OFFICE OF SPECIAL MASTERS

No. 96-469V

(Filed: December 3, 1998)

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	*	
CHERYL BOZICH,	*	
Petitioner,	*	**TO BE PUBLISHED**
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND	*	
HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *		

Rodney Klein and Lawrence Paikoff, Sacramento, California, for petitioner.

Claudia Barnes Gangi, Department of Justice, Washington, D.C., for respondent.

DECISION

HASTINGS, *Special Master*.

This is an action seeking an award under the National Vaccine Injury Compensation Program.[(1)] For the reasons stated below, I conclude that petitioner is not entitled to such an award.

I

STATUTORY BACKGROUND

Under the National Vaccine Injury Compensation Program (hereinafter "the Program"), compensation awards are made to individuals who have suffered injuries thought to be caused by certain vaccines. There are two separate means of establishing entitlement to compensation. First, if an injury listed in the "Vaccine Injury Table" found at 42 U.S.C. § 300aa-14(a) occurred within the time period from vaccination prescribed in that Table, then that injury may be *presumed* to qualify for compensation. Second, compensation may be awarded for injuries not listed on the Table, if the petitioner demonstrates by a preponderance of evidence that the vaccine *actually caused* the injury. § 300aa-13(a)(1); § 300aa-11(c)(1)(C)(ii).

In this case, petitioner's claim is that certain muscle atrophy and other symptoms that she has reported over the past several years were caused by a tetanus toxoid immunization that she received on August 3, 1995. The vaccination is one listed in the Vaccine Injury Table, but petitioner does not allege that she suffered any of the injuries listed in the Table for that vaccination, so this case does not involve an allegation of a "Table Injury." Instead, the issue here is whether petitioner has successfully demonstrated that any of her chronic symptoms were "more probably than not"[(2)] *caused by* that vaccination.

II

FACTUAL BACKGROUND

The following facts are essentially undisputed. The petitioner, Cheryl Bozich, is an unfornate woman who has had a complicated medical history in recent years. Beginning in 1990, apparently after she suffered a viral infection, petitioner began to visit physicians quite often and to describe to those physicians an extensive array of symptoms. These symptoms are described in the extensive medical records filed in this case, especially in petitioner's Exhibits 3 through 12 and Exhibit 17.[(3)] One illustrative summary of the symptoms that petitioner repeatedly reported, during the period from 1990 through 1992, is contained at Ex. 4, pp. 76-81. These symptoms included, *inter alia*, extreme fatigue, muscle and joint pains, weakness, fevers, cognitive problems, and unusual sensations in her peripheral areas in the form of numbness or tingling. Petitioner received various tentative diagnoses, including the diagnosis of "chronic fatigue syndrome," a syndrome of unknown cause that is marked by chronic fatigue over an extended period as the major component, along with minor components consisting of many of the symptoms that petitioner in fact reported. By June of 1991, petitioner was found to be "totally and completely disabled" from employment as a result of these symptoms. (Ex. 3, p. 178.) Petitioner has continued to regularly report these chronic symptoms to the present.

On August 3, 1995, petitioner received a tetanus toxoid immunization after cutting her thumb. On August 15, 18, and 29, petitioner phoned or visited her physicians to report symptoms that she had experienced since the immunization. She reported that she experienced a headache later on the day of the injection, then a fever beginning the next day, and subsequently unusual "burning" and "needle" sensations, weakness and fatigue, muscle and joint aches, and other problems. (See, *e.g.*, Ex. 5, pp. 54-58; Ex. 3, p. 82.)

Since August of 1995, petitioner has continued to report chronic symptoms similar to those described in the two preceding paragraphs. In addition, beginning in the fall of 1996, petitioner's treating neurologist noted muscle atrophy in her hands, forearms, and other areas. No cause for this atrophy has been conclusively determined. As to the other symptoms described above, on the other hand, petitioner's physicians have generally agreed that petitioner suffers from the "chronic fatigue syndrome," and that such symptoms are part of that syndrome.

II

DISCUSSION

A. Summary of the expert opinions

It may be helpful to begin by summarizing the views of each of the three physicians who testified as experts in this proceeding, at an evidentiary hearing held on October 22, 1998. Petitioner presented the testimony of the immunologist Dr. Frederick Herman and the neurologist Dr. Isaac Silberman, both of

whom have treated petitioner for a number of years. Respondent presented the testimony of the neurologist Dr. Barry Arnason.

The three experts agree on a number of points. They agree that petitioner has suffered from "chronic fatigue syndrome" (hereinafter "CFS"), and that most of her chronic symptoms since 1990 are manifestations of that syndrome. They also agree that petitioner has experienced significant muscle atrophy, that this atrophy is a new condition that has appeared since the 1995 tetanus immunization, and that this atrophy is likely the result of some type of neurologic abnormality. But they also disagree on major issues, crucial to the outcome of this case.

First, Drs. Herman and Silberman have opined that petitioner's CFS condition has gotten worse since her tetanus vaccination, and that such worsening was caused by that immunization. Dr. Arnason disagrees. Second, petitioner's two experts believe that the tetanus injection also caused the neurologic abnormality that in turn caused petitioner's muscle atrophy. Again, Dr. Arnason disagrees.

B. My analysis

I have carefully considered the evidence submitted in this case, included the opinions of all three of the experts described above. I found all three of those physicians to be well-qualified, and I have no reason to conclude that any of them were not giving honest opinions. But in the final analysis I conclude that petitioner has clearly failed to show it "more probable than not" that any of her chronic symptoms have been caused by her tetanus toxoid immunization. The simplest explanation for this conclusion is that I found Dr. Arnason's opinion to be substantially more persuasive than those of petitioner's experts. I will further detail my reasoning in this regard below, addressing first the issue of CFS and then the issue of muscle atrophy.

1. Chronic fatigue syndrome

I found the petitioner's case to be quite weak as to the issue of petitioner's CFS. A key point, of course, is that, as all the experts agree, petitioner clearly had CFS for five years *prior* to her tetanus immunization. Petitioner's experts contend that petitioner's CFS is now worse than it was prior to that vaccination, and that the immunization cause the worsening. But, in the first place, it is hard to see exactly how petitioner's condition is actually worse, since the symptoms of CFS for the most part are simply subjective perceptions of the patient that cannot be objectively detected or measured--*e.g.*, fatigue, pain, sensations of numbness or tingling, etc. Petitioner simply has not made a strong case that her CFS condition, which by 1991 had already left her "totally and completely disabled" (Ex. 3, p. 178), is substantially different than it was prior to her vaccination.[(4)]

Moreover, even assuming that petitioner's CFS symptoms have worsened since the immunization, petitioner has certainly failed to demonstrate that it is "more probable than not" that such change was vaccine-caused. To the contrary, the record shows clearly that, as petitioner's experts acknowledged, the cause of CFS is simply not understood by the medical community. To be sure, as the medical article filed as petitioner's Ex. 21G illustrates, there exists some evidence that immunologic abnormalities *may* play a role in CFS, and there is also reason to believe that on rare occasions vaccinations of all types can prompt immunologic dysfunction. But given the extreme state of uncertainty about the nature of CFS and its cause, I found Dr. Arnason to be convincing in arguing that it is sheer speculation to conclude, based upon the points set forth in the previous sentence, that it is "more probable than not" that petitioner's tetanus vaccination worsened her CFS symptoms.[(5)] There is simply a lack of medical literature support, or any other good reason, for concluding that a *tetanus* immunization can substantially aggravate a case of *CFS*.[(6)]

2. Muscle atrophy

Petitioner's muscle atrophy presents a quite different question, since, as noted above, petitioner undoubtedly *has* suffered from a striking process of muscle atrophy, which in fact has taken place since her tetanus immunization. But again, petitioner's experts have fallen well short of showing that it is "more probable than not" that this atrophy was vaccine-caused. On this issue, too, I found Dr. Arnason's testimony to be substantially more persuasive.

On the issue of how the immunization could have caused the atrophy, I found Dr. Herman's opinion to be quite poorly explained. On cross-examination, he seemed quite uncomfortable in attempting to explain his opinion, and was quick to simply defer to Dr. Silberman on the point. And, as Dr. Arnason pointed out, there are readily apparent flaws in Dr. Silberman's stated causation theory.

Dr. Silberman explained that, as Dr. Arnason agreed, petitioner's muscle atrophy is likely the result of a neurologic abnormality. He noted that petitioner also has other neurologic abnormalities, including a loss of sensation in some of her extremities. Dr. Silberman asserted that this loss of sensation was first manifested abruptly after the tetanus vaccination, and first reported during petitioner's visit to Dr. Silberman himself on August 20, 1995. He opined that this "loss of sensation" neurologic abnormality is likely related to the neurologic abnormality that resulted in the muscle atrophy. He believes that the tetanus immunization caused a harmful change in petitioner's immune system function, which in turn caused these neurologic abnormalities. He pointed to a number of medical articles, filed in this case as part of petitioner's Ex. 21, that indicate that various neurologic problems have occurred after tetanus immunizations.

Dr. Arnason, however, persuasively pointed out the problems with Dr. Silberman's theory. First, Dr. Arnason pointed out that Dr. Silberman was wrong in asserting that petitioner's neurologic symptoms involving loss of sensation had their onset abruptly after the tetanus injection. To the contrary, the record shows clearly that petitioner was describing such symptoms long *before* that immunization. As a few examples, I note medical records made on March 15, 1995 (Ex. 3, p. 86-- "numbness and dyesthesias in all four extremities"); March 24, 1993 (Ex. 5, p. 18-- "L. hand & leg tingling"); July 1, 1991 (Ex. 5, p. 100-- "paresthesias of left extremities and trunk"); April 4, 1994 (Ex. 5, p. 124-- "leftsided numbness and paresthesias"); and June 20, 1994 (Ex. 5, p. 126-- "paresthesia in her legs"). Dr. Silberman's theory obviously must fail, therefore, because it is based upon a plainly erroneous assumption of fact.

Secondly, Dr. Arnason pointed out that petitioner's muscle atrophy was not noted until the fall of 1996, more than a year after the tetanus injection. Dr. Silberman, when confronted on this point, admitted that the fall of 1996 was when he first noted the atrophy in his records, but suggested that the atrophy process might have been underway much earlier. Dr. Arnason, however, argued that a thorough examination and testing of petitioner that took place in June of 1996, at the Mayo Clinic, undoubtedly would have identified the atrophy had it existed at that time. I therefore have found persuasive Dr. Arnason's reasoning that the onset of atrophy more than a year after the tetanus immunization[(7)] adds to the reason for doubting that such atrophy was vaccine-caused.

Finally, I found that Dr. Arnason's testimony, as well as my own careful reading, indicates that the medical articles submitted by petitioner offer no substantial assistance to Dr. Silberman's causation theory. To be sure, the articles contained as parts B, C, J, K, L, and M of Ex. 21 do, indeed, document a few instances in which significant neurologic problems have arisen shortly after tetanus toxoid injections. However, it is elementary that when a vaccination such as the tetanus toxoid is given millions

of times, the fact that a very few isolated instances of neurologic problems have occurred shortly after such injections is hardly valid proof of a *causal* connection. Moreover, Dr. Arnason argued, and my own close reading has confirmed, that none of the neurologic problems described in these articles look remotely like *petitioner's* muscle atrophy. And the articles generally involved neurologic events that took place within hours or a few days of immunization, while in this case the atrophy was not noted until more than a year later.

In short, for all the reasons set forth above, I find that petitioner has clearly failed to demonstrate that her muscle atrophy was a result of her tetanus immunization.[(8)]

V

CONCLUSION

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

George L. Hastings, Jr.

Special Master

1. The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (1994 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (1994 ed.).

2. Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than not." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

3. Petitioner filed Exs. 1 and 2 with her petition, Exs. 3 through 13 on February 10, 1997, and additional, consecutively-numbered exhibits on a number of dates thereafter. "Ex." references will be to those exhibits.

4. In this regard, it is significant that petitioner's experts attempted to support their conclusion by arguing that petitioner's CFS had been improving prior to her tetanus immunization. But, as respondent's counsel pointed out, the record indicates that on July 26, 1995, only a week prior to the inoculation, petitioner reported to her physician that the prior two months had been particularly "bad" with respect to her CFS symptoms. (Ex. 3, p. 80.)

5. To be sure, Dr. Arnason explained that as far as petitioner's symptoms in the *several days* immediately following the tetanus inoculation, including her headache and fever, it seems quite possible

that these were the result of the inoculation. But that would still not qualify petitioner for a Program award, which can be made only if petitioner shows a vaccine-caused injury of at least *six months* in duration. § 300aa-11(c)(1)(D)(i). Dr. Arnason was convincing in arguing that any such short-term reaction, which would be a common phenomenon, would have no relationship to any long-term changes in petitioner's condition.

6. I note that Dr. Herman also seemed to suggest that the tetanus immunization aggravated petitioner's *sinusitis* and *bronchitis* conditions, which perhaps may be conditions separate from her CFS. But, again, there was no explanation of how the immunization could have done so. I find much more persuasive Dr. Arnason's view, that there is no good reason to attribute *any* of petitioner's chronic complaints to the tetanus immunization.

7. I note that at the evidentiary hearing, on cross-examination, Dr. Herman indicated that atrophy was noted in March of 1996. However, I could find no evidence of such a notation in either his or Dr. Silberman's records. Moreover, even an onset of atrophy in March of 1996 would still be many months after the tetanus inoculation of August 3, 1995.

8. While reaching this conclusion, I add that in every Program case, I have great respect for, and give strong attention to, the opinions of the actual treating physicians of a petitioner, such as Drs. Herman and Silberman here. However, after carefully considering their opinions, I found that those opinions simply were substantially outweighed by the convincing reasoning of the superbly qualified Dr. Arnason.