

OFFICE OF SPECIAL MASTERS

No. 01-556V

(Filed: September 13, 2006)

To be published¹

SUSAN BERRY,

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Petitioner,

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Vaccine Act Entitlement;

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Causation-in-Fact;

v.

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Rubella/Arthropathy

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Causation Issue

SECRETARY OF HEALTH AND
HUMAN SERVICES,

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Respondent.

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Ronald Homer, Boston, Massachusetts, appeared for petitioner.

Linda Renzi, U.S. Department of Justice, Washington, D.C., appeared for respondent.

RULING CONCERNING “ENTITLEMENT” ISSUE

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 entitled to such an award, in an amount yet to be determined.

¹Because I have designated this document to be published, this document 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.” See 42 U.S.C. § 300aa-12(d)(4)(B); Vaccine Rule 18(b)

²The 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 to demonstrate 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. The burden is on the petitioner to introduce evidence demonstrating 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); *Althen v. Secretary of HHS*, 418 F. 2d 1274, 1278 (Fed. Cir. 2005). 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); see also *Hines*, 940 F. 2d at 1525; *Althen*, 418 F. 3d at 1278. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F. 3d at 1279. 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). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, by evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F. 3d at 1278; *Grant v. Secretary of HHS*, 956 F. 2d 1144, 1148 (Fed. Cir. 1992).

³The 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.

The *Althen* court also provided additional discussion of the “causation-in-fact” standard, as follows:

Concisely stated, *Althen*’s burden is to show by preponderant evidence that the vaccine brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. If *Althen* satisfies this burden, she is “entitled to recover unless the [government] shows also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.”

Althen, 418 F. 3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting the petitioner’s causation contention, so long as the petitioner supplies the *medical opinion* of a qualified expert. *Id.* at 1279-80. The court also indicated that, in finding causation, a Program factfinder may rely upon “circumstantial evidence,” which the court found to be consistent with the “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” *Id.* at 1280.

More recently, the Federal Circuit has addressed the causation-in-fact standard in two more rulings, *Capizzano v. Secretary of HHS*, 440 F. 3d 1317 (2006), and *Pafford v. Secretary of HHS*, 451 F. 3d 1352 (2006). Both opinions affirmed the applicability of the *Althen* test, quoted above. The *Capizzano* opinion cautioned Program factfinders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee’s medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. The *Pafford* ruling, on the other hand, indicated that it is the petitioner’s burden to demonstrate a defined period after vaccination in which one would expect to see the symptoms of a vaccine-caused injury of the type in question.

II

BACKGROUND FACTS

The petitioner, Susan Berry, was born in 1954. She has had a long and complicated medical history. At times, she has suffered from diabetes, hypertension, hyperthyroidism, mitral valve prolapse, heart murmur, depression, and other conditions. During 1996-1997, she experienced exhaustion, and was found to be suffering from “chronic fatigue syndrome,” which then went into remission.

On September 28, 1998, at age 43, petitioner received a rubella vaccination in Troy, Michigan. (Ex. 4, p. 77.⁴) Sixteen days later, on October 14, petitioner visited Dr. Edwin Sadler, where she reported that two weeks after that vaccination she began to suffer arthralgia⁵ of the knees, hands, and wrists, then broke out in a rash. (Ex. 4, p. 72.⁶) Dr. Sadler concluded that petitioner was experiencing a “[r]eaction to the rubella vaccine.” (*Id.*)

On November 4, 1998, petitioner visited Dr. Gowda, an infectious disease specialist. (Ex. 5, pp. 2-6.) At that visit, petitioner reported that she had experienced the onset of joint pain and rash two weeks after the vaccination. She further reported that after a few days in which she felt better, her rash and joint pain had returned. (*Id.* at 5.) Dr. Gowda, too, concluded that it was “likely that her symptoms are due to Rubella vaccination reaction.” (*Id.*)

On October 28, November 10, and November 13, 1998, petitioner consulted with her family physician, Dr. Haeger. Dr. Haeger also concluded that petitioner was likely experiencing a reaction to rubella vaccine. (Ex. 15, pp. 7, 10, 11.) On December 3 and December 21, 1998, petitioner visited Dr. Lerner, an internist and infectious disease specialist, again describing the onset of joint symptoms since the vaccination. (Ex. 3, p. 23.) At the latter visit, she reported that her joint pain was less than it had been. (*Id.*)

The medical records submitted in this proceeding then show several visits by petitioner to physicians during 1999 and early 2000, but for conditions unrelated to her joints. (Ex. 3, p. 97; Ex. 4, pp. 63-64; Ex. 15, pp. 1, 3, 6.)

On March 1, 2000, petitioner visited Dr. Lerner again. (Ex. 3, p. 35.) Dr. Lerner wrote in his notes of that visit that petitioner had been “well” for some unspecified period of time after her last visit to him in December of 1998, but that “[a]t this time she is not well,” with symptoms including pain in her knees and hips. (*Id.*) Petitioner thereafter continued to frequently visit Drs. Lerner and Haeger throughout the years 2000 and 2001, continually reporting fatigue, muscle aches, and joint pain. (Ex. 1, p. 34; Ex. 3, pp. 20, 21-22, 35, 36, 37.)

⁴Petitioner filed Exhibits numbered 1 through 14 on August 19, 2002, and additional, sequentially-numbered exhibits on several occasions since then. Respondent has filed exhibits designated by letters on several occasions. “Ex.” references will be to those exhibits.” “1-Tr.” references will be to the pages of the transcript of the evidentiary hearing held on September 28, 2004. “2-Tr.” references will be to the pages of the transcript of the evidentiary hearing held on July 18, 2006.

⁵“Athralgia” refers to *pain* in a joint, while “arthritis” refers to *inflammation* (swelling) of a joint. *Dorland’s Illustrated Medical Dictionary* (30th ed. 2003), p. 149.

⁶The top of page 72 of Ex. 4 lists a date of “9/28/98,” but at the bottom of the page, “under “date,” is written “D. 10/14/98,” indicating that the note was dictated on October 14, 1998. It seems clear to me that the latter date, October 14, is when petitioner visited Dr. Sadler. (See also Ex. 4, p. 71.)

On September 28, 2000, petitioner for the first time visited a rheumatologist, Dr. Bateman. (Ex. 1, pp. 4-5.) Dr. Bateman wrote that following her rubella vaccination in 1998 petitioner experienced “arthritis for about three months,” and “[s]ince then she has had continued joint pain.” (*Id.* at 4.) Since that time, petitioner has continued to regularly visit a number of physicians, reporting chronic joint pain. (See, *e.g.*, Ex. 1, pp. 18, 21, 22; Ex. 3, p. 72; Ex. 6, pp. 1, 2, 6, 7, 8; Ex. 16, p. 3; Ex. 18, p. 1; Ex. 19, p. 1; Ex. 20, p. 1.)

III

PROCEDURAL HISTORY AND STATEMENT OF ISSUE

A. Procedural history

Petitioner filed her Program petition on September 28, 2001. The case was assigned at that time to Special Master E. LaVon French. On August 19, 2002, petitioner filed an amended petition, along with the medical records necessary for evaluation of the case. The amended petition alleged that petitioner’s chronic joint pain was caused by her rubella vaccination of September 28, 1998. On May 16, 2003, respondent filed his report concerning the case, recommending that compensation be denied. Attached to that report was an expert report of a rheumatologist, Dr. Alan Brenner, who stated the opinion that petitioner’s chronic joint pain was *not* vaccine-caused.

In March of 2004, the case was reassigned to the undersigned special master.⁷ Upon the assignment of the case to my docket, I noted that on August 19, 2003, petitioner had filed a “Motion for Ruling on the Record,” and that respondent had filed a response thereto on October 7, 2003. I reviewed the motion and response, and conducted status conferences to discuss the motion on March 23, April 12, May 10, and June 9, 2004.

On June 29, 2004, I issued my opinion concerning petitioner’s “Motion for a Ruling on the Record.” In that motion, petitioner had argued that I should immediately rule upon the “entitlement” issue in the case; respondent, in opposition, argued that respondent should be permitted to first present the oral testimony of the respondent’s expert, Dr. Alan Brenner, whose written report (Ex. A) had been filed on May 16, 2003. I denied the petitioner’s motion for an immediate ruling, granting the respondent’s request to present the oral testimony of respondent’s expert. 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 25, 2005. However, at that time petitioner’s counsel requested that I refrain from entering a ruling concerning the causation issue in this case until a judge of this court ruled in another pending rubella/arthropathy case. (See my Order filed on June 1, 2005.) That ruling was

⁷About March 15, 2004, I was notified that the case was being assigned to me, and I received the file. Inadvertently, the case was not formally assigned to me at that time; when the error was discovered, the formal assignment was made on March 24, 2004.

issued by the judge (see *Zatuchni v. HHS*, 69 Fed. Cl. 612 (2006)), and, after reviewing that ruling, petitioner's counsel requested that I rule upon the causation issue in this case. (See my Order filed on April 5, 2006.)

Upon reviewing and analyzing the case during May of this year, in order to make the ruling requested by petitioners, I concluded that I would need one additional item of evidence--namely, the petitioner's testimony concerning one point. On June 13, 2006, I conducted a status conference, and the parties agreed to a hearing at which I would hear the petitioner's testimony. That hearing took place on July 18, and the transcript thereof was filed on August 22, 2006. Accordingly, the case is now ripe for review concerning the issue of whether petitioner is entitled to an award.

B. Issue to be decided

In this case, petitioner does not allege that she suffered a "Table Injury."⁸ Instead, she alleges that her chronic joint pain was "caused-in-fact" by her 1998 rubella vaccination.⁹ I will deal with that claim in parts IV through VIII 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 was "caused-in-fact" by her rubella vaccination of September 28, 1998. 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,

⁸Effective in March of 1995, "chronic arthritis" was added as a Table Injury for vaccinations containing the rubella vaccine. See 60 Fed. Reg. 7678 (1995). Petitioner, however, 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* (*i.e.*, joint swelling, observable by a physician).

⁹Petitioner 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).

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 those 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.

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 those criteria. Finally, respondent has presented the testimony of an expert witness specifically addressing petitioner’s case. 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 analyze, as both parties agree that I should, 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.

The petitioner in this case, however, does not rely *exclusively* on the theory that her case satisfies my “causation criteria.” She also advances an additional line of argument. That is, petitioner also relies upon certain statements of her treating physicians, contained in her medical records, indicating that those physicians believe that her chronic joint pain was vaccine-caused. I will deal with that argument in part VII of this Decision.

Finally, I will summarize my *overall* analysis of petitioner’s causation-in-fact contention at part VIII of this Decision.

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 existence. 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 representing respondent. Those counsel developed evidence to put before me concerning the general causation issue, filing a series of written reports from medical experts.¹⁰ 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.¹¹

¹⁰I 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 16, below.

¹¹The 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

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 polyarticular¹² joint symptoms.
3. The petitioner has developed an antibody response to the rubella virus.
4. The petitioner experienced the *onset* of polyarticular arthropathic symptoms during the period between one and six weeks after the vaccination.
5. Polyarticular arthropathic symptoms continued for at least six months after the onset; or, if symptoms remitted after the acute stage, polyarticular arthropathic symptoms recurred within one year of such remission.
6. There is an absence of another good explanation for the arthropathy; the petitioner has not received a confirmed diagnosis of rheumatoid arthritis, nor a diagnosis of any of a series of specific conditions.

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

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.”

¹²“Polyarticular” means “affecting many joints.” *Dorland’s Illustrated Medical Dictionary* (30th ed. 2003), p. 1478.

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 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, while 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, the petitioner received an award either because I formally concluded that the requisite showing of causation was made, or because 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, 7692, 7695 (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). 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 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 criterion 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.¹³

Since 1995, several 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 petitioners and respondent submitted expert reports, and a hearing, at which six such experts testified, was held in 2001.¹⁴

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.”

¹³As noted above (fn. 8) in this case, petitioner has not alleged that her case fits within the “chronic arthritis” Table Injury category, nor does it appear to me that her case fits within that category.

¹⁴A 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.

(I will refer to that document as the “2002 Analysis.”¹⁵) 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 p. 9 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, 2002 WL 31965742 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.

¹⁵The “2002 Analysis” was published as *Snyder et al v. Secretary of HHS*, 2002 WL 31965742 (Fed. Cl. Spec. Mstr. Dec. 13, 2002). A copy of that “2002 Analysis” was filed into the record of this case on March 25, 2004.

VI

APPLICATION OF THE “CAUSATION CRITERIA” SET FORTH IN MY “2002 ANALYSIS” SUPPORTS THE CONCLUSION 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, I have found this argument to be persuasive. 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.¹⁶ I have also considered, of course, the evidence specific

¹⁶I note that counsel for both parties have been well aware that in resolving this case 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. 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 primary "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 order to resolve another Program case. The chief reason is the inherent 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 seems 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 me (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 the rights of *individual petitioners* to fair resolution of their cases is not lost in the efficiency of

to petitioner's own case.

In this case, respondent argued that petitioner's case fails to meet three of my six causation criteria--namely, the criteria numbered 2, 5, and 6. Accordingly, I will divide my analysis concerning these criteria into several parts below. In part B, I will very briefly explain why I conclude that petitioner's case fits within my Criteria 1, 3, and 4--*i.e.*, the criteria that are *not* contested by respondent. Then, in parts C, D, and E, I will explain, in more detail, why I conclude that, contrary to respondent's argument, petitioner's case does satisfy my Criteria 2, 5, and 6.

Finally, in part F, I will deal with the arguments of respondent concerning the validity of my rubella/arthropathy causation criteria *in general*.

B. Criteria 1, 3, and 4

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, 3, and 4. Petitioner received a rubella vaccination at the age of 43 years. (Criterion 1.) After that vaccination, she developed an antibody response to the rubella virus. (Criterion 3.) And, about two weeks after that vaccination, petitioner experienced the *onset* of polyarticular joint pain. (Criterion 4.)

C. Criterion 2

First, respondent argues that petitioner's case fails to meet my Criterion 2, which reads as follows:

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.

With regard to this criterion, respondent points to the fact that certain medical records made during 1996 and 1997 indicate that during that time period petitioner had serious problems with exhaustion,

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.

and that she was diagnosed with a condition known as “chronic fatigue syndrome” (“CFS”).¹⁷ (See Ex. 3, pp. 24-26, 31-34, 40.) Respondent points to certain testimony of Dr. Brenner, who opined that the fact that Dr. Lerner diagnosed CFS means that petitioner likely did have chronic joint pain during 1996 and 1997, as is often the case with CFS. (See Brief filed January 31, 2005, pp. 13-14; 1-Tr. 5-7.) Respondent also points to the fact that on two occasions during that time period, Dr. Lerner noted petitioner’s report of hip pain. (Ex. 3, pp. 24, 40.)

I understand the concerns of respondent and Dr. Brenner on this point. The fact that petitioner had a chronic condition, sometimes involving pain, during 1996 and 1997, is certainly a concern. Could that condition be related to the chronic joint pain that petitioner has suffered since 1998? That is *possible*. But my task here is to determine whether vaccine-causation is “more probable than not;” I need *not* conclude that all other suggested causes are completely *impossible*. In this respect, I simply did not find Dr. Brenner’s point to be persuasive. Dr. Brenner himself acknowledged that the 1996-97 records do not actually show any chronic *joint pain*, and that it was merely his “strong suspicion” that joint pain existed at that time along with the chronic fatigue. (1-Tr. 5.) I do not find sufficient proof to support Dr. Brenner’s inference on this point. It seems likely to me that if petitioner had repeatedly experienced pain in joint areas during this time, she would have so reported to Dr. Lerner, and he would have made a note of it. The two isolated references to pain in a hip are, in my view, not enough to support a conclusion that petitioner was experiencing *chronic* pain in *multiple* joints during this period. In this regard, I also note that the 1996-97 records are in stark contrast to the records made after September of 1998, which contain *explicit, repeated* references to pain in multiple joints.

In short, I conclude that petitioner’s case reasonably complies with Criterion 2.

D. Criterion 5

Respondent also has raised an argument with respect to my Criterion 5, which reads as follows:

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.

Respondent argues that petitioner’s case does not meet this criterion. Respondent notes that petitioner’s medical records note repeated complaints of joint pain in late 1998, and then repeated complaints once again in March of 2000 and thereafter. However, respondent points out, the medical records made during 1999 and early 2000 do *not* contain references to joint pain.

It is true that, as respondent notes, there are records of only a few visits by petitioner to physicians in 1999 and early 2000, and those records contain no mention of joint pain. (Ex. 3, 97;

¹⁷Petitioner’s CFS symptoms seem to have gone into remission in late 1997 or early 1998.

Ex. 4, pp. 63-64; Ex. 15, pp. 1, 3, 6.) However, petitioner has testified in this proceeding that after her joint pain eased somewhat during early 1999, that pain returned strongly sometime in mid-1999. (See Ex. 12, par. 7; 2-Tr. 6-20, 25-26.) And, even more importantly, a large number of *medical record* notations, recorded in March of 2000 and the next several years, provide *strong confirmation* of petitioner's claim that her joint pain, after easing in early 1999, returned in mid-1999.

First, on March 1, 2000, petitioner visited Dr. Lerner, who had treated her in 1996-97 for exhaustion symptoms. Dr. Lerner wrote in his notes of that visit that petitioner had been "well" for some unspecified period of time after her last visit to him, in December of 1998, but that "[a]t this time she is not well," with symptoms including pain in her knees and hips. (Ex. 3, p. 35.) This notation, while nonspecific, confirms that while for *some* period of time after December of 1998 petitioner's joints were feeling better, at *some* point prior to March 1, 2000, petitioner's joint condition took a turn for the worse.

The next notation was made on September 28, 2000, when petitioner for the first time visited a rheumatologist, Dr. Bateman. (Ex. 1, pp. 4-5.) (The fact that this was petitioner's first visit to a *rheumatologist* is significant, since rheumatologists are specialists in joint problems,¹⁸ and thereby may be more likely than other physicians to focus carefully on the history of *joint symptoms*.) In her notes of that visit, Dr. Bateman wrote that following her rubella vaccination in 1998, petitioner experienced "arthritis" for about three months, and "[s]ince then she has had continued joint pain." (*Id.* at 4.) This notation, thus, generally supports the petitioner's current testimony, by showing that in September of 2000 petitioner was reporting, to Dr. Bateman, a similar history of her symptoms. That is, the notation of "arthritis for about three months," followed by "joint pain" continuously thereafter, indicates that petitioner was reporting an initial period of intense joint symptoms ("arthritis"), followed by some lesser but still significant joint symptoms ("joint pain") "since then."

At another treatment visit, on October 10, 2000, petitioner again gave a history of her joint symptoms. (Ex. 8, p. 4.) Her physical therapist wrote on that date that petitioner had joint "swelling" from the vaccination "until March 1999 when it subsided." (*Id.*) The note does not make clear if and when petitioner experienced joint pain during the *middle* part of 1999, but states that her joint pain "worsened" about *September* of 1999. This history, too, while less than clear and comprehensive, supports petitioner's claim that her joint pain eased in early 1999, but then returned later in that year.

Four other histories, recorded in 2001, 2002, and 2003, provide similar general support to petitioner's claim. On March 29, 2001, Dr. Bateman wrote in her record of petitioner's visit, "multiple joint pains x 2.5 years." (Ex. 6, p. 6.) The notation of "2.5 years," of course, would indicate pain since the September 1998 vaccination date. Similarly, when petitioner visited Dr. Eilender on July 5, 2001, he wrote that petitioner's joint pain started after a rubella vaccination in 1998; resolved after three months, but then returned after two more months; and has continued "[s]ince then." (Ex. 1, p. 22.)

¹⁸See *Dorland's Illustrated Medical Dictionary* (30th ed. 2003), p. 1627.

On May 28, 2002, petitioner visited a neurologist, Dr. Clague. (Ex. 16.) Again, she reported the onset of joint symptoms after her rubella vaccination, a “lessening” of symptoms after about three months, then a “recurrence” of joint pain in “May or June of 1999.” (*Id.* at 2.) And finally, on February 21, 2003, petitioner was evaluated by two rheumatologists, Dr. Ogenowski and Dr. Bocks, who also took a history. (Ex. 19.) Those physicians again noted the onset of joint symptoms after rubella vaccination; the “resolving” of the “swelling” sometime “around the 3-month mark;” the return of arthralgias after about one month of improvement; and then continuous arthralgia since that time. (*Id.* at 1.)

In short, based on *both* petitioner’s testimony in this proceeding, *and* the numerous histories cited above that were recorded between 2000 and 2003, I find that it is likely that petitioner’s claim concerning the general history of her joint pain is accurate. That is, she likely did experience strong symptoms for about three months after vaccination, a period of remission or reduced symptoms thereafter, the return of strong joint pain around mid-1999, and then continuous symptoms thereafter.

E. Criterion 6

The third criterion that has been contested by respondent is Criterion 6, which reads as follows:

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

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.

I begin my discussion of this issue with some general background concerning the fibromyalgia syndrome, to which I will hereinafter often refer as “FMS.”¹⁹ 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”). Those afflicted with this syndrome 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 often found to be especially sensitive to pressure at certain “tender points” located at various fibrous tissue areas.

¹⁹See the medical text excerpt concerning FMS that I placed into the record of this case on June 9, 2006.

In this case, there are a number of indications in petitioner's medical records that petitioner is suffering from FMS. Respondent, as noted above, argues that the chronic pain that the petitioner has reported in her joint areas is simply one symptom of her FMS, and, therefore, should not be considered to be vaccine-caused. After fully considering this issue, however, I conclude that, contrary to respondent's argument, petitioner's case does fulfill Criterion 6.

Before discussing the facts concerning this issue, I first note that there certainly exists an unresolved *legal* issue concerning the propriety of this sixth criterion in Vaccine Act "rubella/arthropathy" cases. That is, two judges of this court, on review of decisions in which I applied my six criteria to "rubella/arthropathy" cases, have found this sixth criterion to be legally problematic. See *Wagner v. Secretary of HHS*, 37 Fed. Cl. 134 (1997); *Zatuchni v. Secretary of HHS*, 69 Fed. Cl. 612, 621-23 (2006).²⁰ It is unnecessary for me to address that legal issue in this case, however, for even *assuming* that it is legally appropriate for me to apply this criterion to petitioner's case, I conclude that petitioner's case *does* meet the criterion.

Turning to the facts of this case, it is true that a number of petitioner's medical records indicate that the FMS label has been applied to her case. However, I note that petitioner's case differs substantially from most of the other Vaccine Act cases involving FMS. In most of those other cases, the vaccinee's chronic joint pain seemed to be only a small component part of an overall FMS condition. In petitioner's case, in contrast, the chronic joint pain seems to be the *dominant symptom*. Further, while Dr. Brenner argued that petitioner's post-vaccination FMS should be viewed as merely a continuation of the CFS condition from which petitioner suffered in 1996-97, the medical records do not support his contention. As noted above, while the 1996-97 records provide no evidence at all of pain in multiple joints, the post-vaccination records show that petitioner has *continually* and *explicitly* reported chronic pain in multiple joints. Therefore, in these circumstances --i.e., with the post-vaccination symptoms so different from the 1996-97 symptoms, and with the post-vaccination symptoms dominated by joint pain rather than a more typical FMS presentation-- I cannot agree with respondent that petitioner's FMS diagnosis is a "good explanation" for her chronic joint pain since her rubella vaccination.

Therefore, I conclude that petitioner's case fits within Criterion 6 as well.

²⁰For a different view of the propriety of the sixth criterion, see *Wagner v. Secretary of HHS*, 1997 WL 617035 (Fed. Cl. Spec. Mstr. Sept. 22, 1997). See also *Pafford v. HHS*, 64 Fed. Cl. 19, 34-36 (2005) (it is appropriate to place upon the *petitioner* the burden, as part of the petitioner's initial *prima facie* case, of ruling out any potential alternative causes that have been specifically identified in the record); *Pafford v. HHS*, 451 F. 3d 1352, 1357 (2006) (impliedly affirming the *Pafford* trial court's opinion on this point); *Paulmino v. HHS*, 69 Fed. Cl. 1, 11-12 (2005) (agreeing with *Pafford* on this point). But *cf. DeBazan v. HHS*, 70 Fed. Cl. 687, 693 (2006) (finding it inappropriate to require a *petitioner* to rule out any potential alternative causes).

F. Respondent's arguments concerning the general Omnibus approach

As noted above, respondent, in the "Response" filed in this case on January 3, 2005, raised several arguments to the effect that I erred in my "2002 Analysis," regarding the *general issue* of whether the rubella vaccine causes chronic arthropathy. Essentially, these were the same arguments that respondent raised in oral argument at the 2001 hearing. I have already responded to them in the "2002 Analysis," so I will not repeat that discussion here.²¹ I will, however, specifically discuss respondent's argument in one respect. That is, respondent seems to assert that if I apply my conclusion contained in the "2002 Analysis" to an individual case, I would improperly "create a presumption" similar to a "Table Injury." (Response at 9-10.) Respondent is mistaken.

In setting up the Vaccine Injury Table, Congress did create a *statutory presumption* of causation in certain cases. That is, if the fact pattern of a particular case fits within a Table Injury category, then *by operation of law* the Program factfinder must *presume* that the injury was vaccine-caused, unless the evidence of record preponderates in favor of causation by some specific non-vaccine cause.

In contrast, in this case, as in all of the rubella/arthropathy cases that I have compensated over the past thirteen years, I am *not* employing any "presumption." Rather, in each of the few cases in which I have decided the "entitlement" issue (of the cases that have been compensated, the vast majority *settled*, without any formal ruling concerning the "entitlement" issue), my procedure has been to consider all the evidence available to me, and determine whether, based upon all of that evidence, it is "more probable than not" that this *particular vaccinee's* condition of chronic arthropathy was vaccine-caused. In that respect, these rubella/arthropathy cases are little different from any other Program case in which the issue is "causation-in-fact." The only difference is that, while in a typical Program case the evidence to be considered is contained entirely in the record of that individual case, in the rubella/arthropathy cases I have an *additional* body of evidence--from the *omnibus general causation proceedings*--upon which to draw, in order to *supplement* the evidence brought forth in the individual case record. I am able to *combine* the evidence from the general causation proceedings *and* the individual case record, and, based upon *all* of that evidence, determine whether it is "more probable than not" that the *particular vaccinee's* condition was vaccine-caused.

In other words, as I have stressed before (including a discussion at *Snyder*, 2002 WL 31965742 at *24), in neither my "1993 Order" nor in my "2002 Analysis" did I purport to find causation in *any particular case*. Those documents merely reported that, based upon all of the medical evidence that I had reviewed *up to that point* in time, *if* the circumstances of a petitioner's case fell within certain criteria, and *if* there were no particular circumstances of the case that cast doubt on a causal relationship, and *if* there was no additional medical evidence submitted, then I would find causation in that case. In every individual case, each party has always had the option of putting *case-specific* evidence before me at an evidentiary hearing. The "1993 Order" and "2002

²¹See also Judge Block's discussion and rejection of respondent's identical challenges to my rubella/arthropathy causation criteria, in *Moreno v. HHS*, 65 Fed. Cl. 13, 24-29 (2005).

Analysis,” thus, merely *educated the parties* as to how I viewed the medical evidence that I had *already* evaluated, so that they could attempt to settle any individual case. The individual cases, then, if they did not settle, always had to be decided on a case-by-case basis, perhaps by simply applying the conclusions that I had reached during the general causation proceedings, or perhaps by adding to the mix additional evidence offered by either party in the particular case.

In short, I have not applied any “presumption,” or created the equivalent of a “Table Injury,” in this case. Instead, I have merely made a specific ruling concerning “causation-in-fact” in this particular case, by means of studying the evidence contained in the record of this case, *and also applying to this case* the evidence appearing in the expert testimony and medical studies previously supplied in the general causation proceedings.

VII

NOTATIONS OF PHYSICIANS IN THE MEDICAL RECORDS

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 vaccine-caused. (See petitioner’s Post-Hearing Brief, filed December 3, 2004, pp. 10-12, 15-16; petitioner’s Reply, filed February 28, 2005, pp. 16-18.)

I conclude that certain of these statements of physicians do supply important support for the proposition that petitioner’s chronic joint pain has been vaccine-caused. First, in this case, as in all Program cases, I view with great respect the opinions of physicians who have actually treated the petitioner. Further, it is noteworthy that in the recent *Capizzano* opinion, the U.S. Court of Appeals for the Federal Circuit stressed that “medical records and medical opinion testimony are favored in vaccine cases, *as treating physicians are likely to be in the best position to determine* whether ‘a logical sequence of cause and effect shows that the vaccination was the reason for the injury.’” 440 F. 3d at 1326 (emphasis added). Similarly, in several recent cases, judges of this court have, in resolving Vaccine Act causation issues, relied heavily upon the statements of treating physicians contained in the vaccinee’s medical records. *See, e.g., Zatuchni v. Secretary of HHS*, 69 Fed. Cl. 612, 623 (2006) (involving a rubella/arthropathy case quite similar to this case); *De Bazan v. HHS*, 70 Fed. Cl. 687, 697 (2006); *Kelley v. HHS*, 68 Fed. Cl. 84, 100 (2005). *See also Moreno v. HHS*, 65 Fed. Cl. 13 (2005) (affirming my finding of causation in another rubella/arthropathy case in which I relied, in part, upon notations of the petitioner’s treating physician in the medical records).

In this case, I first note that several of the physician notations, on which petitioner relies, describe the petitioner’s *acute* symptoms--*i.e.*, those symptoms occurring during the first three months after the vaccination--as vaccine-caused. For example, on October 14, 1998, Dr. Sadler concluded that petitioner’s joint pain was part of a “[r]eaction to the rubella vaccine.” (Ex. 4, p. 72.) On November 4, 1998, Dr. Gowda concluded that it was “likely that [petitioner’s] symptoms are due

to Rubella vaccination reaction.” (Ex. 5, p. 5.) On October 28, November 10 and November 13, 1998, Dr. Haeger wrote notations indicating that petitioner was likely experiencing a reaction to rubella vaccine. (Ex. 15, pp. 7, 10, 11.) And on December 3, 1998, Dr. Lerner wrote that petitioner received a rubella vaccination and “promptly developed rubella.” (Ex. 3, p. 23.) Those notations, however, are not of great evidentiary value concerning the issue that I must decide here, *i.e.*, whether petitioner’s *chronic* joint pain, since 1999, was vaccine-caused. Respondent’s expert did not dispute that petitioner’s symptoms *in late 1998* likely did constitute an *acute* reaction to the vaccination; a short-term acute reaction, lasting days or weeks at most, is well-accepted as a very common side effect of rubella vaccination. The controversial and difficult issue, rather, is whether the rubella vaccine can also cause *chronic* arthropathy. Therefore, the physician statements set forth above, describing petitioner’s *acute* symptoms as vaccine-caused, are not particularly helpful.

On other hand, petitioner’s medical records also contain a number of indications that some of petitioner’s treating physicians believe that petitioner’s *chronic* joint pain is causally related to her rubella vaccination. For example, on August 19, 2003, Dr. Ogenowski, a rheumatologist, wrote that petitioner “clearly does have [a] pain syndrome * * *. This has been documented as a possible side effect to the rubella vaccine, and *certainly looking at her clinical course that appears to be a causal relationship.*” (Ex. 19, p. 6, emphasis added.) On August 18, 2004, Dr. Kimpson, a pain management specialist, wrote that one of his “diagnostic impressions” of petitioner was that she had “status post rubella vaccination,” apparently meaning that he concluded that her chronic pain has causally related to that rubella vaccination. (Ex. 18, p. 2.)

Note also that on September 28, 2000, Dr. Bateman, another rheumatologist, wrote that one of her “impressions” of petitioner’s case was “history of rubella arthritis.” (Ex. 1, p. 5.) This reference to “rubella arthritis” perhaps refers only to petitioner’s *acute* period of suffering in late 1998, but could also mean that Dr. Bateman attributed petitioner’s *entire* post-vaccine history of chronic joint symptoms to the rubella vaccine. Further, on May 28, 2002, Dr. Allen Clague noted his opinion that petitioner had suffered a “neurological, neuromuscular, musculoskeletal, and skeletal syndrome *as a result of the adverse reaction*” to the rubella vaccination of September 28, 1998. (Ex. 16, p. 5, emphasis added.²²)

These notations of petitioner’s treating physicians, with regard to petitioner’s *chronic* joint pain, do provide important *additional* support for her contention that her chronic joint pain has been vaccine-caused.

²²I recognize that Dr. Clague apparently was not a physician who saw petitioner in the ordinary course of treatment, but seems, rather, to have been consulted on one occasion to provide support for petitioner’s “worker’s compensation” claim against her employer (her employer had required that she receive the rubella vaccination in question). Accordingly, I place very little weight on this particular medical record notation, but I note it here for purposes of completeness.

VIII

ADDITIONAL DISCUSSION AND SUMMARY

In short, in this case I find that petitioner's chronic joint pain since late 1998 has, more probably than not, been caused by her rubella vaccination of September 28, 1998. This factual finding is based on a *combination* of two factors. First, petitioner's case satisfies my six causation criteria for the rubella/arthropathy cases. Second, petitioner's causation contention is supported by certain statements of her treating physicians in the medical records.²³

To be sure, in my view this causation issue presents a *very* close question. Reasonable minds could differ on the outcome of this issue. I simply find that the balance of evidence tips slightly in favor of causation.

Further, I note that, in their briefs in this case, petitioner's counsel harshly criticized Dr. Brenner, as overzealously assuming the role of an "advocate" rather than an expert witness in this case. I do not agree. I conclude that Dr. Brenner was giving me his honest opinion concerning the case, and that he presented reasonable arguments in support of his view of the case. I simply found that in the unique circumstances of this case, Dr. Brenner's opinion concerning the causation issue in petitioner's case was slightly outweighed by the other evidence of record. In this regard, I note that I had to weigh Dr. Brenner's opinion against not only the statements of petitioner's treating physicians and the other evidence contained in the medical records, but also against the weight of the several distinguished medical experts who provided expert testimony on behalf of petitioners during the above-described *omnibus proceedings* that I held in both 1992 and 2001. I simply conclude that the *overall* evidence tips slightly against Dr. Brenner's view, and in petitioner's favor.

IX

FURTHER PROCEEDINGS

For the reasons stated above, I find it "more probable than not" that petitioner's chronic joint pain was vaccine-caused. Therefore, I conclude that she is entitled to a Program award on account of that chronic condition. Thus, the parties should initiate proceedings toward the goal of agreeing

²³I note also that petitioner's employer, the hospital which required her to receive the rubella vaccination in 1998, apparently settled petitioner's "worker's compensation" claim against that employer. (See Ex. 25.) This indicates that petitioner's employer, too, found it at least reasonably possible that petitioner's chronic joint pain was vaccine-caused.

upon on the appropriate *amount* of the award. We will discuss that topic at the next status conference, which my staff will soon schedule.

George L. Hastings, Jr.
Special Master

**“RUBELLA OMNIBUS FILE”
TABLE OF CONTENTS
(as updated November 2001)**

- Part A. File of expert reports (filed in 1992). (Pages A-1 through G-2; 34 pages total.)
- Part B. Excerpt from Institute of Medicine Report (Pages i through iv and 187 through 205; 23 pages total.)
- Part C. Three-volume transcript of “omnibus hearings” held on November 12, 13, and 16, 1992. (540 pages total.)
- Part D. Second file of expert reports (filed in 2000). (Pages D-1 through D-37.)
- Part E. Two-volume transcript of “omnibus hearings” held on March 26 and March 27, 2001. (443 pages total.)

- ! 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.