance company of petitioner's employer for "workers' compensation" purposes, so that his opinion on the issue of vaccine-causation was hardly unbiased. However, his opinion is entitled to at least some slight weight, as a counterweight to the opinions of the physicians upon whom petitioner relies.

[26]Based on the heading of the letter at Ex. 31, p. 24, along with the references to "Dr. Marsh Williams" and "Marsh's consideration" on Ex. 31, p. 23, it seems quite likely that the author of Ex. 31, p. 24, was Dr. Marshall Williams.

> unknown viral disease or Munchausen syndrome. I have suggested again to her that she * * * get a psychiatric evaluation.

Ex. 31, p. 24.

Further, additional records indicate that certain other treating physicians of petitioner simply seemed *unsure* of the cause of petitioner's joint pain and FMS. For example, on April 7, 1997, Dr. Russell Labowitz, a rheumatologist, wrote a letter acknowledging that petitioner had previously had a diagnosis of "post-Rubella viremia" (Ex. 31, p. 33), but also noting the fact that Dr. (Marshall) Williams did not concur (*id*. at p. 34). Dr. Labowitz seems to have simply taken *no position* as to the cause of petitioner's chronic symptoms.

Therefore, it is fair to say that petitioner's treating physicians have been *divided* in their inclinations as to cause of petitioner's chronic symptoms. And, in any event, after considering the "causation" notations of *all* of petitioner's physicians, whether pointing toward vaccine-causation or the other way, in the context of the *overall evidence* discussed above, I simply reach the conclusion that it is *not* "more probable than not" that petitioner's chronic arthropathy was vaccine-caused.

VII

PETITIONER HAS NOT DEMONSTRATED THAT HER FMS WAS CAUSED BY HER RUBELLA VACCINATION

Petitioner's second argument is that her rubella vaccination caused not only her *chronic joint pain*, but also her *overall FMS condition*. Petitioner's argument concerning this issue is contained at pp. 18-20 of her initial post-hearing brief (filed December 3, 2004) and pp. 9-11 of her post-hearing reply brief (filed February 1, 2005). At p. 20 of the former brief, petitioner asserted that petitioner's "fibromyalgia resulted from her arthropathy, which was caused by her MMR vaccine." Remarkably, however, petitioner's briefs offer *no explanation whatsoever* as to *how* petitioner's arthropathy might have caused her FMS. Petitioner does no more than to cite to three places in petitioner's medical records in which certain physicians indicated, without explanation, the view that petitioner's FMS was related to her vaccination. Specifically, on November 15, 1993, Dr. Stephen Hefferen wrote "probable post-MMR syndrome as manifest by fibromyalgias, polyarthropathy, and polyneuropathy." (Pet. Ex. 14, p. 3.) On February 17, 1994, Dr. Aubrey Tingle wrote as follows:

> On the basis of the clinical history provided to me, I would express the medical opinion that the clinical history is most compatible with a post-rubella vaccine-associated arthropathy with associated secondary fibromyalgia.

(Ex. 21, p. 4.[27]) And, on December 17, 1996, Dr. Susan Keith noted "fibromyalgia secondary to adverse reaction to MMR." (Ex. 31, p. 12.)

As noted above, I generally respect the opinions of physicians who have actually treated a petitioner, and I respect the opinion of Dr. Tingle as well. But as also noted above, I can give only limited weight to unexplained medical record notations, when the authors of such notations are not available to explain *why* they reached their apparent conclusions. Again, I must give greater weight to the testimony of Dr. Brenner, a qualified rheumatologist who has treated many FMS patients, who has studied the literature with respect to FMS, who has studied virtually all of petitioner's lengthy medical file, and who has been willing to *defend and explain* his opinion concerning petitioner's case.[28]

I stress that petitioner simply has provided *no evidence at all* upon which I could base a conclusion that her MMR vaccination caused petitioner's FMS, beyond the three above-quoted unexplained notations in petitioner's medical records. Petitioner has not presented any expert testimony, although apparently for many years she sought an expert to testify on her behalf. She has not supplied any medical literature whatsoever about FMS, much less any literature that suggests that an MMR vaccination, or any other vaccination, can cause FMS. Her posthearing briefs do not even *suggest a theory* as to how the vaccination might have caused her FMS. As previously noted, her brief asserted that the vaccination caused her arthropathy, which in turn "resulted" in her FMS, but did not even suggest a theory as to *how* the arthropathy might have caused the FMS.[29]

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[27]Dr. Tingle, the same physician who testified as an expert for petitioners in both of the above-described "omnibus hearings" concerning the general rubella/arthropathy causation issue, never actually treated petitioner, but she sent medical records to his office, and he provided a written opinion concerning her case.

[28]Petitioner has criticized Dr. Brenner as overzealously assuming the role of an "advocate" rather than an expert witness in this case. I cannot agree. While Dr. Brenner was certainly blunt in criticizing certain notations in petitioner's medical records, based on the record in this case those criticisms seem to have been largely justified. I conclude that Dr. Brenner was giving me his honest opinion concerning the case, and I found his testimony to be knowledgeable and persuasive.

[29]Petitioner has also pointed to the fact that in the "Respondent's Report" filed in this case on May 2, 1994, respondent conceded that petitioner's chronic joint pain met the original "causation criteria" that I had set forth in my "1993 Order." The respondent indicated in that report that, because petitioner's joint pain met those criteria, respondent would not contest that petitioner's chronic *joint pain* was vaccine-caused. Respondent then added the following footnote:

> While Ms. Snyder's medical records indicate that she suffers from fibromyalgia, it appears that this diagnosis *in this particular case* was incidental to her presumed post-rubella vaccination polyarthropathy. For instance, Ms. Snyder's records do not indicate that she suffered from any pre-vaccination stressors which serve as indicators of fibromyalgia.

(P. 2, fn. 1, emphasis in original.) Petitioner seems to imply that this position taken by respondent in 1994 (continued...)

Indeed, the only substantial evidence concerning FMS presented in this case came from *respondent*, in the form of four articles about FMS (Exs. C, D, E, and F, filed on September 23, 2004), plus Dr. Brenner's written report and oral testimony.[30] The medical literature filed by respondent indicates that the cause of FMS is still not well understood by medical scientists. Based upon the medical articles filed in this case, it appears that in recent years some medical scientists have classified FMS as one of the "functional somatic syndromes," a term describing several syndromes "characterized more by symptoms, suffering, and disability than by disease-specific, demonstrable abnormalities of structure or function." (Ex. F, p. 910; see also Ex. E, p. 565.) Apparently, some medical scientists are leaning toward the view that FMS is a disorder in which the patient has a hypersensitivity to pain, perhaps a result of a disturbance in the way that the person's central nervous system processes sensory information. (Ex. D, pp. 687, 690-91, 698; Ex. E, p. 567.) This hypersensitivity is postulated to be the result of a "genetic predisposition," which may be activated by an "environmental trigger." (Ex. E, p. 567.)

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[29](...continued)
is reason for me to conclude now that petitioner's FMS was vaccine-caused.

It is true, of course, that respondent in that report conceded that petitioner's case did meet my "causation criteria;" although respondent never conceded that those criteria were necessarily *valid*, from 1993 through the late 1990's, in Program cases which met the criteria, respondent was willing to negotiate with petitioners to arrive at a figure for compensation for *arthritis and/or joint pain*. And respondent was similarly willing to negotiate with the petitioner in this case for compensation for her *joint pain*. But when petitioner sought compensation for *other symptoms* in addition to joint pain--symptoms of her FMS--respondent balked, arguing that petitioner had *not* proved that her other FMS symptoms were vaccine-caused. And the parties then agreed that petitioner would need to obtain expert opinion supporting her claim that her *other* symptoms were vaccine-caused.

Thus, when respondent stated in the "Respondent's Report" that petitioner's FMS appeared to be "incidental" to her "presumed post-rubella vaccination arthropathy," respondent clearly was *not* conceding that petitioner's FMS was caused by the *vaccination*; nor is it clear that respondent was conceding that the FMS resulted from petitioner's *arthropathy*.

Moreover, the available evidence, concerning both FMS and the theory that the rubella vaccine can cause chronic arthropathy, has simply changed since 1994.

And, finally, an off-hand statement by a party in a pleading simply does not constitute "evidence" concerning the scientific question of whether a certain vaccination caused a certain injury. In this case, as explained above, there was certainly no clear-cut concession by respondent that petitioner's FMS was vaccine-caused. Therefore, it was clearly the petitioner's burden to introduce *evidence* sufficient to support the theory that her FMS was vaccine-caused. Unfortunately for petitioner, she has failed to do so. Therefore, while it seems unusual and unfortunate that I would have to deny petitioner's claim in a case in which the respondent once stated that respondent would not contest a part of that claim, petitioner's ultimate failure to supply adequate evidence for her claim leaves me no choice but to do so.

[30]The record also includes an additional article about FMS that I placed into the record on April 6, 2005.

Dr. Brenner, in his oral testimony, acknowledge that, in persons who are susceptible, FMS apparently can be "triggered" by trauma, disease, or other stressors. He noted that physical or psychological trauma has been thought to trigger cases of FMS, and also two illnesses, Lyme Disease and Hepatitis C, have also been recognized as triggering FMS. (Tr. 22-23, 29, 54-57, 94-96.) The fact that those two illnesses are thought to "trigger" FMS, of course, makes one consider the possibility that *other illnesses* might trigger FMS. It is undisputed that the rubella vaccine sometimes does cause an *acute*, short-lived form of the rubella disease, often involving polyarticular joint symptoms. (See, e.g., *Ahern*, 1993 WL 179430 at *3-*4.) And it appears that petitioner's symptoms in February of 1992--*i.e.*, rash, fever, sore throat, lymph nodes, and joint pains--may have constituted such a reaction.[31] Could this acute reaction have triggered petitioner's FMS? Or could this acute reaction, along with joint pain that *continued* in petitioner for some weeks thereafter, have triggered the FMS?

Such a scenario seems vaguely possible, but the available evidence certainly does *not* show such possibility to be "more probable that not." Of course, no expert witness has explained why such a scenario might be likely. And Dr. Brenner's testimony was to the contrary. Dr. Brenner testified that the available medical literature concerning FMS contains no evidence of an association between the rubella vaccine, or any vaccine, and FMS. (Tr. 23-24.) He opined that it was "highly unlikely" that an acute reaction of petitioner to the rubella vaccination triggered her FMS. (Tr. 97.) Dr. Brenner explained that in the cases in which Lyme Disease is thought to trigger FMS, there is a *long period* of Lyme Disease before the FMS develops. (Tr. 96.) Therefore, he opined, "you can't generalize," from the fact that Lyme Disease seems to trigger FMS, to the conclusion that other illnesses can trigger FMS. (Tr. 96.) He further explained that an acute rubella vaccine reaction would be too short-lived to trigger FMS. (Tr. 98.)

Further, it is also important that while petitioner had the onset of her joint pain about February 24, 1992, it was only about a month later, in late March and early April, that she began reporting pain in *non-joint* areas typical of FMS. (See, *e.g.*, Ex, 4 p. 3, March 23--"bone pain" and "buttocks" pain; Ex. 4, p. 4, April 1--"left leg pain" in between joints; Ex. 4, p. 5, April 2 - - "thighs tender.") And on April 8, 1992, Dr. Cilurso found "multiple tender points" in petitioner, and diagnosed fibromyalgia. (Ex. 4, p.7.) Therefore, petitioner's history is quite different from the Lyme Disease experience, in which, according to Dr. Brenner's testimony, there is a *long period* of Lyme Disease before the onset of FMS. In petitioner's case, classic FMS muscle pain symptoms seem to have appeared only about a month after petitioner's initial joint pain. Accordingly, as Dr. Brenner explained, it does not seem reasonable to conclude, based upon the experience with Lyme Disease triggering FMS, that the rubella vaccine triggered petitioner's FMS in this case.

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[31] Assuming, as I do, that petitioner did suffer an *acute* reaction to the vaccination, nevertheless she would not qualify for a Program award on account of that acute reaction, because the evidence does not demonstrate that petitioner suffered residual effects from the acute reaction lasting more than six months. §300aa-11(c)(1)(D)(i).

In short, petitioner has simply failed to offer *any evidence*, beyond the three unexplained medical record notations, to support her theory that an arthropathic reaction to her rubella vaccination resulted in her FMS. The record in this case simply does not support that theory.[32]

VIII

CONCLUSION

It is clear that the petitioner has suffered a terrible, tragic downturn in her life. She is certainly deserving of great sympathy for her condition. As the above discussion indicates, however, I must conclude that petitioner does *not* qualify for a Program award. Absent a timely motion for review of this Decision, the clerk shall enter judgment accordingly.

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George L. Hastings, Jr.
Special Master

[32]I note that Chief Special Master Golkiewicz recently filed a ruling in *Lee v. Secretary of HHS*, No. 03-2479V (published citation not yet available) (Fed. Cl. Spec. Mstr., reissued for publication on May 6, 2005). I have read and considered that ruling, in which that special master concluded that a Hepatitis B vaccination likely did trigger an acute reaction to the vaccine, which in turn triggered a case of FMS. A major difference between that case and this case, in addition to the difference in the type of vaccine, is that in *Lee* the petitioner offered the case-specific written and oral testimony of a qualified expert witness, who opined concerning the causation question and who explained and defended her reasoning. The Chief Special Master found that testimony to be persuasive. In this case, in contrast, as noted above, the petitioner offered *no evidence whatsoever*, concerning the issue of the trigger of the FMS, beyond the unexplained medical record notations of certain physicians.

"RUBELLA OMNIBUS FILE"
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- Copies of Parts A, B, and D are available for free distribution to any interested party.
- Single copies of Parts C and E, the transcripts, are also in the file. These transcripts may be inspected at the clerk's office, or the clerk will loan them to a party. Or, a copy of either of these transcripts may be purchased from the Heritage Reporting Service.