OFFICE OF SPECIAL MASTERS

No. 90-1466V

Filed: January 24, 1997

NANCY LYNN GHERARDI f/k/a NANCY LYNN PAYNE	*	
Petitioners,	*	PUBLISHED
v.	*	
SECRETARY OF THE DEPT. OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Kevin Hammar, Esq., Albuquerque, New Mexico, for petitioner.

Vincent Matanoski, Esq., Washington D.C., for respondent.

DECISION

On September 26, 1990, Nancy Gherardi filed a petition pursuant to the National Childhood Vaccine Injury Act of 1986 ("the Act").[(1)] Ms. Gherardi's petition alleged that she received an inactivated polio vaccine ("IPV" or "Salk vaccine") on April 26, 1955, and manifested the onset of polio "shortly after the vaccination."[(2)] Pet. at 1-2.

By alleging injury pursuant to an IPV, petitioner's case raised issues similar to those raised in 163 other IPV cases. In manufacturing IPV, as opposed to the oral polio vaccine ("OPV" or "Sabin vaccine"), live virus is "inactivated" or "killed." See J.E. Salk et al., Formaldehyde Treatment and Safety Testing of Experimental Poliomyelitis Vaccine, Am. J. Pub. Health 45, at 563-70, (1954). The underlying

assumption of the Act, which has not been challenged before this court, and therefore is not at issue before this court, is that the live virus in OPV is the potential causal agent for polio. See, e.g., 300aa-14 (Polio is a recognized Table injury within 30 days following OPV, but not following IPV). Thus, in contrast to OPV cases, there is a very real issue as to whether it is biologically plausible for IPV, a vaccine in which the live virus is inactivated, to cause polio in the recipient.

Due to the number of IPV cases, the difficult issues involved, and the need for discovery of government held polio-related information, the court formed a Petitioners' Committee to manage the preliminary stages of Ms. Gherardi's claim and other similar cases. See Order, filed 4/2/92, for a general discussion of the omnibus discovery proceedings for IPV cases.

Based upon information received through that process, the court granted petitioners discovery of relevant information. See Order, filed 4/2/92. Respondent complied fully with the court's directive. Furthermore, the court offered petitioners guidance in presenting their claim that an inactivated polio vaccine could cause polio. Order, filed 4/2/92, at 8-9. Specifically the court set forth five elements of proof. Id. Given the passage of time, the second element of proof appears particularly difficult, if not impossible, i.e., "[i]dentification of the particular manufacturer and lot of the alleged IPV in question." Order, filed 4/2/92, at 8. However, as was the theme of discussions with the Petitioners' Committee, and the focus of the discovery request,[(3)] the primary question presented in these 164 IPV cases was how could an inactivated polio vaccine cause polio? The answer, which has never been contested, is that an IPV can cause polio **if** the vaccine contains some residual live polio virus. Respondent conceded that in the case of Cutter Laboratories, the manufacturing process was flawed and live virus remained in the IPV, resulting in vaccine induced polio. Order, filed 4/2/92, at 6, n. 24. However, respondent contested any claim that an IPV from other than specified batches of Cutter IPV contained live virus and thus caused polio. Accordingly, the court proposed that each petitioner show which batch and manufacturer his/her IPV came from as a predicate to establishing whether there was a flaw in the manufacturing of that IPV so that residual virus remained.[(4)]

On October 8, 1992, respondent filed a report recommending that the court deny compensation to petitioner in the above-captioned claim. See generally R Rpt, filed 10/8/92. After granting petitioner sufficient time to gather information in support of her claim, the court conducted a hearing on August 21-23, 1996,[(5)] on the issues of entitlement and damages (in the event petitioner was determined to be entitled to an award).[(6)]

After a thorough review of the record, and for reasons set forth herein, the court determines that petitioner is ***not entitled*** to compensation under the Act.

FACTS

Briefly, the undisputed facts of the case are as follows. Nancy Gherardi was born on January 4, 1954. P Exh. 1. Ms. Gherardi received a smallpox vaccine manufactured by Cutter laboratories in July, 1954 in California. P Exh. 2. She received an inactivated Salk vaccine on April 26, 1955, in the Philippines where her father was stationed at Clark Air Force Base. P Exh. 2, P Exh. 10, at 2.

On or about May 2, 1955, Ms. Gherardi began favoring her right leg. On May 9, 1955, she was admitted to the hospital at Clark Air Force Base. Ms. Gherardi was diagnosed with polio, and was subsequently

discharged on June 21, 1955. See P Exh. 10.

THE ACT

Under the Act, petitioners have two routes to pursue compensation for a vaccine-related injury or death. If their case fits within the statutory parameters of the Vaccine Injury Table, petitioners may take advantage of a statutory presumption of causation. 300aa-14(a).

Alternatively, petitioners may establish entitlement under the Act by showing by a preponderance of the evidence that an injury or death was in fact caused by a vaccine set forth in the Vaccine Injury Table. 300aa-11(c)(1)(C)(ii). Causation in fact is the traditional tort standard applicable outside of the Vaccine Act. See Strother v. Secretary of DHHS, 21 Cl. Ct. 365, 369 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991).

In order to prove causation in fact,

petitioners must show a medical theory causally connecting the vaccination and the injury. Causation in fact requires 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.

Grant v. Secretary of DHHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted).

Because polio is not a Table injury for IPV, petitioner must proceed under a causation in fact theory in the present case. See 300aa-14(a).

As this court has discussed in previous cases, proof of a logical sequence of cause and effect under the Grant line of cases is in essence a two-pronged showing. ***First***, that it is biologically plausible for the IPV to cause the alleged injury[(7)], and ***secondly***, that the IPV caused the injury, polio, in this case. See, e.g., Schuler v. Secretary of DHHS, No. 92-140V (Fed. Cl. Spec. Mstr., October 13, 1995), slip op. at 7-9; McCummings v. Secretary of DHHS, No. 90-903V (Cl. Ct. Spec. Mstr., July 10, 1992), slip op. at 24-25, aff'd, 27 Fed. Cl. 417 (1992), aff'd, 14 F.3d 613 (1993), cert. den., 114 S. Ct. 1541 (1994); Hines v. Secretary of DHHS, (Cl. Ct. Spec. Mstr. June 22, 1990), aff'd, 21 Cl. Ct. 634 (1990), aff'd, 940 F.2d 1518 (Fed. Cir. 1991).

In the present case, the evidence demonstrated that IPV could plausibly cause polio ***if the vaccine came from one of the two tainted batches of IPV produced by Cutter Laboratories***. In contrast, petitioner failed to persuasively support a theory that batches of IPV, ***other than tainted Cutter IPV***, could plausibly cause polio. In addition, the preponderance of the evidence showed that petitioner received a vaccine other than the Cutter IPV. Therefore, petitioner failed to meet the first prong of proving causation in fact in this case. That is, petitioner failed to show that the vaccine petitioner received, i.e., IPV other than Cutter, could plausibly cause the subsequent injury, i.e., polio. Therefore, petitioner necessarily could not show that the IPV caused the alleged injury in this particular case. A more thorough discussion follows.

EXPERT TESTIMONY

As an initial matter, it is important to outline the relative expertise of the experts proffered at hearing. Dr. Simpson testified on behalf of the petitioners. Dr. Simpson is the Medical Director of Infectious Diseases for the Department of Health for the State of New Mexico. He had particular experience investigating polio cases in 1979, while serving as a visiting professor at the National Institute of Health in Bogota, Columbia. See Dr. Simpson's Expert Report and Curriculum Vitae, dated April, 1993[(8)]; see also Tr. at 307. He was qualified as an expert in infectious diseases. Tr. at 275.

Dr. Nathanson testified on behalf of the respondent. He was tendered as an expert in poliomyelitis. Tr. at 344. From 1955-1957, Dr. Nathanson was Chief of the Poliomyelitis Surveillance Unit which was formed to investigate IPV associated poliomyelitis. He co-authored several publications addressing poliomyelitis outbreaks in 1955-1956, and the "Cutter Incident."[(9)]

The court found both experts to be knowledgeable and forthright. However, Dr. Nathanson was overwhelmingly the more convincing of the two. Dr. Nathanson's first-hand knowledge and experience with polio and the Salk vaccine and his straightforward, cogent presentation of the relevant information was highly persuasive. In contrast, the court found Dr. Simpson's opinions to be unsupported and speculative. By a far margin, the court found Dr. Nathanson the more credible expert.

DISCUSSION

I. The Weight of the Evidence Does Not Support the Biologic Plausibility that an IPV, other than Cutter IPV, Could Cause Polio.

According to epidemiological evidence, two pools of Cutter IPV were incriminated as causing polio in 1955.[(10)] Therefore since, in the words of petitioner's counsel, there is "no direct evidence" that petitioner was administered a Cutter vaccine, Tr. at 290-291, let alone a dose from one of the two high risk pools, the court must first consider whether IPV from another manufacturer can cause polio. In other words, is there evidence that live virus remained in the "inactivated" vaccine produced by manufacturers other than Cutter, which could cause the actual disease in the IPV recipient? After reviewing all of the evidence in the present case, the court concludes that the overwhelming evidence presented indicates that ***only*** two pools of IPV produced by Cutter have been shown to cause polio, and that despite exhaustive research, no other IPV has been implicated as causing polio.[(11)]

In the face of this epidemiological evidence that petitioner did not contest, petitioner's expert testified that he would conclude that petitioner's polio was caused by IPV, regardless of whether or not the administered vaccine was manufactured by Cutter. Tr. at 294. Dr. Simpson stated:

The fact of it is is [sic] that it would be in my view extraordinarily unlikely given the rapidity of the scale-up from the laboratory of the polio vaccine that there weren't problems with other manufacturers as well.

Tr. at 294.

Dr. Simpson's statement was unsupported by medical literature or scientific evidence. Nevertheless in petitioner's post-hearing brief, counsel relied upon Dr. Simpson's testimony to argue that there is a possibility of live virus in all early 1955 polio vaccine.[(12)] Yet, Dr. Simpson's testimony was speculative, unsupported by scientific testing, methodology, or peer-reviewed research, and as such fails to meet the necessary evidentiary threshold for expert testimony. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993).[(13)]

Indeed, Dr. Nathanson effectively rebutted Dr. Simpson's testimony with scientific evidence that only Cutter IPV, and no other manufacturer's IPV, has been implicated as causing polio. Referencing his own research carried out contemporaneously with the Cutter Incident, Dr. Nathanson testified that

we really did firmly conclude it was only those two pools of Cutter vaccine that were associated with polio. And not only was that our conclusion but that conclusion was generally accepted and disseminated globally, really, through the medical community. And not only was it -- And, in fact, that is important because -- in the historical sense because the fact that it was two lots strongly suggested that there was an aberration in the manufacturing process rather than something intrinsic to the formulation . . . .

Tr. at 440-441.

Dr. Nathanson testified that in addition to the epidemiological evidence, individual laboratories conducted virological tests which detected no residual live virus.

Dr. Nathanson: When we went back, not we but the, really, the laboratories that went back and did further tests, they did these strenuous tests which clearly have the sensitivity to pick up the high rate lots, it was really quite striking they never could find anything in the low rate lots. So there was a --

The Court: They never could find any virus?

Dr. Nathanson: Any virus, any live virus. So there was a striking concordance between what was done in the laboratory quite independently of the epidemiology . . . .

Tr. at 452.

Dr. Nathanson's testimony was based on his own contemporaneous research as chief of the poliomyelitis surveillance unit. Petitioner offered no persuasive rebuttal evidence, relying instead on Dr. Simpson's speculative testimony. See P Post Hearing Brief. Based upon Dr. Nathanson's convincing testimony and the number of peer reviewed publications submitted by Dr. Nathanson which documented the same observations and conclusions to which he testified at hearing, the court was persuaded to accept Dr. Nathanson's opinion that only the two implicated pools of Cutter IPV could be linked with cases of poliomyelitis, over the unsupported speculative testimony of Dr. Simpson.

II. The Evidence Did Not Prove that Petitioner Received a Cutter IPV.

Because the court was persuaded by Dr. Nathanson that the only IPV implicated in causing polio was manufactured by Cutter, it is necessary to turn to the next issue - does the evidence tend to show that petitioner received a Cutter vaccine, moreover a dose from one of the two high risk pools manufactured by Cutter? The undersigned concludes that the preponderance of the evidence supports a finding that petitioner received a vaccine ***other*** than Cutter.

A. Petitioner argued that certain factors point toward a finding that petitioner received Cutter IPV.

It is accepted as fact that petitioner received an IPV on April 26, 1955. It is also agreed that petitioner received her vaccine at the Clark Air Force Base in the Philippines, and that the vaccine was procured through commercial channels. Evidence in the record suggests that of the 500,000 doses of IPV released into commercial channels in April, 1955, Parke-Davis supplied 400,000 doses, and Cutter supplied 100,000. Of those 100,000 Cutter doses, about 50,000 doses came from the high risk pools implicated in causing cases of polio. Tr. at 415-416. See Nathanson, et al., The Cutter Incident, Am. J. Hyg. 78, at 16-81 (1963). Therefore, statistically speaking, there is only a 10% chance that petitioner actually received an implicated Cutter vaccine. But the inquiry does not stop there.

Petitioner argued that there are a number of factors which lead to an inference that petitioner indeed received the Cutter IPV, namely that: a) the Department of Defense received Cutter ***smallpox*** vaccine; b) Cutter had a pre-existing relationship as a government contractor; and c) petitioner's treating doctor from 1955 recalled that Cutter vaccine was used on Clark Air Force Base in 1955. Petitioner argues that these factors provide persuasive circumstantial evidence that Ms. Gherardi's IPV was manufactured by Cutter. P Post Hearing Brief, at 11-12. For the following reasons, the court disagrees.

1. The Department of Defense's receipt of Cutter smallpox vaccine is dubious support for the proposition that the Department of Defense likewise received Cutter IPV.

On July 23, 1954, Ms. Gherardi, along with her mother and brother, were immunized in California against smallpox, and their international vaccination cards reflect that the manufacturer of all these smallpox vaccines was in fact Cutter. See P Exhs. 2-4. However, it is a giant stretch to conclude that because Cutter manufactured a smallpox vaccine administered in California, therefore, Cutter most likely manufactured an IPV administered in the Philippines nearly a year later. The connection between the two events is unproven. Petitioner presented no convincing evidence to substantiate the link between the smallpox vaccine and Ms. Gherardi's subsequent IPV; interesting speculation is insufficient support. Accordingly, the court finds that the fact of Ms. Gherardi's smallpox vaccine does not weigh in favor of finding that Ms. Gherardi's 1955 IPV was likewise manufactured by Cutter.

2. Cutter's alleged relationship as a government contractor does not support petitioner's claim.

Petitioner attempted to argue that because Cutter provided smallpox vaccine to the military, Cutter had a pre-existing relationship with the military as a government contractor, and as such most likely provided the IPV to the Clark Air Force Base. The court found this line of thinking purely speculative.

Petitioner pointed to transcript excerpts of Arthur Beckley, vice-president of Cutter, testifying before the Department of Health, Education, and Welfare, on May 23, 1955:

Mr. Beckley: . . . [W]e would dislike very much to have the material already together and waiting for somebody else to write up some orders and tell us where to ship it to them in small batches. That has happened to us on ***some things*** with the Army and Navy and the Armed Forces, and it is a very, very confused picture. ***We are holding material, and people want the material. We can't ship it; we run out of storage room holding it***.

P Exh. 14, at 10 (emphasis added).

Yet as Dr. Nathanson testified, the available transcript excerpt is vague and ambiguous. At best, it illustrates that at ***some time*** Cutter provided ***some vaccine*** to the military. This fact is of course evidenced by the smallpox vaccine records; it does not, however, buttress petitioner's argument that petitioner received a Cutter ***IPV***. Furthermore, Dr. Nathanson testified persuasively that Mr. Beckley's references to a surplus of material - and running out of storage room, probably did not refer to IPV, since there was in fact a shortage of IPV at the relevant time, not a surplus. Tr. at 375. In sum, petitioner indeed proved to the court that Cutter provided smallpox vaccine to the military. Yet petitioner failed to substantiate their theory that Cutter likewise provided IPV to the military. Again petitioner presented interesting speculation, rather than convincing evidence in support of her argument. Speculation does not tip the scales of evidence in petitioner's favor.

3. Dr. Rutledge's letter is vague and unsubstantiated.

Furthermore, petitioner points to a 1992 letter from Dr. Rutledge, Ms. Gherardi's treating physician from Clark Air Force Base in 1955. Dr. Rutledge's letter states that

I was indeed at Clark Air Force Base in May 1955 at the time of the polio vaccinations. At that time we had a constant endemic problem with polio and maintained a polio ward in the hospital. Because of the endemic and on occasion epidemic presence of polio the women and dependent children were selected for one of the first series of inoculation with the Cutter vaccine . . . .

It is my impression that we did receive the vaccine from the Cutter Laboratories but other than this I really don't recall any specific incidences.

P Exh. 12 (emphasis added).

Setting aside the implications of the letter that wild polio was a very real threat in 1955 at Clark Air Force base, petitioner points to this letter as support for her argument that the IPV administered was indeed manufactured by Cutter. Yet Dr. Rutledge was not called to testify as to the basis of his vague

assertion regarding the IPV, despite the fact that Dr. Rutledge is still alive and is now apparently living in the United States. The court is left with Dr. Rutledge's unsupported letter, and without more, cannot give evidentiary weight to Dr. Rutledge's "impression" regarding events occurring 40 years earlier. In light of the fact that Dr. Rutledge's letter remained unsubstantiated, and in light of the compelling evidence, as discussed below, which weighs ***against*** the probability of Cutter IPV administered at Clark Air Force Base in 1955, the court is unpersuaded by Dr. Rutledge's letter.

B. There Is No Record of Military Shipments of Cutter

IPV.

As contrasted with the speculative and unsubstantiated factors discussed above, there was compelling information presented at hearing which convinced the court that the vaccine administered to petitioner was a vaccine other than Cutter.

Petitioner conceded that they had no clear records of Cutter going to Clark Air Force Base. The manufacturers produced letters indicating that such records were largely unavailable.(14) In addition, Ms. Gherardi's immunization record lacked any manufacturer identification for the 1955 IPV. Petitioner argued that since the documentation identifying the manufacturer no longer exists so many years after the fact, the court should accept petitioner's attempt to weave together circumstantial evidence of tainted Cutter IPV on Clark Air Force Base. Yet respondent provided more compelling evidence in the form of Dr. Nathanson's testimony. As Dr. Nathanson testified, while there is no current record of Cutter IPV having gone to the military, ***more significantly there was no such contemporaneous evidence in 1955***. Of course, Dr. Nathanson's testimony on this point was compelling since as chief of the PSU at the time, it was his direct responsibility to gather such evidence. Dr. Nathanson stated that

[W]e really obsessed about the distribution of [Cutter] vaccine. I mean, I'm using a strong word because that, I think, is an accurate description. We went to everybody we could -- every source we could think of . . . we hammered these people for information because what was so critical to this investigation was to determine attack rates. And for that, we had to find out how much of the vaccine had been used and when it had been distributed.

Now one of the things that is very clear is that we found no record that Cutter vaccine, and particularly the high rates, had gone to the military . . .

Tr. at 369-370 (emphasis added).

Dr. Nathanson further testified that the military maintained good communication with the PSU, and thus the fact that the military did not report receipt or administration of Cutter IPV probably indicated that the military did not administer any Cutter IPV.(15)

Considering Dr. Nathanson's direct involvement in the investigation of IPV associated polio, his testimony regarding the good communication between the military and the PSU, as well as his testimony that there was never any record of Cutter going to the military, and finally, the lack of any direct evidence even hinting at military shipments of Cutter IPV, Dr. Nathanson's testimony was more persuasive to the court than petitioner's speculation that she received the Cutter IPV. In sum, for the

reasons discussed above, the preponderance of the evidence indicates that petitioner did ***not*** receive a Cutter IPV on the Clark Air Force Base in 1955.

III. Even Assuming That the IPV Petitioner Received Could Have Caused Polio, the Preponderance of the Evidence Does Not Support a Causal Link between Polio and the IPV in this Particular Case.

Because the preponderance of the evidence indicates: 1) that petitioner did not receive Cutter IPV; and 2) that IPV other than Cutter is not causally related to polio, petitioner failed the first prong of proving causation in fact under the Grant line of cases. That is, petitioner failed to show even a biological plausibility that the vaccine received could cause the subsequent injury. However, assuming arguendo, that petitioner had proven that the IPV received by Ms. Gherardi ***could*** cause her subsequent polio, petitioner must further prove that IPV ***did*** in fact cause polio in this particular case. In this respect, petitioner failed to affirmatively prove that Ms. Gherardi's polio was more likely vaccine associated than caused by wild polio.

The alternative cause of polio, is quite naturally, wild polio virus. Petitioner's expert conceded that the onset period for vaccine induced polio overlapped the typical onset period of wild polio virus exposure. Tr. at 335. However, Dr. Simpson testified that Ms. Gherardi had little opportunity to contract wild polio virus on Clark Air Force Base, Tr. at 297; this testimony was persuasively undermined by Dr. Nathanson. Dr. Nathanson cited medical articles pointing to the high incidence of infectious diseases among persons traveling from developed countries to underdeveloped countries. Tr. at 351-354. Dr. Nathanson further cited several documents submitted by petitioners which supported the fact that there was indeed a high risk of polio at Clark Air Force Base in April and May, 1955. Tr. at 355-356; see, e.g., P Exh. 12 (Dr. Rutledge's Letter).

Dr. Simpson admitted that Ms. Gherardi's "clinical presentation was much as we would expect for wild type disease although not inconsistent with vaccine related." Tr. at 333. This testimony was supported by Dr. Nathanson who testified that "the clinical data don't permit us to really rule other [sic] either possibility." Tr. at 367.

Neither expert could identify a distinguishing characteristic to assign causation to either the vaccine or to wild polio virus. In fact, that is why epidemiological evidence is needed to point the finger at the vaccine. Such evidence only supports two batches of Cutter vaccine. See supra at 8. Based on what the court heard in this case, unless one can show that they received an IPV from one of the two tainted Cutter batches and thus benefit from the epidemiological evidence of causation, the proof of causation is problematic. At best in weighing the competing alternatives, i.e., vaccine associated polio with wild polio virus, the court finds the evidence in equipoise. Because petitioner must prove causation in fact by a preponderance of the evidence, i.e., 50.1%, petitioner has failed to carry her burden of persuasion.[(16)] Accord Knudsen v. Secretary of DHHS, 35 F.3d 543, 550 (Fed. Cir. 1994) (where evidence is in equipoise, party with burden loses). Without epidemiological evidence in support of petitioner's claim, and in light of the experts' testimony that there is no clinical distinction between vaccine induced and wild polio, the court finds that assigning causative blame on one alternative or the other is pure speculation, which is legally impermissible.

CONCLUSION[(17)]

In sum, petitioner's alternative theories:

1) that she received a Cutter vaccine which subsequently caused polio; or alternatively

2) that she received IPV other than Cutter which caused polio,

remain speculative and unsubstantiated. Respondent produced cogent and persuasive evidence which weighs against a finding that petitioner received Cutter IPV, and against a finding that IPV (other than the two high risk pools of Cutter IPV), could plausibly cause polio. Therefore, this court finds that petitioner has failed to make a prima facie case for causation, and the petition is hereby dismissed with prejudice.

The Clerk shall enter judgment accordingly.

Gary J. Golkiewicz

Chief Special Master

-- alternate causation

either petitioner's burden under CIF cases b/c Strothaer, Knudsen say traditional tort standards apply

or respondent's burden under statute - section 13 incorporates section 11 (CIF and Table)

how about saying instead of defining burdens, distinction b/t Table and CIF described in Grant and Strother, including legis history, which says "must affirmatively demonstrate" - P was not able to do so here, since no clinical difference b/t wild polio and vaccine associated. The factors proffered by Dr. Simpson were both weakened by Dr. Nathanson's testimony and by Dr. Simpson's own concessions, and therefore, P failed to affirmatively demonstrate that the vaccine in fact caused her polio.

-- when wild polio exists, impossible to clinically distinguish wild from vaccine associated, need fact of vaccine, no wild polio (See Nathanson testimony) or laboratory test, e.g. titers.

-- at best the evidence in equipoise, and since P has burden (??), P loses. (Can only use this argument if it is in fact in equipoise.)

1. The statutory provisions governing the Act are found at 42 U.S.C.A. § 300aa-1 et seq. (West 1991 &

Supp. 1996). Hereinafter, for ease of citation, individual sections of the Act will be cited without reference to 42 U.S.C.A. §.

2. Ms. Gherardi's petition makes reference to the Vaccine Injury Table. See Pet. at 1-2. Petitioner was apparently attempting to take advantage of the Act's presumption of causation granted to cases proving certain elements set forth in the Vaccine Injury Table. See 300aa-14. However, petitioner's reference to the Vaccine Injury Table was misplaced in the present case, since the ***only*** Table injury included in the Act following IPV is anaphylactic shock manifesting within 24 hours. Polio is not a Table injury following IPV, and therefore petitioner has to prove that the IPV in fact caused her injury, polio. See 300aa-14; see infra p. 4.

3. The court allowed a second discovery request tailored to the "limited . . . issue of the identification of specific batches of IPV which may have contained live particles of polio virus theoretically capable of causing polio." Order, filed 4/2/92, at 6-7.

4. The court specifically granted petitioners the right to prove their cases through other avenues. Order, filed 4/2/92, at 8, n. 32, and 10, n. 36. The court's suggested method was based on information received from the Petitioners' Committee and respondent during the omnibus proceedings.

5. In the time period between respondent's report and the hearing, the parties conducted discovery in this complex case, and then pursued settlement discussions. In 1996, the settlement discussions broke down, and a hearing was scheduled to resolve the case.

6. References to the transcript from this hearing will be cited as "Tr. at --."

7. If it is not biologically plausible for an IPV to cause polio, then it necessarily follows that Ms. Gherardi cannot show that the IPV caused polio in her particular case. Stated another way, it must be shown that the agent **can** cause the event before it can be shown that the agent **did** in fact cause the event.

8. But for Petitioner's Exhibits 1-24, filed on September 23, 1996, after the hearing, many of petitioner's exhibits were filed in piecemeal fashion during the years this case was pending. Therefore most of petitioner's exhibits must be cited according to the date and title of the document described.

9. The "Cutter Incident" refers to the finding and documenting of epidemiological evidence linking IPV manufactured by Cutter Laboratories to cases of poliomyelitis, reported between April and June, 1955. On April 27, 1955, the Surgeon General recalled the Cutter vaccine, and the poliomyelitis surveillance program was initiated to investigate the national vaccination program. See Nathanson, et al., The Cutter Incident I, Am. J. Hyg. 78, at 16-28 (1963).

10. Only these two pools from Cutter Laboratories were implicated as causing polio. It was established that the manufacturing process was flawed, allowing live virus to remain in the inactivated vaccine. Epidemiology established the causative connection to the vaccine recipients. For a more detailed discussion of the Cutter Incident, see Nathanson, et al., The Cutter Incident, Am. J. Hyg. 78, at 16-81 (1963).

11. Dr. Nathanson testified that there "was a question about a couple of cases associated with Wyeth." Tr. at 459. However, Dr. Nathanson testified further that his initial draft report of the Wyeth cases was never published, since the evidence "really wasn't sufficient to pass a peer review." Tr. at 459. Given Dr. Nathanson's conclusion that the epidemiological evidence clearly implicated only the 2 pools of Cutter

vaccine, the court is inclined to find that only Cutter IPV could cause polio. However, the questionable relationship between Wyeth IPV and polio has no effect on this case since both parties agreed that petitioner could not have received a Wyeth vaccine. All of Wyeth's production was given to the National Foundation for Infantile Paralysis for a school vaccination program and was not available through the commercial channels through which petitioner received her vaccine. See Tr. at 460.

12. In petitioner's post-hearing brief, counsel argued that Dr. Nathanson's testimony indicated "that the limits of epidemiology and of testing methods do not foreclose vaccine causation." P Post-Hearing Brief at 13. Petitioner's argument that all IPV can cause polio seems to be in essence, "anything is possible." However, left without reputable medical theory or evidence to back up the argument, petitioner's counsel attempted to support the argument with Dr. Nathanson's testimony. However, in his attempt, counsel misused Dr. Nathanson's testimony, citing statements without the necessary context.

For example, in her post-hearing brief, petitioner included several excerpts from Dr. Nathanson's testimony which were cited out of context, including a statement that there was no live virus detected by the PSU's "somewhat crude limits." Brief at 13. A thorough review of Dr. Nathanson's testimony reveals that the focus of the PSU was on epidemiologic (rather than virologic evidence) which clearly implicated only the two batches of Cutter IPV. Further, Dr. Nathanson went on to say that the individual manufacturers of IPV did more strenuous virologic tests than the PSU, and also found no live virus. Tr. at 452.

13. In Daubert, the Supreme Court held that it is the trial judges' responsibility to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." 113 S. Ct. 2786, 2795 (1993); see also Vaccine Rule 8(b) (The special master is obliged to consider "all relevant, reliable evidence . . . .").

Rule 702 provides that an expert witness may testify to his "scientific, technical, or other specialized knowledge . . . " The term "knowledge," however "connotes more than subjective belief or unsupported speculation." Daubert, 113 S.Ct. at 2795. Thus, the expert's proposition must have been "derived by the scientific method." Id. This requires that the proponent demonstrate that there is "some objective, independent validation of the expert's methodology." Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995), on remand from 113 S.Ct. 2786 (1993), cert. den., 116 S.Ct. 189 (1995). Factors relevant to that determination may include, but are not limited to:

whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known or potential rate of error is acceptable.

Id.; see also Daubert, 113 S.Ct. at 2796-97. The overall touchstone is "whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." Daubert, 43 F.3d at 1317.

14. See Johnson & Johnson Letter, 5/13/96; Warner Lambert Letter, 4/30/96; Eli Lilly and Co. Letter, 5/25/93; Wyeth-Ayerst Letter, 5/6/93; Miles Letter, 5/28/92.

15. Dr. Nathanson testified that there was a "very friendly co-operative" relationship between the military and the PSU. Tr. at 423. In support of this proposition Dr. Nathanson described an incident in Hawaii in the summer of 1956. Military officials stationed at Pearl Harbor contacted the PSU regarding a polio outbreak; officials expressed concern that a certain amount of immunized persons would be coincidentally incubating the disease. Dr. Nathanson testified that they were concerned about ". . .

somebody who's incubated the disease and gets the vaccine and it looks like it's associated." Tr. at 388.

16. The court recognizes that there is an issue with respect to the relative burdens involved in proving causation in fact. Caselaw has held that in proving a case under a causation in fact theory, as opposed to a Table case, traditional tort standards apply. See Strother v. Secretary of DHHS, 21 Cl. Ct. 365, 369 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991). Under traditional tort standards, petitioner must prove the vaccine causative ***more likely than not***. Implicit in this standard, is that petitioner must prove that the vaccine is more likely the cause of the injury than ***some other possibility***. Accord Munn v. Secretary of DHHS, 970 F.2d 863, 865 ("The claimant must prove by a preponderance of the evidence that the vaccine, ***and not some other agent***, was the actual cause of the injury.") (emphasis added).

An apparent conflict thus arises in cases brought under the Act pursuant to a causation in fact theory. On one hand, ***petitioner*** must address the issue of other likely causative agents in proving that the vaccine is the more likely cause of the subsequent injury. See, e.g., Johnson v. Secretary of DHHS, 33 Fed. Cl. 712, 720 (1995) aff'd, 99 F.3d 1160 (Fed. Cir. 1996). On the other hand, once petitioner makes a prima facie case under 300aa-13(a)(1)(A), the court assigns the burden of proving alternative etiologies, i.e., "factors unrelated" to ***respondent***. See 300aa-13(a)(1)(B); see, e.g., McClendon v. Secretary of DHHS, 24 Cl. Ct. 329, 333 (1991), aff'd, 41 F.3d 1521 (1994); see also Wagner v. Secretary of DHHS, No. 90-2208V, slip op. at 6 (Fed. Cl. January 6, 1997). Thus, 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, 33 Fed. Cl. at 721, while other cases assign the burden to respondent under the statute's factor unrelated provision. See 300aa-13(a)(1)(B); see also Wagner, slip op. at 7, n.5 (recognizing the conflict with Johnson, and respectfully disagreeing with that decision.) This conflict is an issue that has not been directly addressed by the higher courts.

In the present case, the possibility that wild polio virus caused Ms. Gherardi's polio was specifically raised and addressed by petitioner's exhibits and expert testimony. The court believes that it is petitioner's burden to prove that Ms. Gherardi's polio was more likely vaccine-related than caused by the wild polio virus. This reasoning is supported by Johnson and Munn, see infra. Nevertheless, because the court finds that this case actually fails on the issue of biologic plausibility, assigning the burden to petitioner on this issue does not affect the final outcome of the case.

17. Because the Court concludes that petitioner is not entitled to compensation, the Court does not need to evaluate the petitioner's request for damages.