OFFICE OF SPECIAL MASTERS

No. 00-664V

(Filed: August 10, 2005)

STEPHEN FRECHETTE, legal representative of the estate of Lisa Frechette,	*	
Petitioner,	*	**NOT TO BE PUBLISHED** (To be posted on Court's website)
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald Homer, Boston, Massachusetts, appeared for petitioner.

Althea Walker Davis, U.S. Department of Justice, Washington, D.C., appeared for respondent.

DECISION[1]

HASTINGS, ***Special Master***.

[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.

Because this document contains a reasoned explanation for my action in this case, I intend to post this order on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Therefore, as provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this entire document will be available to the public.

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 petitioner is not entitled to such an award.

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 by which 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. 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.

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[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."

[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.

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).

II

BACKGROUND FACTS

The case concerns the tragic history of Lisa Frechette (hereinafter "Lisa"). She was born on August 25, 1955. The records filed in this case indicated that prior to the vaccination in question, which she received on January 14, 1999, Lisa had a history of pain in several different joint areas over the previous several years. I will detail that history at pp. 13-14 of this Decision, below.

On January 14, 1999, at age 43, Lisa received an "MMR"--*i.e.*, measles, mumps, rubella--vaccination. Nineteen days later, on February 2, 1999, Lisa telephoned her family physician, Dr. Cotter, and reported that her left knee was swollen. (Ex. 1, p. 2, top of page; Ex. 7, p. 2 [4].) She called again two days later to say that her right knee had also started bothering her. (Ex. 7, p. 2.) Dr. Cotter apparently examined her on February 5, 1999, noted the knee symptoms, and wrote that she was suffering from "mild synovitis/arthralgias"[5] that might have been "vaccine-related." (Ex. 7, pg. 2).

Lisa's joint symptoms continued. On March 29, 1999, April 15, 1999, June 3, 1999, and June 21, 1999, she visited either Dr. Cotter or Dr. Upchurch, a rheumatologist, registering complaints of pain and/or swelling in her knees, shoulders, wrists, hands, and left hip. (Ex. 1, pp. 5-6, 8, 10-12.) An X-ray taken on April 15, 1999, revealed that petitioner was suffering from "degenerative changes" in her knees. (Ex. 1, p. 34; Ex. 3, p. 2.)

Lisa thereafter continued to often report chronic joint pain. (See, *e.g.*, Ex. 2, pp. 4-7.) She committed suicide in December of 2002. (Ex. 8; Ex. A.)

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[4]Petitioner has filed exhibits numbered 1 through 16; "Ex." references will be to those exhibits. "Tr." references will be to the pages of the transcript of the evidentiary hearing held on November 19, 2004.

[5]"Arthralgia" means joint pain, and "synovitis" means inflammation of the synovial membrane of a joint or joints. *Dorland's Illustrated Medical Dictionary*, 27th ed. 1988 (W.B. Saunders Co.), pp. 147, 1649.

III

PROCEDURAL HISTORY AND STATEMENT OF ISSUE

A. *Procedural history*

On March 9, 2000, Lisa filed the instant Program petition, seeking Program compensation on account of chronic joint pain, which she believed to have been caused by the rubella vaccine contained in her MMR vaccination on January 14, 1999. After proceedings before Special Master French, the petition was transferred to my docket on February 21, 2001. At that time, I was involved, along with Lisa's own counsel and other attorneys, in preparing for a hearing concerning the *general issue* of whether the rubella vaccine can cause chronic joint pain. Accordingly, at the suggestion of Lisa's counsel, we deferred any proceedings specific to her case until after I issued an opinion concerning that general issue. I issued that opinion, filing it into the record of this and seven other cases involving that same general issue, on December 13, 2002.

Tragically, however, we soon learned that Lisa had committed suicide on December 10, 2002. Lisa's widower, Stephen Frechette, then become the petitioner in this case, as the legal representative of Lisa's estate. After a series of status conferences, petitioner, on February 18, 2004, filed a motion asking that I issue a final decision in this case based upon the record as it then existed. Respondent opposed the motion, and filed the expert report of Dr. Alan Brenner, presenting his opinion that petitioner's chronic joint pain between her vaccination and her death was *not* vaccine-caused.[6] Petitioner's counsel declined the opportunity to present an expert opinion on petitioner's behalf, but requested the opportunity to cross-examine Dr. Brenner, and to present testimony by Lisa's widower and daughters. Accordingly, I conducted a hearing on November 19, 2004, during which I heard the testimony of Dr. Brenner and the family members.

After the hearing, petitioner's counsel requested post-hearing briefing. The final brief in that process was filed on March 29, 2005.

B. Issue to be decided

Petitioner no longer advances the theory that Lisa suffered the "Table Injury" known as "chronic arthritis."[7] Rather, petitioner's sole contention is that Lisa's chronic joint pain, suffered

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[6]I did not issue a written ruling denying petitioner's motion for an immediate final decision on the case. Instead, at an unrecorded status conference, I informed both counsel that I believed that it was proper that I consider the expert testimony that respondent wished to present. I urged petitioner's counsel to also present expert testimony, but counsel declined to do so.

[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 (Feb. 8, 1995). However, petitioner, in his brief filed on February 18, 2005, stated (page 2) that he does not contend that Lisa's case qualifies under that Table Injury category.

between January of 1999 and her death, was "caused-in-fact" by her 1999 rubella vaccination. I will deal with that claim below in parts IV through VIII of this Decision.[8]

IV

"CAUSATION-IN-FACT" ISSUE: INTRODUCTION

As noted above, the petitioner's contention in this proceeding is that Lisa's chronic joint pain, from 1999 until her death, was "caused-in-fact" by her rubella vaccination of January 14, 1999. 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 the claim that Lisa's 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." I have stated that if a particular vaccinee's case falls within those criteria, *and* there is no significant 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 vaccinee's chronic arthropathy. Petitioner asserts that Lisa's case fits within my published "causation criteria," and that, on that basis, without need for any case-specific expert testimony, I should conclude that Lisa's chronic joint pain was vaccine-caused.

Respondent, on the other hand, argues that petitioner has *not* demonstrated that Lisa's 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, Lisa's case fails to meet several of my criteria. Finally, respondent, unlike petitioner, has presented the testimony of an expert witness specifically addressing Lisa's case in detail. Respondent urges that the testimony of that witness, Dr. Brenner, supports a conclusion that Lisa's chronic joint pain was *not* vaccine-caused.

In considering the 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*

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[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 the 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).

"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 Lisa's case demonstrates that Lisa'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 Lisa's case meets my "causation criteria." Petitioner also relies in part on several notations of Lisa's treating physicians contained in the medical records. I will deal with that 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.[7] I also conducted an extensive

[7]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

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.[8]

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.

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.

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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 10, below.

[8]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."

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, however, 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, then 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 (Feb. 8, 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 (Feb. 20, 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 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, six Program petitioners have successfully established that they have suffered compensable injuries under the new "chronic arthritis" Table Injury category. A number of other 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 those 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.[9]

[9] 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

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). 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. 7-8 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 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.

File.

VI

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

A. Introduction

As noted above, petitioner's first argument in this case is that Lisa's case history 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.[10] I have also considered, of course, the evidence specific to

[10]I 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 entire "causation-in-fact" argument *in this case* is that I *should* apply to Lisa's 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, which 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 the rights of *individual petitioners* to fair resolution of their cases is not lost in the efficiency of

Lisa's own medical course.

To be sure, Lisa's case arguably meets *some* of the six "causation criteria" from my "2002 Analysis" set forth above at p. 10--namely, Criteria #1, 3, 4, and 5. Lisa received a rubella vaccination at the age of 43 years. (Criterion #1.) After the vaccination, she developed an antibody response to the rubella virus. (Criterion #3.) Slightly more than two weeks after vaccination, Lisa reported pain and swelling in two joints--her knees. (Criterion #4.) And, Lisa continued to regularly report intermittent pains in multiple joints for months thereafter. (Criterion #5.)

However, as respondent points out, it is doubtful whether petitioner's case meets criteria #2 and #6. I conclude that petitioner's case *fails* to meet both of those criteria; therefore, I conclude that petitioner has failed to establish "causation-in-fact" by the possible avenue of satisfying the six criteria.

B. Lisa's case fails to meet Criterion #2

Criterion #2 of my "causation criteria," after modification in the "2002 Analysis," currently stands as follows:

> 2. The [vaccinee] 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.

Unfortunately for petitioner, however, the record of this case indicates that Lisa likely *did* experience persistent or recurring polyarticular joint symptoms during the three years prior to her rubella vaccination of January 14, 1999.

First, I note that on March 15, 1996, Lisa reported to her family physician, Dr. Cotter, that she had been suffering from hip pain for two months; X-rays were ordered, and Dr. Cotter noted "calcified tendonitis" in Lisa's left hip. (Ex. 1, p. 59.) Another record of Dr. Cotter, dated March 26, 1996, states that Lisa reported left hip pain "off and on for a long time." (Ex. 1, p. 58.)

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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.

Another record indicates that on June 17, 1997, Lisa raised a question of "Heberden's nodes," which, Dr. Brenner explained, means that she was questioning whether the small joints of her hands were enlarged. (Tr. 70-71; Ex. 1, p. 47.) Lisa also reported "various other hand aches" on that visit. (Ex. 1, p. 47.) On June 26, 1997, X-rays of both Lisa's hands were taken, which showed "mild osteoarthritis of the DIP joints." (Ex. 1, pp. 27, 30.)

On June 8, 1998, Lisa again complained of "hands achy," prompting Dr. Cotter to write "arthralgias" and "mild Heberden's nodes." (Ex. 1, p. 42.) On December 10, 1998, Lisa reported left hip pain to Dr. Cotter, and that physician also wrote "shoulder impingement" in his notes of the visit. (Ex. 1, p. 39.) X-rays were done that same day on her left hip, prompting the radiologist, Dr. Berman, to write "calcifications in the pelvis." (Ex. 1, p. 28.) On December 15, 1998, according to a handwritten note on the X-ray report, Lisa was "still having pain" in the left hip area. (Ex. 1, p. 28.)

Finally, a note made by Dr. Upchurch on June 21, 1999, stated that Lisa had been experiencing left hand pain "as long ago as 1997." (Ex. 2, p. 1.)

Those notations indicate that on a number of occasions in 1996 through 1998, petitioner was reporting to her physicians that she was experiencing joint pain in a number of different joints, including hand, shoulder, and hip joints. And, as discussed in my 1993 Order and 2002 Analysis, reports of polyarticular joint pain in the years immediately preceding the rubella vaccination in question are *extremely problematic* to a conclusion that a person's chronic post-vaccination joint pain was vaccine-caused. That is, *all* of the experts who testified in the 1992 and 2001 hearings, including those who testified on behalf of the *petitioners*, indicated that a conclusion of "vaccine-causation" in a particular case would be reasonable *only* if the vaccinee had been *free* from any polyarticular joint complaints, other than any complaints associated with a specific traumatic injury, for at least three years pre-vaccination. That is simply not the case with respect to Lisa.

Petitioner seems to argue that I should disregard Lisa's 1996-98 joint pain reports because, according to the testimony of petitioner and Lisa's daughters at the evidentiary hearing in this case, the pain in 1996-98 was substantially *lesser* in severity than Lisa's arthralgia after the vaccination. I, of course, have no way of measuring the severity of pain. However, the 1996-98 arthralgias were at least of sufficient degree that Lisa reported them to her physicians. More importantly, the experts who testified in the 1992 and 2001 hearings seemed to view *any* history of chronic, pre-existing pain in multiple joints, *regardless* of reported severity, as a factor that would dissuade them from concluding that a person's chronic post-vaccination arthralgias were vaccine-caused. Thus, I cannot rely on the opinion of *those experts*, as petitioner would have me do, to reach the conclusion that Lisa's chronic post-vaccination joint pain was vaccine-caused.

In short, petitioner has not presented his own expert witness in this case. He has elected to rely primarily, in effect, upon the expert testimony of those experts who testified in the 1992 and 2001 hearings concerning the *general* rubella/arthropathy causation issue. However, as explained above, those experts testified that they could infer "vaccine-causation" *only* when the vaccinee had

a history free from chronic pain in multiple joints during the three-year period pre-vaccination. And as I interpret the evidence, that is simply not the case with respect to Lisa, who does seem to have reported chronic pain in multiple joints to physicians during 1996-98. Therefore, I *cannot* find "causation-in-fact" in this case based upon the "causation criteria" developed in my "1993 Order" and "2002 Analysis" documents.

C. Lisa's case fails to meet Criterion #6

Since I conclude that Lisa's case does not meet Criterion #2, I do not necessarily need to resolve the issue of whether her case meets Criterion #6. However, I will briefly discuss my reasons for concluding that Lisa's case also does not meet Criterion #6.

In my "2002 Analysis" document, in defining my "causation criteria," I listed Criterion #6 as follows:

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

Snyder, 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.

After analyzing the record, I agree with respondent that in Lisa's case, there does exist another reasonable explanation for her post-vaccination joint pain--that is, Dr. Brenner pointed to medical records indicating that Lisa's post-vaccination joint pain was likely the result of osteoarthritis in some joints, and calcium deposits in other joint areas. (See, *e.g.*, Ex. C, p. 5; Tr. 50-54, 56-62, 134, 158-161.) Dr. Brenner explained that Lisa's 1996-98 symptoms also appear to have been the result of osteoarthritis and calcium deposits, so that the post-vaccinations symptoms were likely merely a continuation of the pre-vaccinations symptoms. (Ex. C, p. 5; Tr. 50-62, 73-74, 78-79, 96-97.)

I found the testimony of Dr. Brenner, in this regard, to be logical, persuasive, and supported by the medical records. Petitioner in his briefs has made no serious effort to refute that testimony, other than to make unsupported personal criticisms of Dr. Brenner.[11] Further, I note that Dr. Brenner is the *only* witness in this case who has directly and fully addressed the question of whether there is an alternative explanation for Lisa's chronic joint pain. On the record before me, I see no reason not to credit his testimony on this point.

[11]Petitioner has criticized Dr. Brenner as overzealously assuming the role of an "advocate" rather than an expert witness in this case. I cannot agree. I conclude that Dr. Brenner was giving me his honest opinion concerning the case, and I found his testimony to be knowledgeable and persuasive.

VII

ADDITIONAL ANALYSIS OF RECORD

The fact that I have found that Lisa's case does not meet the "causation criteria" set forth in my "2002 Analysis" does not completely end the inquiry in this case. That is, meeting those criteria is not necessarily the *only* method by which it might be shown that a vaccinee's chronic arthropathy was "more probably than not" caused by a rubella vaccination. As in every case, I must evaluate the *entire record* of this case to determine whether the evidence contained therein preponderates in favor of a conclusion that the vaccinee's chronic arthropathy was vaccine-caused.

In this case, in addition to arguing that Lisa's case meets the above-described "causation criteria," petitioner's other argument has been to point to a few notations in Lisa's medical records, which, petitioner suggests, indicate that some of Lisa's *treating physicians* may have thought that Lisa's post-vaccination joint pain was vaccine-caused. However, after considering the notations to which petitioner points, I do *not* find that those physicians' notations provide strong support for the proposition that Lisa's chronic joint pain was vaccine-caused.

Petitioner has pointed to medical record notations of two physicians. First, Lisa's family physician, Dr. Eric Cotter, in his record of his physical examination of Lisa on February 5, 1999, wrote "? vaccine-related synovitis," meaning that he questioned whether Lisa's knee pain on that day was related to her vaccination of the previous January 14.

However, this note of Dr. Cotter does not constitute strong evidence in petitioner's favor, for two reasons. First, Dr. Cotter was only *questioning* whether there was a causal connection, not stating an affirmative opinion. Secondly, Dr. Cotter was questioning only whether joint symptoms occurring *two to three weeks* after vaccination were vaccine-caused; this fact sheds no significant light on the issue of the cause of Lisa's *chronic* joint pain. That is, as the record of the 1992 and 2001 hearings on the general causation issue makes clear, it is well-accepted that the rubella vaccine sometimes causes *acute episodes* of joint symptoms about two weeks post-vaccination, usually lasting a few days. Therefore, it is unsurprising that Dr. Cotter would question whether Lisa's *acute* symptoms of two-to-three weeks post-vaccination were attributable to her vaccination on January 14, 1999. On the other hand, it is highly controversial whether the rubella vaccine causes *chronic* joint symptoms. Therefore, this notation made on February 5, 1999, tells us *nothing* about whether Dr. Cotter ever concluded that Lisa's *chronic* joint complaints were vaccine-caused.

In addition, petitioner points to certain notations made by Lisa's treating rheumatologist, Dr. Katherine Upchurch. When Dr. Upchurch first examined Lisa on June 21, 1999, she noted in her records that acute arthritis can sometimes result from an MMR injection, and added that such acute arthritis "can rarely evolve into a chronic arthropathy." (Ex. 2, p. 2.) Dr. Upchurch added, however, in the next sentence, that, "alternatively," the MMR might have simply been "coincidental." (*Id.*) Dr. Upchurch then wrote that "I don't think we're going to be able to sort this

out with certainty," but that "I do think [Lisa's joint pain] should be reported, however, as a complication of MMR vaccine." (*Id*.)

Similarly, in the records concerning an examination of Lisa on November 29, 1999, Dr. Upchurch wrote that "this patient has post-MMR diffuse arthralgias," but added that while these arthralgias are a "a possible MMR related complication," nevertheless "serologically, there have been no definite etiologies[12] identified for her complaints." (Ex. 2, p. 6.)

Later, on March 8, 2000, Dr. Upchurch wrote "diffuse joint pain, s/p [status post] MMR vaccination." (Ex. 2, p. 7.)

I have carefully considered these notations of Dr. Upchurch, who, as petitioner has pointed out, was described by Dr. Brenner himself as a highly qualified rheumatologist. (Tr. 135-36.) However, these notations do not change my overall view of the case, for two reasons.

First of all, the notations quoted above from the records of both June 21 and November 29, 1999, make it quite clear that Dr. Upchurch was far from certain as to the cause of Lisa's chronic pain. In the June 21 records she noted that, "alternatively," the MMR vaccination might merely have been "coincidental." (Ex. 2, p. 2.) In the November 29 record, she described the vaccination only as a "possible" cause. (Ex. 2, p. 6.) Therefore, from the documents available to us, we certainly do not know whether Dr. Upchurch could *affirmatively opine* that Lisa's chronic joint pain was vaccine-caused.

Moreover, 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, derived from spending much time during the last 13 years studying this issue, is that very few physicians, even rheumatologists, have done any particular study of the issue of whether the rubella vaccine can cause chronic joint pain. And it is unclear whether Dr. Upchurch has any more knowledge in this area than the typical physician. Nor do Dr. Upchurch's records indicate exactly *why* she suspected the vaccination as a cause, or explain whether she considered the alternative explanation advanced now by Dr. Brenner.

In these circumstances, I simply must view with considerable caution the unexplained notations of Dr. Upchurch in the medical records, suggesting a *possible* causal link between Lisa's vaccination and joint pain. Ultimately, as to the very specialized and complicated issue of the causation of Lisa'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

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[12]"Etiology" means a "cause." *Dorland's Illustrated Medical Dictionary*, 27th ed. 1988 (W.B. Saunders Co.), p. 587.

explain and defend his opinion of Lisa's case in both a detailed written report and oral testimony in this case.

Therefore, after considering the above-cited notations of Drs. Cotter and Upchurch, in the context of the *overall evidence* discussed above, I simply reach the conclusion that it is *not* "more probable than not" that Lisa's chronic arthropathy was vaccine-caused.

VIII

SUMMARY OF "CAUSATION-IN-FACT" RULING

In short, I have carefully reviewed both the above-described evidence that I have taken concerning the *general* "rubella/arthropathy" causation issue, and the complete record of *this* case. After that review, I conclude that petitioner has *failed* to demonstrate that Lisa's case meets the "causation criteria" set forth in my "2002 Analysis." Therefore, petitioner has failed to demonstrate "causation-in-fact" by that possible avenue of proof. I also conclude that when I consider *all* of the record before me in this case, in which petitioner has *not* offered a case-specific expert opinion, the evidence simply does *not* preponderate in favor of a conclusion that Lisa's rubella vaccination "more probably than not" caused her chronic joint pain.[13]

IX

CONCLUSION

It is, of course, very unfortunate that Lisa Frechette suffered from chronic joint pain; moreover, the story of her suicide is a tragic one. Her family is certainly deserving of great sympathy for their loss. As the above discussion indicates, however, I must conclude that petitioner has *not* demonstrated that Lisa's chronic joint pain was vaccine-caused. Absent a timely motion for review of this Decision, the clerk shall enter judgment accordingly.

[13]Petitioner has suggested (see brief filed 2-18-05, p. 18, fn. 18) that the record may support "significant aggravation" as an alternative theory of relief. But petitioner failed to develop that suggestion, and I find no evidence that the vaccination aggravated petitioner's pre-existing joint conditions.

"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.

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George L. Hastings, Jr.
Special Master