

OFFICE OF SPECIAL MASTERS

No. 96-188V

(Filed: November 20, 2003)

MARGARET WALLACE as natural	*	
mother of AIMEE WALLACE, decedent	*	
	*	
	*	
Petitioner,	*	
	*	To be Published
v.	*	
	*	
SECRETARY OF THE DEPARTMENT OF	*	
HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Clifford Shoemaker, Esq., Vienna, Virginia, for Petitioner,

Vincent Matanoski, Esq., United States Depart of Justice, Washington, D.C., for Respondent.

DISMISSAL ORDER

On 10 April 1996, Petitioner filed a claim under the National Childhood Vaccine Injury Compensation Act (Vaccine Act or Act)¹ alleging a vaccine-related death to his daughter Aimee Wallace. Petitioner filed her claim *pro se*. On 28 May 1997, this Court issued its first Order to Show Cause in this case because in the more than one year since Petitioner had filed the claim, no medical records had been filed. Additionally, Petitioner had not contacted the Court to pursue his claim in over eight months. The Court issued its second Order to Show Cause for failure to prosecute on 2 September 1998. Between the 28 May 1997 and 2 September 1998 Orders to Show Cause, Petitioner took absolutely no action to further her case. Petitioner secured the services of attorney Clifford Shoemaker and filed his notice of appearance on 18 December 1998. Over the next eighteen months, Petitioner’s counsel filed monthly status reports with the Court. The reports informed the Court on the status of the on-going medical record

¹ The statutory provisions governing the Vaccine Act are found at 42 U.S.C. §§ 300aa-1 to 300aa-34 (1991 & Supp. 2002). Hereinafter, for ease of citation, all references will be to the relevant subsection of 42 U.S.C. § 300aa.

collection. On 7 June 2000, the Court issued an order demanding that the Petitioner shall confer with Respondent to determine how this case shall proceed and, on or before 23 June 2000, Petitioner and Respondent should confer on dates for a July 2000 status conference. No status conference was conducted. On 27 July 2000 and 30 October 2000, Petitioner's counsel filed additional status reports informing the Court about the on-going problems in securing medical records. Additionally, Petitioner's counsel moved that prosecution of the case be delayed in order to investigate a theory of causation. The Court granted Petitioner's motion. On 10 April 2001, tiring of the unreasonable delays in prosecuting this case, the Court issued an order demanding that on or before 23 April 2001, Petitioner shall contact Respondent to determine how this case shall proceed and both parties shall then contact the Court and apprise it of their joint determination.

On 15 June 2001, the Court issued its third Order to Show Cause. The Court stated its reason for issuing such as follows:

“As noted in the previous order, this case has been delayed for several months pending an investigation into the theory of causation. Fourteen status reports have been filed and there has been little movement in this case that has been pending for five years. While the Court appreciates the fact that Petitioner and her attorney may not have the funds available to develop a theory of causation that entails comparative DNA testing of the vaccine with autopsy samples, Petitioner must sooner or later prosecute their case.”

The Court gave Petitioner until 14 August 2001 to show cause why this case should not be dismissed for failure to prosecute or file a Motion to Dismiss. The Court issued an order on 8 November 2001 authorizing Petitioner to issue a subpoena *duces tecum* directed at Southwest Foundation for Biomedical Research for any and all records relating to the care and treatment of Amy Wallace. On 28 February 2002, the Court granted Petitioner permission to issue a subpoena *duces tecum* requiring Dr. Julia Hilliard of Georgia State University, to relinquish possession of all records relating to the care and treatment of Amy Wallace. Additionally on 28 February 2002, the Court issued an order giving Petitioner until 12 July 2002 to complete her filings. On 9 September 2002, the Court once again granted Petitioner permission to issue a subpoena *duces tecum* requiring Dr. Julia Hilliard of Georgia State University, to relinquish possession of all records relating to the care and treatment of Amy Wallace.

On 6 January 2003, the Court issued its fourth Order to Show Cause. The Court stated its reason for issuing such as follows:

This case was filed on 10 April 1996. Petitioner has proffered the theory that Aimee Wallace's tragic death was a sequela to the enteritis she contracted as a result of an OPV vaccination. This theory of course falls under the rubric of causation-in-fact. As with any causation-in-fact case, Petitioner faces an uphill challenge. During a status conference held on 6 January 2003, Petitioner's attorney informed this Court that important medical records related to this case could not be obtained. Specifically, Petitioner's attorney stated

that pathological materials had been destroyed. Without such materials, Petitioner's attorney stated it would be highly unlikely that Petitioner could prove her case.

The Court gave Petitioner until 6 February 2003 to show cause why this case should not be dismissed for failure to prosecute or it would file a Motion to Dismiss. On 5 February 2003, Petitioner filed with the Court, in answer to an Order to Show Cause, a status report in which Petitioner proposed a singular testing protocol by which to help prove her case. Petitioner's Status Report (hereinafter "Pet. Stat. Rep"), 7 January 2003. Upon receipt of the proposal, the Court tasked Respondent to respond to Petitioner's proposal by securing a medical expert to opine on the reasonableness and viability of the Petitioner's proposal and to state whether the proposed protocol would be probative based on the facts of this case. Respondent complied by filing a medical expert's report authored by Jerome Klein, M.D.,² on 25 April 2003. Dr. Klein's report stated, *inter alia*, that Petitioner's proposed testing protocol would not help in determining the cause of Aimee's death. Respondent's Exhibit (hereinafter "Res. Ex.") A.

On 7 May 2003, the Court issued its fifth Order to Show Cause in this case tasking Petitioner to respond to Dr. Klein's report with the opinion of a qualified medical expert. The qualified medical expert was to respond point-by-point to Dr. Klein's report, and provide a logical sequence of events as to how the OPV vaccination was the cause of the acute enteritis that caused Aimee's death approximately seven weeks after its administration. For whatever logic, Petitioner elected not to secure a qualified medical expert to opine on Dr. Klein's report. Instead Petitioner's husband authored a response. Pet. Stat. Rep, 23 May 2003. Petitioner's husband's only claim to be a qualified expert is that "[he is] a scientist."³ Pet. Stat. Rep., 7 January 2003 at 1. He has not proffered any credentials qualifying him as an expert.

² Dr. Klein received his bachelor's degree from Union College in 1952 and his medical degree from Yale University in 1956. He is board certified in pediatrics. He has held numerous teaching positions at Harvard Medical School and Boston University School of Medicine. He is a member of the Vaccine and Related Biologic Products Advisory Committee of the Food and Drug Administration and a member of the Scientific Review Committee for Vaccine Trials. He has held the position of editor for several peer reviewed publications including *INFECTION*, which is published in Germany, *VACCINE BULLETIN* and the *REPORT OF THE COMMITTEE ON INFECTIOUS DISEASES*. His publications number approximately 300. He has had extensive experience with poliomyelitis and polio vaccines.

³ It is extremely doubtful that Petitioner's husband fulfills the American Medical Association (AMA) guidelines for expert witnesses: H.265-994 Expert Witness Testimony: (3) (a) "Existing policy regarding the competency of expert witnesses ... (BOT Rep. SS A-89) is reaffirmed, as follows: The AMA believes that the minimum statutory requirements for qualification as an expert witness should reflect the following: (i) that the witness be required to have comparable education, training, and occupational experience in the same field as the defendant; (ii) that the occupational experience include active medical practice or teaching experience in the same field as the defendant; and (iii) that the active medical practice or teaching experience must have been within five years of the date of the occurrence giving rise to the claim." Petitioner's husband proffers no objective evidence that he has the proper education, training or occupational experience. He has not proffered any credentials qualifying him as a neurologist, immunologist, pediatrician, or even a general practitioner.

The Court cannot conclude as to the reasonableness of the proffered protocol. Further, the Court cannot conclude that this protocol will assist the Court in reaching a conclusion by a preponderance of the evidence. Petitioner failed to adequately answer the 7 May 2003 Order to Show Cause. Consequently, the Court must dismiss this case.

I. DISCUSSION

Aimee Wallace was born 8 October 1992 by normal full term delivery. Res. Ex. A at 1. Aimee Wallace had an uneventful medical history prior to her untimely death. *Id.* Aimee received OPV vaccinations on 13 January 1993, 21 April 1993 and 23 February 1994. *Id.* Petitioner alleges that Aimee experienced a “reduction in health” starting in February 1993 and such was first noted in the medical records when Aimee was ten months old. Pet. Stat. Rep., 5 May 2003 at 4; Res. Ex. A at 1. Aimee died on 15 April 1994, seven weeks after her third OPV vaccination. *Id.* The pathologist recorded her cause of death as dehydration following acute enteritis. Res. Ex. A at 1. Petitioner alleges that the OPV vaccine caused Aimee’s death. Pet. Stat. Rep., 7 January 2003 at 1. Aimee’s autopsy samples have been destroyed. *Id.*

Because the autopsysamples were destroyed, Petitioner proposes an “‘experiment’ . . . that would still prove that Aimee died from the OPV.” *Id.* Petitioner proposes that testing for OPV by polymerase chain reaction (PCR) or oligonucleotide sequencing (OS) can be performed on family members that contracted the OPV virus through contact with Aimee. *Id.*⁴ The PCR or OS testing will be able to determine which strain of the polio virus the family members contracted and such strain can be matched to the strain in the OPV lot administered to Aimee. *Id.* Additionally, Petitioner suggests that she can then track down other recipients throughout the country of the same lot number of OPV who have suffered a reduction in health, test such recipients, and compare the strain of polio virus contracted by them to that contracted by his family members. *Id.* If the polio viruses are substantially similar, accounting for mutations, Petitioner posits that would be enough to prove that Aimee’s cause of death was due to the OPV vaccinations she received. Pet. Stat. Rep., 7 January 2003. Some caveats with Petitioner’s proposal are that other recipients must be identified, located and they must agree to the testing.

In the alternative to the “experiment,” the Petitioner proposes that his daughter’s body be exhumed. *Id.* at 4. Petitioner proposes that once the body is exhumed, the medulla oblongata could be tested for the presence of the polio virus, thereby establishing the link between the polio virus and the cessation of her heart and pulmonary functions. *Id.*

1. **Petitioner’s proposed “experiment” is unreasonable and will not assist in answering the question of causation.**

(a) Unreasonable

⁴ Petitioner has filed a case for other family members. The docket number is 97-836V. Pet. Stat. Rep. at 2.

“There may be no discovery in a proceeding on a petition other than the discovery required by the special master.” 12(d)(2)(B). In Vaccine Act cases there is no discovery as a matter of right. R.C.F.C. Appendix B Rule 7. A guidepost that the undersigned follows when determining the discovery the Court will require is whether the information is reasonably available and whether it will assist the Court in answering the medical causation questions presented. 12(d)(2)(B)(i)-(ii).

The Court cannot conclude that the proffered “experiment” is a reasonable request in this case, nor can it conclude that the evidence is reasonably available. On behalf of Respondent, Dr. Jerome Klein proffered his opinion as to the reasonableness of the request and further indicated that even if all went according to Petitioner’s plan, the results would still be inconclusive. While the scientific underpinnings of Petitioner’s proposed “experiment” may have merit, actually conducting such would be prohibitive and open ended. No one knows how long this process could take; Petitioner presented no estimate on this topic. First, Petitioner must identify a number of unknown third parties, locate such parties, contact them and then get them to agree to participate in his proposed testing protocol. Thus, the proposed “experiment’s” success hinges upon the cooperation of persons not involved in the case and who have no duty to cooperate. Additionally, the Court has no power, other than its putative power of persuasion, to make them cooperate.⁵ Second, Petitioner admits that she cannot afford to conduct the “experiment” and would like this Court to issue an open ended stay until such time that she can. Pet. Stat. Rep., 7 January 2003 at 4. This case has already been on the Court’s docket for over seven years. This Court has been most liberal in granting time extensions repeatedly to Petitioner. Allowing for an open ended stay would be diametrically opposed to “Congress’s objective in the Vaccine Act to settle claims quickly and easily.” *Brice v. Sec’y of HHS*, 240 F.3d 1367, 1373 (Fed. Cir. 2001).

(b) Will not assist in answering the question of causation.

Respondent filed a report authored by Dr. Jerome Klein which critiqued Petitioner’s proposed “experiment” as set forth in Petitioner’s 9 January 2003 status report. Dr. Klein concluded that the experiments designed by Petitioner would not be able to determine the cause of Aimee’s death. Res. Ex. A. at 4. On the matter of possible exhumation, Dr. Klein concluded any finding of polio virus in the body would indicate that Aimee had a prior experience with the virus, as could be expected when receiving OPV seven weeks prior, but that no conclusion about causation could be made from such a finding. *Id.* at 3.

As stated *supra*, the Court tasked Petitioner to secure a qualified medical expert to respond to Dr. Klein’s report and to file such response within a specified time period. Petitioner did not secure a qualified medical expert as directed, instead Petitioner’s husband authored his own response. The Court’s only indication that Petitioner’s husband is qualified to write such a response is his self proclamation that “[he is] a scientist.” Pet. Stat. Rep., 7 January 2003 at 1. Petitioner’s husband’s detailed objection to Dr. Klein’s analysis, opinion, and conclusion must be taken *cum grano salis* inasmuch as he is not a sufficiently

⁵ The Court is aware of the possible Fourth Amendment proscriptions against unreasonable search and seizure that may arise if the Court were to subpoena blood samples from persons not party to this case.

qualified medical expert so as to write an opinion that can be acceptable to this Court. In fine, this Court has little reliance in his critique.

Because Dr. Klein is the only qualified expert to opine on the issue as to whether Petitioner's "experiment" would be conclusive, the Court places its reliance on his opinion. Therefore, the Court finds that Petitioner's proposed testing protocols and alternative exhumation would not assist in answering the question of causation and, accordingly, will not be allowed.

2. Petitioner has failed to comply with this Court's order.

If a Petitioner fails to comply with any order of the Court, the special master may dismiss the claim. R.C.F.C. Appendix B Rule 21(c). On 7 May 2003, the Court issued the following Order to Show Cause tasking Petitioner to respond to Dr. Klein's report:

The Court now tasks Petitioner to respond to Dr. Klein's report. Petitioner's reply must be authored by a qualified medical expert, respond point-by-point to Dr. Klein's report, and provide a logical sequence of events as to how the OPV vaccination was the cause of the acute enteritis that caused Aimee's death approximately seven weeks after its administration. **Petitioners shall file this response by close-of-business 23 June 2003, approximately forty-five (45) days from the date of this order, or show cause why this case should not be dismissed.** A failure to meet the Court's deadline, unless good cause is shown, will result in the dismissal of this case.

Petitioner did not secure a qualified medical expert, therefore, she did not comply with the Court's order.

CONCLUSION

This Court hereby orders the immediate **DISMISSAL WITH PREJUDICE** of this case for the reasons contained in this decision. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

Richard B. Abell
Special Master