OFFICE OF SPECIAL MASTERS

No. 97-0573V

(Filed: April 15, 1999)

* *		
	*	
PAULINE FADELALLA,	*	
	*	
	*	
	*	
Petitioner,	*	**TO BE PUBLISHED**
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *		

Sylvia Chin-Kaplan, Boston, MA, for petitioner.

Mark W. Rogers, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

On August 18, 1997, Pauline Fadelalla filed a petition for compensation on her own behalf under the National Childhood Vaccine Injury Act of 1986[(1)] (hereinafter the "Vaccine Act" or the "Act"). Pursuant to 42 U.S.C. § 300aa-11(c), petitioner has satisfied the requirements for a prima facie case by showing that: (1) she has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine injury; (2) rubella vaccine was administered to her in the United States; and (3) she has incurred $1,000.00 in unreimbursable medical expenses prior to filing the petition.

Petitioner alleges causation-in-fact Guillain-Barre Syndrome (GBS) from rubella vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Respondent concedes that petitioner had GBS, but denies that rubella vaccine caused petitioner's GBS.

The court held a hearing in this case on January 25, 1999. Testifying for petitioner at the hearing was Dr. Albert L. Goodgold. (Ms. Fadelalla was sworn to answer a brief question.) Testifying for respondent

was Dr. Barry G.W. Arnason.

FACTS

Pauline Fadelalla was born on October 12, 1957. Med. recs. at Ex. 6, p. 1. She received rubella vaccine on August 22, 1994 when she was 37 years old. P. Ex. 1, p. 1. She alleges that one week after receiving rubella vaccine, she developed pimples on her right cheek. P. Ex. 1, p. 2. These developed into a rash. Id. Then her arms and fingertips began to itch. Id. By September 5, 1994, she had a burning sensation in her palms and fingertips. Id. On September 10 and 11, 1994, her feet felt wobbly and she staggered. Id. She felt as if she were going to fall and had tingling in her palms, fingertips, and soles by September 12, 1994. Id. She was hospitalized from September 12 to 23, 1994 at Lenox Hill Hospital with a diagnosis of GBS. Med. recs. at Ex. 6.

The doctors described on September 21, 1994 serum sickness-related neuropathy following rubella immunization. Med. recs. at Ex. 6, p. 38. Dr. Jerome M. Block wrote on September 13, 1994 that she had a probable serum reaction. Med. recs. at Ex. 6, p. 42. It was not classical GBS by any means but the mechanism might be the same. Id.

TESTIMONY

Dr. Albert L. Goodgold, Ms. Fadelalla's treating neurologist, testified first. Tr. at 5. He has been a neurologist since 1960 and is Professor of Clinical Neurology and Radiology at NYU Medical Center. Id. He first saw Ms. Fadelalla on September 12, 1994, referred by her obstetrician Dr. Clarel Antoine. Id. Ms. Fadelalla had symptoms of facial and finger paresthesias and transient rash. Tr. at 6. Her feet were involved and she was unsteady. Id. He diagnosed polyradiculoneuropathy, a form of GBS, which was post-immunization. Tr. at 7. She did not have any risk factors for GBS except the rubella vaccine. Id. He had previously had a case like this in grand rounds years before, but that individual was quadriplegic. Id. Ms. Fadelalla's GBS was mild. Id. Dr. Goodgold testified that the course of rubella vaccine causing GBS is not understood. Tr. at 8. Something in the vaccine or in the rubella acts as an antigen. Id. The process goes awry and tissues in the peripheral nervous system are damaged. Id.

Because he could not get a bed for Ms. Fadelalla at NYU, he put Ms. Fadelalla at Lenox Hill Hospital. Tr. at 8-9. She worsened for four to five days, with more paresthesias and unsteadiness. Tr. at 9. She had a slow recovery. Id. She was discharged on October 18, 1994 with paresthesia about the mouth, fingers, and toes. Id. She still uses a cane. Id. She had a monophasic course. Tr. at 11. His opinion about causation is based on his knowledge of GBS, the temporal association between the vaccination and the onset of GBS, the lack of other causes, and the literature. Tr. at 12.

Ms. Fadelalla had abnormal liver function tests from September 12 to 15, 1994, but Dr. Goodgold was unimpressed. Tr. at 26-27. He thought it stretched the imagination to implicate cytomegalovirus (CMV) or liver infection as the cause of Ms. Fadelalla's GBS. Tr. at 29. Ms. Fadelalla's erythrocyte sedimentation rate (ESR) was abnormally high, which is not a feature of GBS. Tr. at 34. It was consistent with an infectious process. Tr. at 38. She had abnormal proteins in her blood. Tr. at 35. CMV infection can cause a skin rash and fatigue. Tr. at 39.

Ms. Fadelalla did not have any marked increase in antibody titer or in IgM titer; therefore, Dr. Goodgold thought she did not have CMV. Id. A rash on the face is not typical for GBS, but Dr. Goodgold would not be surprised if it were related to the rubella vaccine. Tr. at 40.

Dr. Goodgold stated that rubella vaccine acts as an immunogen, i.e., an antigen. Tr. at 42. He could not state whether all vaccines cause GBS. Tr. at 42-43. He stated that the Physicians' Desk Reference (PDR) mentions that GBS is associated with rubella vaccine.(2) Tr. at 43. Also Dr. Goodgold testified that the Saeed (P. Ex. 15, Tab A) and Schaffner (P. Ex. 15, Tab D) articles offer support for his opinion.(3) Dr. Goodgold reiterated that the basis of his opinion of causation is his knowledge of GBS, the PDR list of adverse effects, and his experience at grand rounds with a similar patient years ago. Tr. at 46. He preferred not to answer whether isolated reports of polyneuropathy, including GBS, following rubella vaccination prove a causal relationship. Tr. at 65. Dr. Goodgold was not familiar with the material petitioner submitted as Exhibit 15, Tabs A through I. Tr. at 68.

Dr. Goodgold agreed that inapparent causes do precipitate GBS, and rubella vaccine does not always cause GBS. Tr. at 71. He has patients who contracted GBS after tetanus vaccine, flu vaccines, and other immunologic exposures. Tr. at 86. He had two patients with GBS after tetanus vaccine and four to five patients with GBS after swine flu vaccine. Id. If he has a patient who was given a vaccine and a week to ten days later develops either a paralytic brachial neuritis or GBS, he assumes the vaccine caused it. Tr. at 87. Dr. Goodgold stated he did not know any way to prove whether the rubella vaccine caused or was just coincidental to Ms. Fadelalla's GBS. Tr. at 90.

Dr. Barry Arnason testified for respondent. Tr. at 114. He is a neurologist who has seen one hundred to two hundred GBS patients. Tr. at 115-16. He testified that there is no known cause of Ms. Fadelalla's GBS. Tr. at 118. He does not know why she had a rash on her face and right arm. Tr. at 119. Her onset of a rash seven days after the vaccination is too soon for a rubella onset which should take from nine to twenty days. Tr. at 119-20.

One-third of GBS patients have no obvious antecedent event. Tr. at 124. Campylobacter causes twenty-five percent of GBS. Tr. at 130. Ten percent of GBS have CMV. Id. Five percent of GBS have mycoplasma pneumoniae. Id. Five percent of GBS have Epstein-Barre virus (EBV). Id. The theory is that the body generates a response to an infectious agent. Tr. at 131. Dr. Arnason has never had a rubella vaccine-GBS case. Tr. at 127. He has no doubt that swine flu vaccine in 1976 caused GBS because the data are overwhelming. Tr. at 132. The causative factor may have been in the eggs, not the virus. Tr. at 133. Subsequent swine flu vaccines have not caused GBS until 1998. Tr. at 134. And swine flu vaccine did not cause GBS in countries other than in the US. Tr. at 133.

When asked how to distinguish between a cause and coincidence, Dr. Arnason said that, firstly, the frequency of the antecedent event among the studied GBS population must exceed the number in the control population. Tr. at 135-36. Thus, campylobacter occurred in seventeen percent of GBS, but only in three percent of the control group, showing a five-fold increase of that event in the GBS cases. Tr. at 136. This is epidemiological evidence that exceeds chance. Id. Secondly, there may be in vitro evidence. Tr. at 137. Antibodies to GM1, a glycolipid, are found in twenty to forty percent of GBS cases, much higher than in the general population. Tr. at 138. Glycolipid is sugar and fat, present in cell membranes, particularly nerve cells. Id. Campylobacter has in its capsule a structure similar to GM1 which cross-reacts with GM1 in the nerves. Id. Italy marketed gangliosides to cure dementia, but the patients developed GBS, clearly showing a cause. Tr. at 138-39.

Dr. Arnason testified there must be several million rubella vaccinations each year. Tr. at 139-40. If there were 125 million vaccinations over the last thirty years, or ten million doses per year, there would be a two in 100,000 or 1 in 50,000 chance per year of having GBS. Tr. at 140-41. One would need 40 GBS cases per year among rubella vaccinees to have causation. Tr. at 141. CDC receives VAERs reports for rubella vaccine and would pick up an increased incidence. Tr. at 142. However, there is no evidence that the risk of GBS after rubella vaccine exceeds the background, based on the medical literature and his

clinical experience.[4] Tr. at 146.

Dr. Arnason thought Dr. Goodgold's reasoning was faulty because he concluded that the rubella vaccine caused Ms. Fadelalla's GBS because both were in close proximity. Tr. at 148. One can have brachial neuritis after any toxin, but he has not seen GBS after rubella vaccination. Id. Since thirty percent of GBS cases do not have an obvious antecedent, statistics favor a silent infection over rubella vaccine as the cause of Ms. Fadelalla's GBS. Tr. at 151. Ms. Fadelalla's doctors did not do a thorough search for infection. Tr. at 153. Articles dealing with vaccine made in the dog kidney cell are inapplicable to the instant case because that type of rubella vaccine was withdrawn in 1973. Tr. at 159.

Even though it is biologically plausible that rubella vaccine could cause GBS since all vaccines could, there is an absence of case reports of rubella vaccine followed by GBS, leaving the issue of causation open. Tr. at 190-92. Without an increase in the incidence of GBS among rubella vaccinees over the background rate, the anecdotal case reports are insufficient to substantiate that rubella vaccine causes GBS. Tr. at 193-95.

DISCUSSION

The Vaccine Act affords petitioners two alternate theories of recovery, thereby allowing them to prove causation by showing that either: (1) a Table-injury occurred or (2) the vaccine was the cause-in-fact of the injury. The former theory is governed by Section 14(a) of the Act which contains a Vaccine Injury Table. If the injuries described in this Table occur within the statutorily defined time period, petitioners have proven the existence of a "Table-injury," creating a rebuttable presumption of causation. To rebut this presumption, respondent must provide affirmative evidence demonstrating that a known factor unrelated was the cause-in-fact of the vaccinee's condition.[5]

If the onset of the illness is outside the appropriate Table time and/or the illness itself is not a Table injury, petitioners must prove that the vaccine caused in fact the illness. The burden does not pass to respondent to show a known factor unrelated to the vaccine caused the illness. Petitioner in the instant action had a non-Table injury, i.e., GBS. Therefore, she is limited to proving her case by the causation-in-fact standard.

Guillain Barre Syndrome

Petitioner alleges that rubella vaccine caused in fact her GBS. To satisfy her burden of proving causation in fact, petitioner must offer "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." See Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992); Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). "[E]vidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149.

Petitioner must not only show that but for the vaccine, he or she would not have had the injury, but also that the vaccine was a substantial factor in bringing about his or her injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

On the other hand, the court per Knudsen, supra, does not require petitioners to satisfy a burden of showing medical or scientific certainty in order to prevail. 35 F.3d at 549. The Federal Circuit stated "to require identification and proof of specific biological mechanisms would be inconsistent with the

purpose and nature of the vaccine compensation program." Id.

Thus, the court must derive a logical sequence of cause and effect from evidence showing medical probability without a detailed roadmap of step-by-step biological processes.

Petitioner, herein, has not satisfied her burden. Firstly, other than temporal association and the absence of known other causes, she has not submitted anything to prove a causal association between rubella vaccine and her GBS except Dr. Goodgold's firm belief that there is one. He relies on his experience which includes other cases of GBS arising after various vaccinations. However, on cross-examination, he admitted that there was no way he could prove whether Ms. Fadelalla's rubella vaccination was causal or coincidental to her GBS.

Dr. Goodgold also relied to some extent on the literature which petitioner submitted. He was not familiar, however, with most of the literature. Even the literature upon which he relied is faulty because it discusses rubella as a disease rather than the vaccine, or the rubella vaccine as it was once made (in dog kidney cells) but which was withdrawn from use in 1973. In addition, the literature is purely anecdotal. As Dr. Arnason, who has vastly greater experience with GBS than Dr. Goodgold, testified, one important way to determine if there is a causal relationship between an antecedent event and a disease is to compare the rate of the incidence of that disease after the antecedent event with the background rate.

Millions of people receive rubella vaccine and yet, although the Centers for Disease Control (CDC) receives vaccine adverse event (VAERs) reports, there has not been a higher incidence of GBS reported among rubella vaccinees than among baseline. This contrasts markedly, e.g., with the increased incidence of GBS among swine flu vaccinees in this country in 1976. Although Dr. Arnason opined that the immunologic insult to which GBS patients responded may have been in the eggs from which the swine flu vaccine was harvested, rather than in the vaccine itself, nonetheless the increased incidence was clear and uncontrovertible evidence to him of a causal relationship. Dr. Arnason, besides distinguishing himself in the fields of central and peripheral neuropathies, has co-authored the chapter on acute inflammatory demyelinating polyradiculoneuropathy (AIDP), also known as GBS, in the seminal textbook on peripheral neuropathy: P.J. Dyck, et al., Peripheral Neuropathy, Vol. III, ch. 80 (3d ed. 1993) 1437-97 (co-authored with B. Soliven). R. Ex. E.

Pertaining to vaccines and GBS, Dr. Arnason discusses in his chapter that rabies vaccine and swine flu vaccine have been causally related to GBS. The former caused AIDP when it was made from rabbit spinal cord or brain, but when the vaccine was made from chicken or duck embryos or in tissue culture, the incidence of AIDP was drastically reduced if not eliminated. Id. at 1444. Swine flu vaccine in 1976 caused a higher incidence of GBS among 45 million civilian vaccinees in the U.S. than baseline GBS.

Referring to other vaccines, Dr. Arnason writes in his chapter, "Most large AIDP series contain scattered cases involving individuals who had received some sort of recent vaccination." Id. at 1445. He continues, "Scattered reports of AIDP occurring after administration of measles vaccine, rubella vaccine, DPT inoculation, and even BCG revaccination have been recorded, but the event is rare in the extreme and there is no good evidence that the incidence exceeds background. [footnotes omitted]." Id. at 1446. Other than associating AIDP with nervous tissue containing rabies vaccine, US civilian swine flu vaccine in 1976, and tetanus vaccine, Dr. Arnason concluded: "Association of AIDP with other vaccines remains doubtful at present." Id.

It is certainly true that the timing of the onset of Ms. Fadelalla's GBS occurring one week post-vaccination together with a rash of unknown etiology makes the association of her GBS with the rubella

vaccine medically plausible. GBS is an autoimmune disease and it is the body's "aberrant immune response" to an antigenic insult that sends lymphocytes and macrophages to peripheral nerves where they destroy myelin, leading to paralysis. Id. at 1437. However, medical plausibility does not meet the level of legal probability. Petitioner, through her expert, must prove that more likely than not the vaccine caused her illness based on more than temporal association or the absence of other known causes.

Petitioner may prove causation a number of ways. She may show the biological mechanism if it is known. In the case of GBS, no one knows why it occurs even though doctors know how GBS occurs once the body attacks itself (hence, the autoimmune description). Petitioner may show in vitro tests, if such exist, which link the antecedent event to the illness. There are no in vitro tests here. Petitioner may show animal experimentation. There is a disease, experimental allergic neuritis (EAN), which has mimicked GBS in humans. However, the antigen, P2 protein, used to initiate EAN has not been shown to play any relevant role in human GBS. Moreover, there is no evidence that P2 protein is in rubella vaccine. Id. at 1460-61, 1466.

The clinical experience of the expert witness may prove a causal relationship. In this case, Dr. Arnason, who has had many more GBS cases than Dr. Goodgold, has never seen a rubella vaccine-GBS patient, whereas Dr. Goodgold has a handful of vaccinees (receiving different types of vaccine) with GBS. A handful of vaccinees with different vaccines prior to contracting GBS is merely suggestive, rather than supportive, of a causal relationship. Lastly, epidemiological evidence may show an increased incidence of GBS among rubella vaccinees over baseline GBS if, indeed, rubella vaccine causes GBS. Although millions of rubella vaccinations have been administered, there is no increase in baseline even though CDC receives VAERS reports as part of its role in the government.

Were this court to rule based solely upon the temporal association of vaccination and illness and the absence of a known factor unrelated, it would be wrong as a matter of law. See Hasler, supra, and Grant, supra. The indicia of reliability, Daubert, supra, 509 U.S. at 597, and intellectual rigor, Kumho Tire Co., Ltd. v. Carmichael, 119 S. Ct. 1167, 1176 (March 23, 1999), that must characterize an expert witness's testimony in order to be persuasive are missing in this case. For a good portion of Dr. Goodgold's testimony, he refused to answer questions on cross-examination and he was unfamiliar with most of the medical literature that petitioner submitted (albeit that medical literature is not persuasive). Although the court is grateful for any treating physician's testimony, its gratitude cannot extend to acceptance of cursory, conclusory opinions grounded on the doctor's instinct. His instinct may very well be right, but it has no legal effect when based upon mere anecdotal literature, his own handful of cases in his practice, failure to comprehend the biological process (which is, at present, unknown), and absence of confirmatory epidemiological studies, animal experimentation, or in vitro testing. There is no legal basis to find that rubella vaccine was a substantial factor in causing petitioner's GBS. See generally, Ashe-Robinson v. Secretary, HHS, No. 94-1096V, 1998 WL 994191 (Fed. Cl. Spec. Mstr. Feb. 5, 1999) (insufficient evidence to find OPV causes GBS).

Petitioner has failed to present a prima facie case that rubella vaccine caused her GBS.

CONCLUSION

This case is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

DATE: _____ _____

Laura D. Millman

Special Master

1. [1] The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. § 300aa-1 et seq. (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.

2. The 1998 PDR at page 1833 states, "Isolated reports of polyneuropathy including Guillain-Barre syndrome have been reported after immunization with rubella-containing vaccines. Clinical experience with live rubella vaccines thus far indicates that encephalitis and other nervous system reactions have occurred very rarely in subjects who were given the vaccines, but a cause and effect relationship has not been established."

3. A.A. Saeed and L.S. Lange, "Guillain-Barré syndrome after rubella," 54 Postgraduate Med J 333-34 (1978) (describing GBS developing 6 days after infection with rubella disease) (P. Ex. 15, Tab A); W. Schaffner, et al., "Polyneuropathy Following Rubella Immunization. A Follow-Up Study and Review of the Problem," 127 Am J Dis Child 684-88 (1974) (the rubella vaccine in question was prepared in dog kidney cells, a methodology no longer in use by 1974; the children developed a crouching gait called "catcher's crouch") (P. Ex. 15, Tab D).

4. Dr. Arnason cited to P. Ray, et al., "Risk of Chronic Arthropathy Among Women After Rubella Vaccination," 278 JAMA 551-56, (1998), who studied, inter alia, whether rubella vaccine increased the incidence of neuritis and neuropathies among vaccinees and concluded it did not. The study population was 4884 women, which may not have been large enough to detect an elevated vaccine-associated risk. Id. at 554. R. Ex. F.

5. 42 U.S.C § 13(a)(1)(B).