OFFICE OF SPECIAL MASTERS

No. 90-3322V

Filed: July 28, 1997

TAMOTU MULITAUAOPELE, a/k/a TAMOTU PELE,	*	
Petitioner,	*	
v.	*	TO BE PUBLISHED
SECRETARY OF THE DEPT. OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Stanley T. Kaleczyc, Helena, Montana, for petitioner.

Vince Matanoski, Washington, D.C., for respondent.

DECISION AND ORDER

GOLKIEWICZ, Chief Special Master

I. PROCEDURAL BACKGROUND

On October 1, 1990, Petitioner filed a petition pursuant to the National Childhood Vaccine Injury Act of 1986 (hereinafter referred to as "the Act").[(1)] Petitioner Tamotu Mulitauaopele alleged that on May 20, 1961, he received "2 drops of Trivalent Polio Vaccine, an activated vaccine, at the United States Public Health facility in American Samoa." Petition, filed 10/1/90, at 2. Petitioner further states that he received his second and third doses of the vaccine on June 30, 1961, and July 29, 1961, respectively. Petitioner alleges that soon after receiving his first polio vaccination (at nine months[(2)]), and as a result thereof, he contracted poliomyelitis. Pet. at 2. Petitioner currently suffers from "a deformity of the right lower extremity diagnosed as polio with atrophy and shortening of the extremity." Pet. at 2.

Respondent contested Petitioner's entitlement under the Act, and moved to dismiss Petitioner's claim. R.

Rpt, filed 6/17/93. First, Respondent argued that Petitioner failed to clearly identify which polio vaccine (s) he received. The Petition alleged an oral polio vaccine was given; in contrast, Dr. LeiatoTupua's affidavit (dated 11/23/92 and filed 12/11/92) indicated Petitioner received an inactivated polio vaccine (IPV). R. Rpt. at 1, 2-3. Second, Respondent alleged Petitioner failed to demonstrate "he received any polio vaccine prior to the onset of his paralytic polio." R. Rpt. at 1, 2-3. Lastly, Respondent contended that, assuming Petitioner was alleging he received IPV, he failed to prove his injury was caused in fact by the vaccination, since paralytic polio is not a table injury for this vaccine.(3) R. Rpt. at 1, 3-4.

From June 1993 to January 1997, the parties supplemented the record in this case. Their efforts were complicated by several factors: Petitioner's vaccinations occurred over thirty years ago, the immunizations were administered in American Samoa, many of Petitioner's early medical records have been destroyed and/or are conflicting, and the American Samoan Government's records on their polio vaccination process and/or any test shipments received are unavailable and cannot be found.(4) At this time, one factual issue requires resolution before the case can proceed: did Petitioner receive an oral polio vaccine (OPV) or an inactivated polio vaccine (IPV) in the Spring and Summer of 1961? The court conducted a hearing on January 13, 1997, wherein Petitioner presented the telephonic testimony of Faatafuna Afalava in support of his allegation that he received a series of OPV vaccinations between May 1961 and July 1961. Ms. Afalava worked as a licensed practical nurse in American Samoa from 1948 until her retirement in 1990, and was the Assistant Director of Public Health Nursing in American Samoa from 1962 through 1990. The parties presented post-hearing arguments on May 12, 1997. After reviewing the entire record, and for the reasons set forth below, the court finds Petitioner did not receive a trivalent oral polio vaccine, as alleged, in May 1961-July 1961; in other words, assuming a polio vaccine was received at that time, it was the IPV.(5) A full discussion of the evidence before the court follows.

II. DISCUSSION AND LEGAL ANALYSIS OF THE FACTUAL EVIDENCE PRESENTED

A. Petitioner's Evidence

Petitioner relied primarily on two pieces of evidence to support his allegation that he received a series of oral polio vaccines beginning in May 1961. The first was Petitioner's International Certificate of Vaccination, filed 10/1/90. The second was the testimony of Faatafuna Afalava, as presented at the January 13, 1997, hearing and by her affidavit dated March 13, 1996. Because Ms. Afalava testified she created the International Certificate of Vaccination, the significance of this evidence will be discussed in combination with the analysis of Ms. Afalava's oral testimony.

Testimony of Faatafuna Afalava and the International Certificate of Vaccination

Ms. Afalava worked as a licensed practical nurse in American Samoa from 1948 to 1990; her duties included visiting the various villages and providing immunizations to children. Tr. I at 7.(6) From 1962 until her retirement in 1990, she was the Territory's Assistant Director of Public Health Nursing. In this position, she supervised the field nurses' work and handled the "record keeping of immunization records of all the children." Tr. I at 8. In addition, as the Coordinator for the immunization program, she "prepared the international certificate or vaccination card for the children who [were] ready to move out or off [the] island to the United States"(7); this vaccination information was necessary for school admissions and general infant care. Tr. I at 8, 14.

In 1990, before her retirement, Ms. Afalava prepared Petitioner's international vaccination card. Tr. I at 10. This card was filed with the Petition as Exhibit 1. To prepare the card, Ms. Afalava consulted a computer printout of Petitioner's immunizations; Petitioner's individual baby record(s) could not be

found. Tr. I at 10-11, 19. It appears from Ms. Afalava's testimony that the American Samoan government had a local "computer systems" office which managed the government's limited computer base; this office and computer system were created several years after Ms. Afalava became the Assistant Director. Tr. I at 27-28, 32. Apparently, other governmental offices, including the public health office, were not equipped with their own computer systems in 1990. Tr. I at 32. The system contained an "immunization" file; the immunization information for the children of the island was entered into the computer by government employees assigned this task[(8)]. Tr. I at 19, 20. The computer systems office periodically printed out the information contained in the computer's immunization file. Tr. I at 11, 32, 34. The computer systems office then notified the public health office that the paper printouts could be picked up by public health personnel. Tr. I at 32, 34-35.

Ms. Afalava testified that the printout relevant in this case indicated Petitioner received only DPT and "trivalent polio" vaccines (Tr. I at 11, 19); she stated, "I found out from there [i.e., the computer printout] it was a trivalent polio because trivalent polio is the same as Sabin polio." Tr. I at 11. Initially, when filling out the card, Ms. Afalava attested she began writing down Salk Vaccine; after reviewing the printout she entered trivalent polio. [(9)] Tr. I at 11. She attributed her initial thought that Petitioner had received the Salk vaccine to her understanding that between 1944 and 1948, when she was in nurses training, the Salk polio vaccine was being administered. Tr. I at 22. Most compelling for Petitioner, however, is Ms. Afalava's confirmation that the vaccination record in the printout indicated "two drops" of the shot were administered. Tr. I at 11. She averred, "During my experience working for the public health department, oral dosages of vaccines were always recorded as 'drops.'" Affidavit of Faatafuna Afalava, dated 3/13/96, filed 3/25/97, at 2. Although she did not administer the vaccine to Petitioner, Ms. Afalava noted placing the drops in sugar was the way it was given in 1960 and 1961[(10)]. Tr. I at 12. She elaborated that the "two drops were dropped into the block of sugar"...and then they "divided the block of sugar" to make the oral administration to infants easier. Tr. I at 11-12.

Ms. Afalava remembered administering trivalent OPV, but could not recall when the vaccine was first used on the island or when she herself first administered the OPV. Tr. I at 24-25. This brings into question her earlier statement that she recalled giving sugar cubes in "1960 and 1961". Tr. I at 12. Even after becoming the Assistant Director, she administered vaccinations when the office was short-staffed with nurses. Tr. I at 25. Immunizations were provided in different locations. Individuals living near the office could receive them there. Others would receive them at an immunization clinic planned by the village nurse; the mayor of the village would gather the children together for the vaccinations. In other cases, nurses would make house-calls. Tr. I at 26. No matter the manner of administration, Ms. Afalava testified that the nurses worked only Monday through Friday, not on the weekends; they were not paid by the government for weekend work, Ms. Afalava implied. Tr. I at 26-27, 33.

Ms. Afalava also discussed her role in the ordering of the polio vaccine. Her testimony on this point was rather convoluted. In any event, from the court's review of the testimony, it appears at some point, and clearly after 1962 when Ms. Afalava became the Assistant Director, the nurses "filled out the form for the order and gave it to the front office [i.e., "medical supply" office]."[(11)] Tr. I at 17. The "medical supply" office would then order the vaccine from U.S. manufacturers located off the island. When the medical supply office received the vaccine from the supplier, the vaccines were kept in a freezer; the nurses then obtained the vaccine from the medical supply office. Tr. I at 13, 17, 29-31. Ms. Afalava remembered that in the beginning of 1961, the trivalent OPV was ordered directly from a U.S. manufacturer. Tr. I at 16-17, 18. She remembered it was this year because it was "the time the Navy moved away from [the] island."[(12)] Tr. I at 17.

Petitioner pleaded for court leniency given the unavailability, by no fault of Petitioner, of some records in this case. Petitioner contended the printout which Ms. Afalava relied on was based on governmental

business records which were themselves based on original records created contemporaneously with the administration of the vaccinations. Petitioner deemed this the "best evidence" available; the printout itself, as well as the original records, were unavailable. Tr. II at 6, 7. Petitioner further asserted Ms. Afalava's testimony corroborated the printout information that OPV was being administered in 1961. Tr. II at 7. Petitioner deemed her testimony all the more reliable because although she expected the inoculation was Salk, she later determined it was the trivalent vaccine after reviewing the printout. Tr. II at 23. In addition, Petitioner argued Ms. Afalava's testimony did not preclude that some nurses may have provided inoculations on the weekends. Tr. II at 23. Lastly, Petitioner conceded the inconsistency of the records on the onset issue, but noted that the historical information provided by the mother in some medical records was substantiated by Semalama Godinet's affidavit that Petitioner became ill in the Spring of 1961. Tr. II at 25.

Respondent, on the other hand, questioned the reliability of the vaccination card and Ms. Afalava's testimony. Counsel noted that the vaccination card was created almost thirty years after the inoculations were allegedly given. Moreover, the "source of information that went into that document [i.e., vaccination card] is not contemporaneous either. Ms. Afalava testified that she received the information from a computer printout, not from original records. So, essentially, we don't know what any of the original records would have said in this case." Tr. II at 14. In reviewing Ms. Afalava's recollection of events, Respondent argued that the events happened over thirty years ago, memories were likely to fade, and Ms. Afalava thought, in 1990 when she prepared the vaccination card, that Salk was being administered in 1961, thus demonstrating her failing memory and inconsistent testimony. Tr. II at 14-15. In addition, two of the alleged vaccination dates were Saturdays, and Ms. Afalava confirmed that vaccinations were not given on the weekends. Tr. II at 15. Ms. Afalava also indicated the vaccine came directly from the manufacturer, but Respondent noted his evidence showed no companies were licensed for monovalent OPV distribution until August 1961; trivalent OPV was not licensed until June 1963. Tr. II at 15-16. Lastly, Respondent not only contested the dates alleged and indicated that the medical records reflected the first OPV was received October 15, 1962 (Tr. II at 15, citing P Exh. 3 at 117); but he also questioned whether Petitioner had shown the onset of injury was *subsequent* to any vaccinations. Tr. II at 20-21.

The court finds Respondent's arguments persuasive. Under §13(a)(1) of the Act, a special master may not make a finding of entitlement based on the claims of petitioners alone unsubstantiated by medical records or medical opinion. While contemporaneous medical records have been found to be more probative than witness testimony, clear, cogent, and consistent testimony can overcome missing or contradictory medical records. See Tweten v. Secretary of HHS, 26 Cl. Ct. 405 (1991); see also Stevens v. Secretary of HHS, No. 90-221V, 1990 WL 608693 (Cl. Ct. Spec. Mstr. Dec. 21, 1990). Thus, although contemporaneous medical records are not required to prove the fact of vaccination, the sufficiency of the evidence must be weighed under the preponderance of evidence standard, and therefore in light of the entire record. See Centmehaiey v. Secretary of HHS, 32 Fed. Cl. 612 (1995), *aff'd* (Fed. Cir. Dec. 15, 1995). It is with these legal principles in mind that the court reviews Ms. Afalava's testimony.

Clearly, this case is plagued by missing and contradictory medical records. Ms. Afalava's testimony was presented to provide the missing link, i.e., that Petitioner would have in 1961 and did in fact receive a series of oral polio vaccinations in May-July 1961. However, the court seriously questions the reliability of the vaccination card upon which Petitioner's allegations are based. The card was created in 1990, founded on a printout resulting from information placed in the computer several years after Ms. Afalava became the Assistant Director in 1962 (the computer system itself was not installed until sometime after 1962). Simply put, none of the information relied on by Ms. Afalava or provided in the computer file and subsequent printout is contemporaneous with the vaccinations themselves, and although medical records closer in time to 1961 yielded conflicting information as to which polio vaccine was administered when,

no records substantiate Ms. Afalava's reading of the printout that trivalent OPV was given in May-July 1961. Indeed, Respondent's evidence outlined later in this decision reveals trivalent OPV was not even approved by the Food & Drug Administration until June 1963. Even if the court were to find, as Ms. Afalava testified in part, that government employees (or nurses, the testimony is unclear), acting within their scope of governmental duties, accurately entered the island children's immunization information into the computer from the original medical records, this finding would not outweigh the other evidence submitted in this case, most compelling of which is that trivalent OPV was not approved until 1963. Lastly, no evidence exists to substantiate Petitioner's allegations that isolated shipments may have made their way to American Samoa.

In addition, Ms. Afalava's own testimony reveals her difficulty in recollecting the events of the time. In preparing the vaccination card in 1990, she expected the vaccine given in 1961 to be Salk; however, she later testified that clearly in 1960 and 1961, OPV was being given. She even detailed the procedure by which it was administered to infants at that time. In the end, Ms. Afalava could not remember when the OPV first came to the island, or when she herself first administered the vaccine; although she could recall it was ordered from a U.S. manufacturer. This leads the court to believe that Ms. Afalava's specific recollection of the events which occurred thirty years ago has simply been diminished by the passage of time; her testimony does not overcome either the medical records which have been filed or the evidence submitted by Respondent.

The court's discounting of Ms. Afalava's testimony that OPV was **the** polio vaccine given in 1961 is further supported by Petitioner's own submissions, which either unpersuasively supported Petitioner's claim, or outright supported Respondent's contentions. A discussion of that evidence follows.

Affidavit of Julie Hail dated 6/13/96

Ms. Hail, Petitioner's counsel's paralegal, informed the court, in various affidavits, of her exhaustive efforts on behalf of Petitioner to obtain support for his claim.(13) In Ms. Hail's June 13, 1996 affidavit, she attested to a conversation she had on May 28, 1996, with Dr. Nkowane, a physician with the World Health Organization. Ms. Hail testified:

Dr. Nkowane advised me that the World Health Organization in Geneva, Switzerland, has no information on specific countries where polio vaccines were distributed in the late 1950s and early 1960s and further advised that because there were so many trials and studies conducted during that period of time, it is impossible to determine where, globally, the live polio vaccine was distributed and by whom.

Affidavit of Julie Hail, dated 6/13/96, filed 6/19/96, at 2-3. Despite her request, Dr. Nkowane would not sign an affidavit and instead referred Ms. Hail to the Organization's legal department for confirmation of the information he provided. Affidavit of Julie Hail at 3. As truthful as Dr. Nkowane's statement might be, this information provides no persuasive evidence that any studies were conducted in American Samoa in 1961. Furthermore, evidence submitted by Respondent, and discussed later in this decision, convincingly tips the balance in the government's favor that OPV was not administered in American Samoa at the time of Petitioner's vaccinations; it would be pure speculation to believe otherwise.

Debra Taub's letter to Julie Hail dated 12/7/92

On December 21, 1992, Petitioner filed a letter dated December 7, 1992, from Debra P. Taub, a Consumer Safety Officer with the Food and Drug Administration of the Department of Health & Human Services.(14) Apparently, Ms. Taub was responding to a request for information made by Ms. Hail for "information regarding the availability of injectable polio vaccine in 1961." Ms. Taub responded that six

companies were licensed to manufacture the *injectable* polio vaccine in 1961. However, this information does not support Petitioner's allegations that he received OPV in 1961. Oral polio vaccine was, and always has been, given orally (hence the name), whereas inactivated polio vaccine was provided by injection. This information only substantiates that the IPV was available in 1961, which is not in dispute. Letter from Taub to Hail of 12/7/92, filed 12/21/92, at 1.

Letter from Dr. Leiato Tupua dated November 23, 1992

On December 11, 1992, Petitioner filed the letter of Dr. Leiato Tupua; he was a retired physician and had been with the American Samoa Hospital. He wrote, "I recalled back in the year 1960 when this boy Tamotu Mulitauaopele Jr. was born and had been hospitalized for such a period of time on treatments due to his affection from a Polio Vaccine that was *injected* into his body." (Emphasis supplied) Dr. Tupua indicated that his son also received and was affected by the "Polio Vaccine Injection". Letter from Dr. Tupua dated 11/23/92, filed 12/11/92, at 1. This evidence persuasively demonstrates that the immunization administered at the time and to Petitioner was the IPV, which was given by injection. Dr. Tupua's statement is made all the more credible by his relation that his son also received an injectable polio vaccine, from which he later died.

Statement of Dr. Albert Sabin

On October 28, 1992, Petitioner filed a Motion for Extension of Time Within Which to Comply with Order Requiring Affidavit Concerning Availability of Polio Vaccine, wherein he stated:

On September 29, 1992, Petitioner received a written response to a request for information from Dr. Albert Sabin, one of the pioneering researchers in polio vaccine. Dr. Sabin advised it was his opinion that oral polio vaccines were not available in American Samoa until after licensure in December 1962. Dr. Sabin further advised if Petitioner received a polio vaccine in 1961 it must have been the trivalent Salk vaccine by injection.

P Mot. For Extension, filed 10/28/92, at 2. (Emphasis in the original) The court has no reason to doubt the reliability of this information, given Dr. Sabin's stature in the polio vaccine field, and given further that this information was provided by Petitioner despite its damaging effect on Petitioner's case and its support of Respondent's contention that OPV was unavailable.

Medical Records

Although the court is not determining the actual dates of vaccination at this time, it is important to note that of the medical records available, none state that an OPV was administered in May-July 1961, even though typically the medical histories obtained by healthcare professionals often come from parents' own statements. For instance, the Shriners Hospital for Crippled Children, medical history record dated 6/18/92, states "Even though polio immunizations have been practiced for five years in Samoa, the child did not receive Salk vaccine until this year or approximately one year after acquiring the acute disease." P Exh. 3 at p.3 of 161. The physician's orders located at P Exh. 3 at p.26 of 161 states, "9/19/[62], 200pm, 1) give polio #3", whereas the one located at Exh. 3 p.27 of 161 states, "10/15/62, Sabin oral polio vaccine #1 , vo Dr. Watson/J. Buyese (illegible)". Another physician's order states "12/3/62, Sabin oral vaccine #2, vo Dr. Watson...(illegible)". P Exh 3 at p.28 of 161. The history record, dated December 16, 1967, and located at P Exh. 3 at p.43 of 161 states, "He has had routine immunization except for polio." The Shriners Hospital's Contagious Disease and Immunization Report, signed by Petitioner's mother and dated December 2, 1967, states that his Salk vaccines were given 9/21/63 (or this may read 7/21/63, the first number is illegible), 3/11/65, 10/10/66, and 12/1/67; there are no entries under the Sabin oral polio list. P Exh. 3 at p.52 of 161. The Physician's Certificate, dated March 2, 1962, states Petitioner had polio

in 1960, and that he received his polio vaccine (a distinction between Salk and Sabin was not made) in three doses after the onset of polio. P Exh. 3 at p.107 of 161. Lastly, another Shriners Hospital Contagious Disease and Immunization Report, again signed by Petitioner's mother and dated April 24, 1962, indicates the first three doses of Salk were administered on 1/22/62, 2/19/62, and 9/19/62. It also states that the first Sabin OPV was given 10/15/62, the second on 12/3/62. P Exh. 3 at p.117 of 161. Thus, the medical records show that every vaccine purportedly given was received after the onset of polio in Petitioner.

B. Respondent's Evidence

Under the Vaccine Act, Petitioner carries the burden of proving by a preponderance of evidence each required element. See §300aa-13(a)(1)(A); see also McClendon v. Secretary of HHS, 24 Cl. Ct. 329 (1991), *aff'd*, 41 F.3d 1521 (Fed. Cir. 1994). Respondent's burden of proof is only called upon when allegations arise that a "factor unrelated" to the administration of the vaccination caused Petitioner's injuries.[(15)] See §300aa-13(a)(1)(B). In this case, the determination of a "factor unrelated" is not an issue at this time. Nevertheless, Respondent participated heavily in the fact-finding phase of the case and presented documentary evidence in support of his assertion that OPV was unavailable in American Samoa in the Spring and Summer of 1961. This evidence is outlined and discussed below.

Annual Reports of the Governor of American Samoa for 1961-1963

In support of their contention that the OPV was unavailable, *by any means*, in American Samoa in 1961, Respondent filed excerpts from the yearly Annual Reports made by the Governor of American Samoa to the U.S. Secretary of the Interior. Those annual reports covered the following fiscal years: July 1, 1960-June 30, 1961; July 1, 1961-June 30, 1962; and July 1, 1962-June 30, 1963. They are marked as Respondent's Exhibits H, I, and J, respectively. The 1961 Annual Report, for the fiscal year ending June 30, 1961, stated: "During the months of November and December 1960, simultaneously with Western Samoa, an outbreak of poliomyelitis occurred leaving a residual of 11 cases with varying degrees of paralysis." R Exh. H, filed 9/16/96, at 2 (p. 25 of the Report itself). The report further stated: "Studies completed to date confirm the poliomyelitis as being due to polio virus, type I. ...Of particular importance now is the need for immunization of the population against poliomyelitis." R Exh. H at 3 (p. 26 of the Report itself).

The 1962 Annual report, for the fiscal year ending June 30, 1962, stated: "Routine immunizations against diphtheria, tetanus, pertussis, typhoid-para-typhoid, smallpox and polio *(Salk)* are given by the division. *The feasibility of administering Sabin vaccine islandwide in the near future is being investigated*." R Exh. I, filed 9/16/96, at 4 (p.28 of the Report itself)(Emphasis supplied).

Lastly, the 1963 Annual Report, for the fiscal year ending June 30, 1963, stated: "Routine immunization against diphtheria, tetanus, pertussis, typhoid-paratyphoid, smallpox and poliomyelitis (*Salk and Sabin*) are given. *Presently, the department is investigating the use of Sabin Trivalent vaccine for island-wide use*." R Exh. J, filed 9/16/96, at 3 (p.35 of the Report itself)(Emphasis supplied).

Respondent argued in his post-hearing closing that "a fair reading of those exhibits . . . indicates that oral polio vaccine was not being used as a routine immunization or as an immunization on American Samoa prior to 1962." Tr. II at 19. Instead, Respondent maintained the documents suggest that OPV was not available until the 1963 fiscal year (i.e., July 1, 1962-June 30, 1963), and the use of the Sabin Trivalent was under consideration as of June 30, 1963, but was not yet being administered in American Samoa. Tr. II at 19-20.

Petitioner, asserting that these reports were inconclusive, stated:

[W]ith respect to the sabin vaccine, they're talking about the potential use of that vaccine, island-wide. Now, I believe the court can take judicial notice of the fact that American Samoa is not just one island. When the phrase "island-wide" is used, that suggests to me and, I believe, should suggest to the Court, that what they were considering was the use of the oral polio vaccine on all of the islands that comprised American Samoa, which islands are a fairly lengthy chain, extending across some distance of the Pacific Ocean . . . It suggests that it [Sabin vaccine] was not available to everyone on every island for universal usage. That does not preclude the fact that Tamotu may have received the sabin vaccine in May, June, and July of 1961.

Tr. II at 8-9.

The court agrees with Respondent's reading of these annual reports. Of particular persuasion is that the 1962 and 1963 reports distinguish which polio vaccine is being administered; it is not until the 1963 report that Sabin is routinely given. Moreover, even if you grant Petitioner's interpretation of the language "island-wide", it is not until the 1963 report (i.e., July 1, 1962-June 30, 1963) that Sabin trivalent is even mentioned--one full year after the alleged inoculations in this case. To permit the interpretation that Sabin trivalent was being administered in various locations in 1961, two years prior to its consideration (vs. distribution) for island-wide use, the court would have to do so on the basis of mere speculation, unsupported by medical records, reliable testimony, or official documentation; this the court cannot do.

Affidavit of Debra P. Taub, dated 2/13/91

Ms. Taub's affidavit reveals that the Food and Drug Administration's ("FDA") earliest approval date for an oral polio vaccine was August 17, 1961, nearly three months after Petitioner allegedly received the first polio vaccination and almost one month after the third and final polio vaccination. The approved manufacturer was Pfizer Inc. and the specific vaccine was "Poliovirus Vaccine Live, Oral Type 1". Pfizer Inc. was subsequently approved for the Oral Type 2 on October 10, 1961, and the Oral Type 3 on March 27, 1962 (as was Lederle Laboratories). However, the Oral Trivalent, which is the vaccine Ms. Afalava testified was being given in the Spring and Summer of 1961, was not approved by the Food and Drug Administration until *June 26, 1963*, nearly two years after Petitioner claims he received a series of oral trivalent polio vaccinations. Ms. Taub's affidavit also reveals that the IPV was approved on April 12, 1955, for manufacture/distribution by six companies. Exh. A, filed 7/29/96, at 1. This evidence clearly supports Respondent's contentions that the oral polio vaccine, and more specifically, the oral trivalent, could not have been the polio vaccine administered, at least legally and absent a clinical trial situation, to Petitioner in American Samoa in May, June, and/or July of 1961.

Declaration of Michael L. Hooton, dated 9/15/95

At the time of Mr. Hooton's Declaration, he was a Supervisory Consumer Safety Officer with the Division of Congressional and Public Affairs, Center for Biologics Evaluation and Research, Food & Drug Administration. In this post, Mr. Hooton was assigned the task, in October of 1990, of continuing an already-in-progress collection and review of "all existing records maintained by the Food and Drug

Administration concerning the oral polio vaccine (OPV)." R Exh. B, filed 7/29/96, at 1. Mr. Hooton prepared the Declaration in another case[16] in response to the Department of Justice's request "to provide information concerning the records of clinical studies carried out on OPV as part of the requirement for a manufacturer to obtain a U.S. license for marketing a biological product, including OPV." R Exh. B at 2. Mr. Hooton stated that he reviewed the official product license applications and the clinical studies documentation of three companies which were originally granted licenses to manufacture OPV; they were Pfizer Laboratories, Wyeth Laboratories, and Lederle Laboratories.[17] He indicated that "to the best of [his] knowledge, these three manufacturers are the only manufacturers to have conducted clinical trials with OPV in the U.S., in the 1950s in pursuit of licensure, and are the only manufacturers that filed a Product License Application (PLA) for a U.S. License for marketing OPV during the late 1950's or early 1960's." R Exh. B at 2. After reviewing other FDA records, including correspondence and notes from meetings, Mr. Hooton concluded that only Pfizer, Lederle, and Wyeth conducted OPV field trials or studies throughout the U.S. in the 1950's; moreover, American Samoa was not listed as a test site. R Exh. B at 3-4. Mr. Hooton's Declaration makes it more likely than not that OPV clinical trials were not conducted in American Samoa during the time of Petitioner's inoculations; once again, it would be speculation on the court's part to believe otherwise without persuasive support.

Presumably in response to the information provided by Mr. Hooton, Respondent contacted the various laboratories involved with the manufacture of OPV for information on any clinical trials conducted by them. Respondent's results from that request are detailed below and substantiate Mr. Hooton's statements that there is no affirmative information linking OPV with clinical trials being conducted in American Samoa in the Spring and/or Summer of 1961.

Letter from Alice Gianni of American Home Products Corp., dated 7/23/96

Respondent specifically requested information from the American Cyanamid Company on clinical polio trials conducted in American Samoa[18]. Ms. Gianni indicated they "have been unable to locate any information" on the subject.[19] R Exh. C, filed 7/29/96, at 1.

Letter from Hedy M. Powell of Wyeth-Ayerst Laboratories, dated 7/24/96

Ms. Powell advised that while her company was looking into the request for a final answer, she had "never heard of any clinical study with any biological being performed by Wyeth/Wyeth-Ayerst in American Samoa." R. Exh. D, filed 7/29/96, at 1.

Letter from Sabrina E. Allan of Pfizer Inc., dated 7/25/96

Ms. Allan noted that "given that these trials occurred over thirty years ago, we have been unable to find any comprehensive record or set of records that address this issue." However, information which was obtained revealed that Pfizer sponsored trials in four states in Spring-Summer 1961. Ms. Allan further stated that she was "unable to find any reference to trials conducted in America Samoa", but that Pfizer would continue searching their records on this issue. R Exh. E, filed 7/29/96, at 1-2.

Petitioner contended that Respondent's documentation, i.e., the annual reports and the letters from Mr. Hooton and the various manufacturers, was inconclusive and circumstantial. Particularly, Petitioner asserted that Mr. Hooton's declaration and the letters from the various manufacturers addressed only clinical trials; and therefore, did not "preclude the existence of test shipments or isolated shipments to American Samoa." Tr. II at 9-10. Afterall, Petitioner noted, Tamotu's vaccinations were administered in the month(s) immediately preceding the approval of licenses, thus implying tests of some sort, formalized or isolated shipments, would be likely or at least plausible. Tr. II at 9-10.

Respondent argued the information clearly showed no trials were conducted in American Samoa, and testing in the territory would have been impractical; whereas trials conducted in the U.S. (Mainland) would have cost less and provided easier access to follow up. Tr. II at 16-17. Moreover, Respondent noted that while Petitioner implied that a foreign county could have supplied the OPV to the island for the time period at issue, no evidence was presented in support of this allegation[(20)], and even Ms. Afalava testified that the vaccine was from a U.S. manufacturer. Tr. II at 17, 18.

Based on Respondent's and Petitioner's own persuasive evidence and without substantiation, versus mere speculation, of Petitioner's claim that isolated shipments of trivalent OPV made their way to American Samoa, prior to its approval by the FDA in June 1963, the court cannot accept Petitioner's argument that he received the trivalent OPV in May-July 1961. At most, the court can conclude that if a polio vaccine was administered to Petitioner in May 1961-July 1961, it was the inactivated polio vaccine.

III. CONCLUSION

In conclusion, Petitioner has not met his burden of proving by a preponderance of evidence that it is more likely than not that he received the trivalent OPV beginning in May 1961. Within fourteen days after the receipt of this Decision and Order, Petitioner shall confer with Respondent and contact this court, via my law clerk, Meredith A. Mills, at (202) 504-2183, with three possible dates and times for the next status conference to be held in this matter. The Petitioner shall be prepared to discuss the nature of any further proceedings in this IPV case and/or the need for court resolution of any outstanding issues.

IT IS SO ORDERED.

Gary J. Golkiewicz

Chief Special Master

1. The statutory provisions governing the Act are found at 42 U.S.C.A. §300aa-1 *et seq*. (West 1994 and Supp. 1997). Hereinafter, for ease of citation, individual sections of the Act will be cited without reference to 42 U.S.C.A.

2. Petitioner was born on August 5, 1960, in American Samoa. See Memorandum in Support of Petition for Compensation, filed 10/1/90, at 1.

3. The Vaccine Injury Table provides that paralytic polio is a presumptively compensable injury if the first symptom or manifestation of the onset occurs within 30 days of an oral polio vaccine (i.e., polio vaccine "other than Inactivated Polio Vaccine") in a non-immunodeficient recipient. The injury must occur within 6 months of the OPV if the recipient is immunodeficient. Any other claimed injury relating to OPV must be proven under an actual causation theory. The only presumptively compensable injury under the inactivated polio vaccine is anaphylaxis or anaphylactic shock, which must occur within 24 hours (while not applicable to this case, the table was later revised to reduce the time period to 4 hours) of the administration. Any other illness or injury claimed due to IPV must be proven by causation in fact. See §300aa-14(a).

4. See Affidavit of Diana Tuinei, dated 11/25/96, filed 1/22/97, at 1-2. Ms. Tuinei was the Director of Public Health Nursing for the American Samoan Department of Public Health Services at the time of her

testament. See also Affidavit of Stanley T. Kaleczyc, dated 8/2/91, filed 8/5/91, at 3-4 (wherein attached was the June 11, 1991 letter from Dr. Iotamo T. Saleapaga, Director of Health Services for the LBJ Tropical Medical Center in Pago Pago, American Samoa, indicating that the medical records for Petitioner, prior to June 1968, have been destroyed).

5. Two issues remain in this case which will require resolution in the future if this case proceeds further. First, when did Petitioner actually receive his IPV vaccinations? The medical records are conflicting. Second, depending on the vaccination dates established, does the onset of Petitioner's poliomyelitis, which Petitioner concedes occurred before July 1961 (Tr. II at 25), preempt compensation? That is, does the evidence show that Petitioner suffered poliomyelitis prior to his vaccinations? The court does not require resolution of these questions to determine the probability that Petitioner received an OPV in May 1961-July 1961, as alleged. Instead, the court will withhold determination of these issues unless and until such time as they become relevant by Petitioner's desire to proceed with his IPV case under an actual causation theory. The parties will then be offered the opportunity to expand upon the arguments presented in their closings on May 12, 1997, with respect to these two issues, and a factual decision will be rendered thereafter.

6. The hearing conducted on January 13, 1997, will be referenced as "Tr. I at #"; the parties' oral closings presented May 12, 1997, will be referenced as "Tr. II at #".

7. Ms. Afalava stated she prepared about 40 or 50 vaccination cards as Assistant Director. Tr. I at 13.

8. Ms. Afalava's testimony was slightly unclear about how the information got into the computer, from where or whom, and which office the computer system was with. Ms. Afalava later testified that the village nurses filled in the records and then "merge[d] [this information] inside the computer, the Government computer system." Tr. I at 27.

9. Ms. Afalava could not confirm whether the printout she reviewed in 1990 was still available or in the custody of the Public Health Office at the time of the hearing. Tr. I at 14-15. However, she indicated that the person to contact for that information would be Diana Pele, a.k.a. Diana Tuinei, who was the Director of the Public Health Office in January 1997. Tr. I at 35-36. Ms. Tuinei's affidavit, dated 11/25/96, filed 1/22/97, indicated that Petitioner's early immunization records cannot be found.

10. In 1960, Ms. Afalava worked as a village nurse in an island off of American Samoa; in 1961, she was at the public health office as an office nurse. Tr. I at 12.

11. Again the testimony is unclear. Ms. Afalava also testified that at one time, before the nurses placed the orders through the medical supply office, the vaccines were ordered "straight...through the United States"; the vaccines arrived packed in dry ice. Tr. I at 13, 16.

12. In contrast, Ms. Afalava also testified that "[t]he Navy was finished *in 1950* from our country over here." (Emphasis supplied) Tr. I at 22-23.

13. Ms. Hail attested she contacted a number of individuals and/or organizations for informational assistance. They included: Bob Snyder in the Immunization Division for the Center for Disease Control, Lederle Laboratories through the American Cyanamid Company (See Affidavit of Julie Hail, dated 8/11/92, filed 8/17/92, at 3), Dr. Roland Sutter at the Center for Disease Control (Dr. Sutter is a renowned researcher in the polio vaccine field), Dr. Richard Leonards, U.S. Department of Health, U.S. Department of Defense, U.S. Department of the Navy, U.S. Department of Administration, Eli-Lilly and Company, Thomas Registries, Salk Institute, the International Polio Network, Public Health Facility in American Samoa (as managed by the Public Health Services Division of Hospitals and Clinics) (See Affidavit of

Julie Hail, dated 9/25/92, filed 9/28/92, at 2-4), World Health Organization, Pan American Health Organization (office of the Special Program for Vaccines and Immunization), Dr. Katherin Carbon (Director of Virology, Center for Biologics Evaluation and Research, Food and Drug Administration), Government of American Samoa (See Affidavit of Julie Hail dated 6/13/96, filed 6/19/96, at 2-5). In addition, Ms. Hail conducted her own review of pertinent literature, including medical journal articles on and by Drs. Salk and Sabin, and a publication of Live Poliovirus Vaccines, Papers Presented and Discussions Held at the First International Conference on Live Poliovirus Vaccines (See Affidavit of Julie Hail, dated 9/25/92, filed 9/28/92, at 2-4). None of Ms. Hail's efforts resulted in affirmative proof that clinical trials were conducted in or test shipments were sent to American Samoa in 1961.

14. Ms. Taub's proper position, as identified under her signature, is as a Consumer Safety Officer with the Freedom of Information Branch, Congressional and Public Affairs Staff, Center for Biologics Evaluation and Research, Food and Drug Administration.

15. Case law is split on this issue. With regard to causation in fact cases, case law appears to assign the burden of showing no competing etiologies to petitioner under traditional tort theories, see, e.g., Johnson v. Secretary of HHS, 33 Fed. Cl. 712, 721 (1995), *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996), while other cases assign the burden to respondent under the statute's factor unrelated provision, see, e.g., Wagner v. Secretary of HHS, 37 Fed. Cl. 134 (1997). See Gherardi v. Secretary of HHS, No. 90-1466, 1997 WL 53449, *8 (fn 16) (Fed. Cl. Spec. Mstr. Jan. 24, 1997), *appeal pending*, for a more detailed discussion.

16. Engle v. Secretary of HHS, No. 90-1084V.

17. Mr. Hooton notes that "the first U.S. license for an OPV product was issued in 1961." R Exh. B at 2. This comports with Ms. Taub's affidavit dated 2/13/91.

18. It appears that Lederle Laboratories was a division of American Cyanamid Company, and that the latter was responsible for addressing any requests for information sent to Lederle Laboratories. See Affidavit of Julie Hail, dated 8/11/92, filed 8/17/92, at 3.

19. This comports with the information received by Petitioner from Ronald J. Cracas, Manager of the Legal Department for the American Cyanamid Company. In his August 6, 1992 letter to Ms. Hail, he wrote, "American Cyanamid Company [Lederle Laboratories] did not distribute polio vaccine in 1961 and was not licensed to do so. Moreover, we did not conduct any clinical trials in American Samoa." See Affidavit of Julie Hail, dated 8/11/92, filed 8/17/92, at attachment.

20. Petitioner "raised" this in Ms. Hail's affidavit, dated 8/1/92, at 4.