

OFFICE OF SPECIAL MASTERS

No. 90-3001V

(Filed: May 19, 2000)

JOSE GARCIA ROBLES and INES SANCHEZ TORRES, for themselves and for the conjugal society consisting of both of them, and on behalf of their daughters, INES MARI GARCIA SANCHEZ and MERCEDES YVONNE GARCIA SANCHEZ,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

PUBLISHED

Isabel Pico Vidal, Hato Rey, Puerto Rico, for petitioners.

Claudia B. Gangi, Washington, D.C., for respondent.

DECISION

GOLKIEWICZ, Chief Special Master

Petitioners, parents of a child who suffered from, and subsequently died as a result of, subacute sclerosing panencephalitis (hereinafter "SSPE")¹, seek compensation under the National Vaccine Injury Compensation Program (hereinafter "Vaccine Program") for the death of their daughter, Inesita. Petitioners contend Inesita's SSPE and subsequent death were caused by the

¹"SSPE is a rare form of panencephalitis . . . characterized by the insidious onset of a progressive cerebral dysfunction developing over the course of weeks or months. . . . The entire course of SSPE is quite variable, lasting from weeks to years with periods of remission. The average patient dies within 2 years of the onset . . . but in rare cases, patients have remained in the vegetative state for 10 or more years." Respondent's Ex. A at 51 (hereinafter R. Ex. ___).

Measles-Rubeola (“MR”) vaccination Inesita was administered on December 11, 1974. Because petitioners have failed to prove by a preponderance of the evidence that Inesita’s MR vaccination more likely than not caused her SSPE and subsequent death, petitioners’ claim must fail.

FACTS

The essential background facts are not in dispute. Ines Mari Garcia Robles (“Inesita”) was born in Colombia, South America, on December 22, 1973. Petitioner’s Exhibit A-1, A-7 (hereinafter P. Ex. ___). Petitioners Ines Sanchez-Garcia and Jose Garcia adopted Inesita in June 1974 and brought her to Puerto Rico in July 1974. P. Ex. B at 1. A physical examination conducted prior to her departure from Colombia indicated Inesita was “normal.” P. Ex. A-8. Inesita was administered her Measles-Rubeola vaccination (the vaccination at issue in this case) on December 11, 1974. P. Ex. A-1.

Inesita began to experience frequent falling episodes and weakness in April 1978. P. Ex. A-2. Initially diagnosed with myoclonic epilepsy, P. Ex. A-9, Inesita was referred to Dr. Isabelle Rapin, a professor of pediatric neurology at the Albert Einstein College of Medicine in New York after a seven-day hospitalization. P. Ex. A-10, 19. Dr. Rapin examined Inesita on May 15, 1978 and determined that even though there was no evidence that Inesita had suffered from clinical measles, her symptoms were strongly suggestive of SSPE. P. Ex. A-19. Testing of Inesita’s cerebrospinal fluid indicated elevated levels of the measles serum antibody, the results of which doctors felt were most consistent with a diagnosis of SSPE. P. Ex. A-10. On June 20, 1978, this diagnosis was confirmed. Id.

Inesita suffered from SSPE for over twenty years. On June 6, 1999, while this case was pending, Inesita died of respiratory failure and bacterial pneumonia P. Ex. L. Both parties agreed

Inesita's death was most likely a sequella of her SSPE. See Respondent's July 29, 1999 filing.²

PROCEDURAL HISTORY

Petitioners filed their claim on September 9, 1990, seeking damages for an injury they alleged Inesita suffered as a result of a 1974 MR vaccination. The petition was initially dismissed by the undersigned on March 28, 1997, pursuant to respondent's motion to dismiss on jurisdictional grounds. The dismissal was affirmed by Judge Hodges at the U.S. Court of Federal Claims, but the Court of Appeals for the Federal Circuit reversed and remanded the case for a decision on the merits on June 29, 1998. Robles v. Secretary HHS, 155 F.3d 566, *unpublished disposition*, 1998 WL 228174 (Fed. Cir. 1998). An expert hearing was conducted on March 15-16, 1999 in San Juan, Puerto Rico. Dr. Ramon H. Bermudez Del Valle (hereinafter "Dr. Bermudez")³ and Dr. Edmundo

²Although respondent stated that Inesita's death was more than likely a sequella of her SSPE, respondent maintained her position that petitioners failed to show that Inesita's MR vaccination was the most probable cause of her SSPE.

³Dr. Bermudez is board-certified in internal medicine and infectious diseases. Transcript at 49 (hereinafter Tr. at ___). He has been specializing in infectious diseases in Puerto Rico since 1968. Tr. at 45. He is presently an associate professor of medicine at the University of Puerto Rico, an associate professor at the Department of Microbiology and Immunology at Universidad del Caribe Vayey in Puerto Rico, and a visiting professor at the Ponce School of Medicine in Ponce, Puerto Rico. P. Ex. H. Dr. Bermudez is also the chief of the infectious diseases section at the Veterans Administration Hospital in San Juan, Puerto Rico. Id. Dr. Bermudez has not been involved in research specific to the measles virus, nor has he conducted any research with SSPE. Tr. at 89.

Nelson Kraiselburd (“Dr. Kraiselburd”)⁴ testified on behalf of petitioners. Dr. Neal Halsey⁵ testified for the government.

The transcript from the hearing was filed on April 15, 1999. On June 28, 1999, petitioners informed the court that Inesita had passed away. Thus, the case shifted from an injury case to a death case, and a new issue was raised -- whether Inesita’s death was a sequella of her SSPE. The court issued an order on June 28, 1999, directing petitioners to file the medical records surrounding Inesita’s death and ordering respondent to file a response to the records. Petitioners provided the records to respondent in mid-July, and respondent filed her response on July 29, 1999. Petitioners filed their post-hearing brief on October 29, 1999, and respondent’s responsive brief was filed on November 22, 1999. The case is now ripe for decision on the merits.

STATUTORY REQUIREMENTS

A petitioner may establish causation in Vaccine Act cases in one of two ways: either through the statutorily prescribed presumption of causation (a “Table” injury) or by proving that the vaccine was the cause-in-fact of the injury. A petitioner must prove one or the other in order to recover under the Act.⁶ The Vaccine Injury Table lists certain injuries and conditions which, if found to

⁴Dr. Kraiselburd received master’s degrees in physics in 1965 and molecular biology in 1971. P. Ex. H. He obtained his Ph.D. in virology in 1973. *Id.*; Tr. at 124. Presently, Dr. Kraiselburd is a professor at and director of the virology facility at the University of Puerto Rico. P. Ex. H. Dr. Kraiselburd’s research is focused primarily on the study of sexually transmitted diseases. Tr. at 125. Dr. Kraiselburd is not a medical doctor and has not treated patients with measles or SSPE. Tr. at 180.

⁵Dr. Halsey is board-certified in pediatrics and pediatric infectious diseases. He is presently a professor at Johns Hopkins University, Department of International Health. Tr. at 236-37; R. Ex. C at 2. The measles vaccine has been one of his primary areas of research. Tr. at 237. He was involved in measles and measles vaccine research in Puerto Rico in 1976-77 and in Haiti in 1982-1986. R. Ex. C at 3. He is currently involved in a research project in Peru, on which he started work in 1987, involving measles vaccines for immunization of children under nine months of age. *Id.* He has also conducted research relating to SSPE, the results of which petitioners attempted to rely upon. *See* Expert Testimony, *infra*.

⁶Petitioners must prove their case by a preponderance of the evidence, which requires that the trier of fact “believe that the existence of a fact is more probable than its nonexistence before [the

occur within a prescribed period of time, create a rebuttable presumption that the vaccine caused the injury or condition.⁷ To overcome this presumption, respondent must show that a factor unrelated to the vaccine was the actual cause of the injury. 13(a)(1)(B). If a petitioner's evidence cannot support the finding of a Table injury, petitioner may still be entitled to compensation if petitioner provides sufficient proof that the vaccination was the cause-in-fact of the injury.

In order to establish entitlement to compensation in a causation-in-fact case, a petitioner must demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the alleged injury.⁸ This requires petitioner to prove that the vaccine was not only a but-for cause but also a substantial factor in bringing about the injury. See Shyface v. Secretary of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999).⁹ The mere temporal relationship between a vaccination and the injury and the absence of other apparent etiologies for the injury are patently insufficient to prove actual causation. Wagner v. Secretary of HHS, No. 90-1109V, 1992 WL 144668, at *3 (Cl. Ct. Spec. Mstr. June 8, 1992). The Federal Circuit in Grant v. Secretary of HHS summarized the legal criteria required in an actual causation case: "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." 956 F.2d 1144,

special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-373 (1970) (Harlon, J., concurring) (quoting F. JAMES, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

⁷See Section 14(a).

⁸See Section 11(c)(1)(C)(ii)(I) and (II)

⁹After the hearing, the court instructed the parties to discuss the applicability of Shyface to this case. Respondent provided a thorough analysis, ultimately arguing that Shyface is inapplicable to the case at hand. R. Closing at 6-11. Petitioners failed to provide any analysis of Shyface. However, after reviewing the record and as will be discussed in the decision, petitioners did not produce convincing evidence which demonstrates that the MR vaccination can be *any* factor in causing SSPE, much less a "substantial factor." Therefore, whether or not the "substantial factor" test set forth in Shyface is applicable in this matter, it would not affect the outcome of this case.

1148 (Fed. Cir.) (citations omitted).¹⁰ An additional factor is required in death cases – petitioners must also show that, more likely than not, the death was a sequella of the injury.¹¹

Because Inesita’s SSPE is not a condition listed on the Vaccine Injury Table, petitioners’ claim that Inesita’s MR vaccination caused her condition must be analyzed under the causation-in-fact rubric. This analysis consists of a two-part inquiry: first, can the MR vaccine cause SSPE?; second, if it can, did the MR vaccine cause the SSPE in this case? See Corder v. Secretary HHS, No. 97-125V, 1999 WL 476256 (Fed. Cl. Spec. Mstr. May 28, 1999); Guy v. Secretary of HHS, No. 92-779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995); Alberding v. Secretary of HHS, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. March 18, 1994) (two-step causation-in-fact analysis applied). As stated above, petitioners must provide proof of a cause and effect relationship between the vaccination and the injury. Further, petitioners must produce reputable medical or scientific explanations to support this relationship. Petitioners filed numerous articles about SSPE and presented the testimony of Drs. Bermudez and Kraiselburd in support of their claim. After

¹⁰A reputable medical or scientific explanation does not simply mean, however, any theory that a medical expert is willing to espouse. In construing the Federal Rules of Evidence, the Supreme Court held that it is the trial judge’s responsibility to ensure that “any and all scientific testimony or evidence admitted is not only relevant, but reliable.” Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2795 (1993). The Court added that an expert’s “knowledge . . . connotes more than subjective belief or unsupported speculation . . . [and must have been] derived by the scientific method.” Id. at 2795. 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) (Kozinski, J.), on remand from 113 S. Ct. 2786 (1993). 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 potential rate of error is acceptable.

Daubert, 43 F.3d at 1316; 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 1316.

¹¹See Hellenbrand-Sztaba v. Secretary of HHS, 1995 WL 650678 (Cl. Ct. Spec. Mstr. October 19, 1995); aff’d, 35 Fed. Cl. 222 (1996); aff’d, 106 F.3d 426 (Fed. Cir. 1997).

reviewing the entire record, the court finds that petitioners have failed to prove by a preponderance of the evidence that the measles vaccine can cause SSPE. Further, the court finds that even if the measles vaccine can cause SSPE, petitioners have failed to prove that the measles vaccine caused Inesita's SSPE.

MEDICAL EXPERTS

Extensive expert testimony was presented by the parties. The court considered all the testimony in making its decision, but only the essential components of the testimony will be addressed in this decision.

A. Petitioner's Experts – Drs. Bermudez and Kraiselburd

Petitioners' experts presented several arguments they claim support the theory that Inesita developed SSPE from an MR vaccination. These include: statements in the Merck package insert and Merck's Manual; the possibility that the vaccine virus can mutate and/or revert to the wild-type virus; the assertion that Inesita's only known exposure to the measles virus was through her vaccination; and the belief that even if Inesita was exposed to the measles virus before her vaccination, the maternal antibodies she acquired from her birth mother would have protected her from the virus. The court will examine, in turn, each of these arguments.

1. Merck Information

Dr. Bermudez testified that Merck, the manufacturer of the vaccine in question in this case, includes on its warning label a statement that the risk of acquiring SSPE from the vaccine is “.5 or 1 cases per million vaccinations.” Tr. at 73; Ex. I-1. In response to a question posed by petitioners' counsel, Ms. Pico-Vidal, Dr. Bermudez stated his belief that information gathered by Merck is more reliable than information used by researchers. Tr. at 73. He also indicated that based on the warning label, he did not have any problem finding a causal relationship between SSPE and the measles vaccine. Tr. at 62. Dr. Kraiselburd, petitioners' other expert, echoed Dr. Bermudez's statement

during his testimony, asserting that “there is a package insert also that says that there is an association between the SSPE and the vaccine. If there were no association whatsoever, I see no reason why the company would have to put it in in the first place.” Tr. at 148.

On cross-examination, however, respondent’s counsel, Ms. Gangi, asked Dr. Bermudez to read from P. Ex. I-6, a letter from Merck’s Dr. Nalin to Dr. Halsey, respondent’s expert, which stated that “the fact that Merck includes in its product labeling the adverse experiences that have been reported, in terms of association with the vaccine, does not reflect that a conclusion [has] been made about causality.” Tr. at 101. Further, Dr. Halsey testified that the results of studies he conducted were used by Merck to support the information contained in their MR vaccination. Tr. at 257. Dr. Halsey explained that the warning relates an association, “a calculation of the rate of SSPE that occurred” in children with SSPE who had received measles vaccine, Tr. at 259-60. According to Dr. Halsey, there was no mention of and no intention of implicating causation on the part of the vaccine. Id. Petitioners made no effort to rebut this persuasive testimony.

Petitioners also seek to implicate the measles vaccine in causing SSPE by relying on a statement in the 1987 Merck’s Manual of Diagnosis and Therapy which states that “an altered measles virus acquired through vaccination or natural measles infection is the probable cause of SSPE.” P. Closing at 28; P. Ex. I-7. Respondent, however, contests petitioners’ implication, and filed the corresponding section of the most recent edition of Merck’s Manual, from which this language has been deleted, in rebuttal. The most recent edition states that “SSPE has been reported in children who did not have a history of natural measles but who did receive measles vaccine, although some of these cases may have resulted from unrecognized measles in the first year of life,” R. Ex. X at 3; further, it states that some of the reports of SSPE associated with vaccine (1 case per million doses) “may be due to unrecognized measles before vaccination.” Id. at 4. Again, petitioners presented no rebuttal evidence.

Petitioners cannot rely upon either the package insert or the 1987 Merck’s Manual to support a causal connection between the vaccine and SSPE. First, petitioners’ statement that Merck’s information is more reliable than that of the researchers is clearly in error, as Merck based the insert

language on the results of these researchers, including Dr. Halsey. Second, Dr. Halsey, on whose research results Merck relied for their insert, is more qualified than petitioners' experts to interpret the language of the insert, and he testified that the insert only describes an association, or rate, among children with SSPE who had, at some point, been administered the measles vaccine. As indicated previously, this interpretation was confirmed by Dr. Nalin, a company representative. Lastly, the most recent version of Merck's Manual no longer contains the language upon which petitioners rely to support their contention. Thus, petitioners' reliance on these materials is nothing more than mere speculation and lacks any persuasive value. Respondent, through Dr. Halsey's testimony, showed the dubious quality and questionable interpretations of the information upon which petitioners' experts relied. Quite frankly, petitioners' experts' highly questionable use of these materials negatively impacted their credibility before the court.

2. Reversion to Wild-Type Virus and Mutation

A second theory propounded by petitioners involves the possibility that the vaccine virus can revert to the wild-type virus, mutate, and ultimately cause SSPE. Dr. Kraiselburd posited that a study done by Kawashima et al., P. Ex. E-25, showed that the measles virus vaccine strain is capable of persisting like the wild-type measles virus strain and can cause a persistent infection. Tr. at 143-145. Dr. Kraiselburd testified that "SSPE is a result of a persistent infection with a measles virus," Tr. at 135, and that SSPE "has properties of both – wild type and vaccine [viruses]." Tr. at 136. He further asserted that Kawashima's study found that the vaccine strain could persist in the host for many years, and Dr. Kraiselburd opines that the virus then has opportunities to replicate and cause mutations. According to Dr. Kraiselburd, these mutations can lead to neurotropic mutations and eventually to SSPE. Tr. at 144-148. Dr. Kraiselburd read from a letter from Dr. Nalin to Dr. Halsey which stated that SSPE has been found to have occurred in individuals who harbored measles strains with mutations from wild strains and vaccine strains. Tr. at 136. The next sentence from this letter, which Dr. Kraiselburd read into the record, stated that Dr. Nalin "know[s] of no case of SSPE from which the vaccine strain has ever been isolated." Tr. at 137; R. Ex. D at 6. Dr. Kraiselburd was not concerned with this statement, however, alleging that "you will never isolate the vaccine virus, and you will never isolate the wild type virus." Tr. at 137. Dr. Halsey, on direct examination, contested

Dr. Kraiselburd's statements, testifying that investigators have isolated viruses from the brains of children with SSPE and that all of the isolates that have been looked at to date originated from wild-type viruses. Tr. at 331.

Dr. Kraiselburd also attempts to rely on a study by Okuno et al., P. Ex. E-3, interpreting the study as concluding that "the epidemiological data has shown probable cause between vaccine and SSPE. Not possible, probable." Tr. at 140. He stated that the vaccine was the probable cause in 5.4% of all SSPE cases in Japan. *Id.* The paper, however, did not conclude that there was a probable cause between the vaccine and SSPE; rather, similar to the Merck package insert, it stated that the researchers noticed a probable *association* with the vaccine. P. Ex. E-3. As Dr. Halsey explained in his testimony, association with a vaccine does not imply causation, it merely expresses an observed rate of occurrence. Tr. at 259-60. Dr. Halsey opined that petitioners have misinterpreted the results of the studies. Tr. 303-306. Petitioners presented no further explanation regarding the use of this data or rebuttal to Dr. Halsey's testimony.

Dr. Kraiselburd testified that a study by Cathomen et al., P. Ex. K, also supported his theory. According to Dr. Kraiselburd, this study shows that mutations can occur in the matrix protein (M) and the envelope protein (F) of the vaccine virus strain. Tr. at 161; P. Ex. K at 3907. He testified that these mutations can generate a neurotropic virus and slowly lead to SSPE. Tr. at 158-162. Dr. Kraiselburd also relied on a study whose lead author was Dr. Fumino Kobune, which he stated shows that the measles vaccine virus can revert to the wild-type virus. Tr. at 215-16. Dr. Halsey, however, again opined that petitioners misinterpreted the medical literature. In support of this opinion, Dr. Halsey produced a letter he received from Dr. Kobune in response to questions Dr. Halsey raised, which stated that the study did not show a reversion from the vaccine virus to the wild-type virus; rather, Dr. Kobune indicated the study showed that the vaccinees who developed SSPE had been infected with the wild measles virus at the time they were vaccinated. Tr. at 346-49; R. Ex. N.¹²

¹²During the hearing, petitioners objected to respondent's use of Dr. Kobune's unpublished letter to Dr. Halsey and again objected in their closing. P. Closing at 24. As respondent indicated, however, the letter was filed with the court prior to the hearing and its use at the hearing should not

Earlier, in support of his opinion, Dr. Bermudez referred to a study conducted by the National Vaccine Injury Compensation Program, P. Ex. E-13, which he stated revealed that the vaccine could cause an encephalopathy and encephalitis. Tr. at 74. Dr. Bermudez relied on this study because he said it “shows that the attenuated measles vaccine can cause very serious and even death.” P. Closing at 10. Petitioners then attempted to make a leap from the vaccine causing encephalitis to the vaccine causing SSPE. No basis, however, was provided for this leap.

Again, petitioners’ attempt to find a causal connection between the vaccine and SSPE must fail. Their theories of reversion and defective particles are highly speculative and without support in the medical literature. Further, the court agrees with respondent’s expert that again petitioners’ experts misinterpreted some of the literature, particularly in light of the statements from the original researchers supporting respondent’s expert’s opinion. The court found petitioners’ experts’ testimony to be highly speculative and unsupported by objective medical literature. Dr. Halsey persuasively pointed out the flawed analyses, to which petitioners had no response.

3. Subclinical Measles

A third argument posed by petitioners alleges that there is no proof that Inesita ever had measles, clinical or subclinical. Petitioners state in their closing that Inesita did not have measles as a child and at no time exhibited symptoms of measles, rubella, or rubeola. P. Closing at 5. They argue that the only documented exposure Inesita had to the measles virus was with the administration of the vaccine at eleven months of age. P. Closing at 9.

Dr. Bermudez relied on a history in the medical record given when Inesita received her measles vaccine which stated that the history was “negative for previous history of measles . . . [a]nd positive for chicken pox.” Tr. at 54. Dr. Bermudez also stated that there was no evidence in the

have surprised petitioners. Further, the Vaccine Program has relaxed standards of admissibility, and unless a submission severely prejudices a party or is entirely irrelevant, it should be considered by the court. See Cox v. Secretary of HHS, 30 Fed. Cl. 136 (1993). In addition, petitioners never attempted or requested an opportunity to contact Dr. Kobune or otherwise rebut Dr. Halsey’s testimony.

record that petitioner ever had measles or a measles-like infection, Tr. at 56, and that there is not any evidence in Inesita's medical records suggesting she might have had a case of subclinical measles. Tr. at 57. He thought it highly unlikely that Inesita could have had measles before receiving the vaccine because of the presence of maternal antibodies. Tr. at 97-98. Dr. Kraiselburd later supported Dr. Bermudez's opinion, stating that the only measles infection Inesita could have had "comes from the vaccine that has measles virus," Tr. at 220, and that "the probability of an asymptomatic infection with measles is so negligible in comparison with any other virus." Tr. at 222.

Dr. Kraiselburd indicated that the keys to his opinion were twofold: first, Inesita's only known exposure to the measles virus was through the vaccine; second, because of Inesita's home life, it was highly unlikely she would have developed an asymptomatic infection. Tr. at 220. Dr. Kraiselburd then opined that based on Dr. Halsey's data, the likelihood that Inesita could have developed asymptomatic measles was .8%, or a 99.2% likelihood that she did not have an asymptomatic infection. Tr. at 223. It is unclear how Dr. Kraiselburd came up with these probabilities, as Dr. Halsey stated in his opinion on causation that in certain studies, subclinical measles was the documented cause, through serologic evidence, in 10% to 20% of children with SSPE who had not had clinically recognized measles. R. Ex. B at 4.

Petitioners attempt to rely on the fact that Inesita had no *known* exposure to measles, that she did not suffer from a *clinical* case of the measles.¹³ Dr. Halsey, however, testified that "subclinical measles is a common entity." Tr. at 282. Further, as respondent points out in her brief, subclinical measles is, by definition, measles infection without clinical manifestations of the disease. R. Closing at 24. If Inesita had had subclinical measles, her disease may have gone unnoticed by her doctors and her mother. A case of subclinical measles could easily be missed by even an attentive, intelligent parent. Dr. Halsey referred to a visit Inesita had with a doctor in September 1974 where she had an illness with fever, malaise, hyperemic throat, and was not eating – all signs and symptoms

¹³Petitioners are correct in their assertion that Inesita's medical records make no mention of Inesita ever having measles. In fact, as Dr. Bermudez testified, the medical records specifically indicated an absence of a history of measles.

of mild respiratory infections, which Dr. Halsey states are very common and have been documented in people who have subclinical measles. Tr. at 301. Because subclinical measles presents itself, by definition, without manifestation of measles symptoms, the court cannot accept petitioners' assertion that Inesita could not have had subclinical measles based on the fact that her mother and doctors never noticed any symptoms.

4. Maternal Antibodies

Although petitioners aver that Inesita was never exposed to the measles virus, they contend that even if she was exposed prior to her vaccination at age eleven months, she would have been protected by maternal antibodies. In fact, the possible presence of maternal antibodies was the key to Dr. Bermudez's testimony. When asked how he explains his opinion that there is a causal link between the vaccine and SSPE, and why a subclinical case of the measles would not be the more likely cause of Inesita's SSPE, he stated that "as long as maternal antibodies are present and protective, it is very unlikely that [Inesita], in the first months of life, would have clinical measles, or subclinical measles." Tr. at 97-98. He further stated that he would "accept the fact that she may have had subclinical measles" if the time frame discussed was Inesita's "second year" of life. Tr. at 98. Dr. Bermudez also testified that during the first year of a child's life, "it would be very difficult to determine which antibodies – from whom are the antibodies coming; from the mother; or from subclinical measles." Tr. at 67.

Dr. Bermudez testified that if a child's mother has had measles, maternal antibodies will often protect the child for up to twelve months of age. Tr. at 67, 68, 79, 98, 115. According to Dr. Bermudez, a subclinical case of measles can only occur in the absence of maternal antibodies. Tr. 79. However, when asked on cross-examination about Inesita's chicken pox, Dr. Bermudez opined that she might have had a "small amount of . . . maternal antibodies against chicken pox, that protected her, in some way." Tr. at 94-95. Dr. Bermudez seems to be stating that a child could have a modified presentation of chicken pox even if maternal antibodies are present, yet he continually testified that measles could not occur in the presence of maternal antibodies. He did not explain this discrepancy. Further, Dr. Bermudez, in forming his opinion, presumed that Inesita's birth mother

had had measles. Upon cross examination by respondent, however, Dr. Bermudez admitted this information about Inesita's mother was not known:

- Q: Does measles occur in the first year of life, in children?
A: It does occur, it does occur, it does occur, it does occur.
Q: But does it occur in the first six months of life?
A: It may occur, it may occur, yes. But this is probably from a mother who did not have measles.
Q: And we don't . . . know who Inesita's mother, birth mother is or was, do we?
A: Yes, we don't know.

Tr. at 98-99.

Dr. Bermudez referred to a study by H. Gans, P. Ex. E-22, which he argued supported the finding that maternal antibodies last longer in children whose mother had had the measles virus. Tr. at 71-72. Dr. Bermudez also attempted to rely on a study conducted by Dr. Krugman, arguing that Krugman proved that maternal antibodies protect a child for a whole year. Tr. at 115. Dr. Bermudez also claimed that the Krugman study determined that maternal antibodies acquired from women who had had a natural history of measles could last until between seven and twelve months. Tr. at 68. Further, Dr. Bermudez stated that the Krugman study was the only one to which he could refer to in support of his opinion. The undersigned, however, referred to a passage in Krugman's study, R. Ex. G at 485, which stated: "Infants whose mothers have had measles are born immune to the disease. Their passively acquired measles antibody may decline to nondetectable levels as early as 2 months or as late as 11 months of age." In response, Dr. Bermudez simply stated that "It's [the presence of maternal antibody] variable." Tr. at 122. Even though the Krugman study established 11 months as the outer limit for maternal antibody protection, Dr. Bermudez testified that Inesita could not have had measles because she would have been protected by her maternal antibodies at 11 months of age.

Again, petitioners' line of reasoning is far too speculative. First, the studies on which petitioners rely determined that the outside limit for maternal antibody protection is 11 months.

Inesita received her vaccination at 11 months. Second, and perhaps more importantly, nothing is known about the medical history of Inesita's birth mother. Although possible, it is not known whether she had suffered from measles. However, even if the birth mother had suffered from measles, the studies supported the finding that antibody protection could last as short as 2 months or as long as 11 months. Petitioners did not provide sufficient evidence to support an assumption that Inesita's protection would have lasted until the 11 month extreme. Similar to the other arguments petitioners present, to accept petitioners' maternal antibodies argument, one must assume all unknown facts in petitioners' favor, accept the many liberties petitioners took in interpreting the medical reports, and resolve all matters of speculation in petitioners' favor. While the court accepts the experts' good faith efforts to support the tragic case of Inesita, the court cannot accept the thinly supported, speculative reasoning.

B. Respondent's Expert – Dr. Halsey

Dr. Halsey addressed each of petitioners' arguments and explained why he felt they were incorrect. In response to petitioners' assertion that the Merck package insert and Merck's Manual are more reliable than information used by researchers, Dr. Halsey explained that Merck based the language of its package insert on the results of his research. Second, in responding to petitioners' argument that the vaccine virus can revert to the wild virus and mutate, Dr. Halsey opined that petitioners' experts misinterpreted the various studies on this issue. Tr. at 303-06. He vigorously contested Dr. Kraiselburd's statement that the vaccine virus and wild-type virus could not be isolated, stating that not only can they be isolated, but they have been isolated and all isolates from children with SSPE have originated from wild-type viruses. Tr. at 331. Dr. Halsey also stated that petitioners' experts equated "association" with "causation." Dr. Halsey emphasized that association merely expresses a rate of occurrence, not a causal link. Tr. at 259-60. Third, Dr. Halsey attacked petitioners' testimony that Inesita could not have had subclinical measles. Dr. Halsey stated that subclinical measles occurs quite frequently, Tr. at 282, and he stated that symptoms Inesita exhibited at a September 1974 doctor's visit could have been associated with a case of subclinical measles. Tr. at 301. Dr. Halsey also testified that in a country like Colombia, it is fairly common for a child

to have a subclinical measles infection. Tr. at 281.¹⁴ Finally, in response to petitioners' last argument that even if Inesita had been exposed to measles before her vaccination, she would have been protected by maternal antibodies, Dr. Halsey stated that the length of time Inesita would have been protected by maternal antibodies cannot be determined. According to Dr. Halsey, "you cannot state that all babies will be protected for a given number of months after birth because some babies are protected for only a couple months; most of them are protected for four or five months; and some babies are protected for ten or eleven months." Tr. at 277. As indicated during Dr. Bermudez's cross-examination, nothing is known about the medical history of Inesita's birth mother, Tr. at 98-99; therefore, any discussion about the amount of maternal antibodies Inesita acquired is mere speculation. Dr. Halsey's highly persuasive testimony was left essentially unrebutted.

¹⁴Respondent later stated in her closing that subclinical measles is, by definition, measles infection without clinical manifestations. R. Closing at 24.

ANALYSIS

The court finds that petitioners, through their experts, Drs. Bermudez and Kraiselburd, have failed to prove by a preponderance of the evidence that the MR vaccine caused Inesita's injuries. The crux of the court's ruling is one of credibility, and the court found overwhelmingly that Dr. Halsey was more knowledgeable, more familiar with the issues, and far more credible than Drs. Bermudez and Kraiselburd on the issues presented in this matter. Drs. Bermudez and Kraiselburd have excellent credentials, and the court does not doubt that Dr. Bermudez is a fine clinician and Dr. Kraiselburd an able researcher. Their testimony on the issues presented here was, however, unpersuasive. Compared to Dr. Halsey's testimony, which is bolstered by his impressive credentials, years of studying the measles virus and vaccine, and published medical literature, Dr. Bermudez's and Dr. Kraiselburd's testimony can be afforded little weight.

Petitioners, through briefs, expert reports, and testimony, continually point to the fact that there was no known exposure to measles other than the measles vaccination. They argue that Inesita's mother would have noticed if Inesita had had subclinical measles. Unfortunately, petitioners have a very difficult burden. They must prove that it is more likely than not that the vaccination caused Inesita's SSPE. It is not the government's burden to prove an alternate cause unless and until petitioners have satisfied their initial burden, which they have not.

To meet this burden, petitioners have not offered any medical literature or documents of even a single occurrence of vaccine-caused SSPE; they have only submitted articles analyzing vaccine-associated SSPE and the proposed theory that it might be **possible** that measles vaccine can cause SSPE. The court found their testimony highly speculative and unsupported by medical literature. Without any substantive evidence, the court cannot find in favor of petitioners. It may be biologically plausible that the vaccine can cause SSPE. Even respondent's expert, Dr. Halsey stated that "it's theoretically possible" that the vaccine could cause SSPE. Tr. at 325. Dr. Halsey, however, indicated that of all of the isolates that investigators have looked at from the brains of children with SSPE, all had originated from the wild-type virus. Tr. at 331. According to Dr.

Halsey, all of the available evidence supports his opinion that “there has never been a case of SSPE that has been attributed or shown to be caused by the measles vaccine virus.” Tr. at 337.

Dr. Halsey, who has been involved extensively in work on measles vaccine and SSPE, is well qualified to state what the present state of medical opinion is on this issue. It is clear that petitioners have not met their burden of showing that, more likely than not, Inesita’s MR vaccination was the cause of her SSPE. While petitioners aver that nowhere in the medical records does it state that Inesita had a clinical case of the measles, petitioners have not been able to prove that the measles vaccine has ever been proven to cause SSPE. Even though the IOM¹⁵ concedes, as does Dr. Halsey, that it is biologically *plausible* that the vaccine could cause SSPE, a causal connection has not yet been established between the two in current medical literature. Further, Dr. Halsey stated that there has never been a single case of SSPE causally linked to the vaccine.¹⁶ Tr. at 337.

In sum, petitioners have failed to overcome the burden of proving that the measles vaccination Inesita received in December 1974 more probably than not was the cause of her SSPE.

CONCLUSION

¹⁵The law establishing the Vaccine Program, P.L. 99-660, charged the Institute of Medicine (IOM) of the Academy of Sciences to review the medical and scientific literature regarding risks associated with the various vaccines covered under the Program, including measles vaccine. A committee was formed, the review was conducted, and a report was published: Institute of Medicine, *Adverse Events Associated with Childhood Vaccines* (National Academy Press 1994). Considering the IOM’s statutory charge, the scope of its review, and the cross-section of experts making up the committee, the court has consistently accorded great weight to the IOM’s findings.

¹⁶In the early years of the Program, two decisions were entered involving the measles vaccine and SSPE which held for petitioners; however, these cases were decided when respondent was not actively defending the cases. See Pruitt v. Secretary of HHS, 1989 WL 250077, No. 89-10V (Cl. Ct. Spec. Mstr. July 19, 1989); Edgar v. Secretary of HHS, 1900 WL 293376, No. 89-67V (Cl. Ct. Spec. Mstr. Sept. 28, 1990). Once respondent began contesting liability, the court has held that petitioners did not meet their burden of proof. See Watson v. Secretary of HHS, 1993 WL 196880, No. 90-1316V (Fed. Cl. Spec. Mstr. May 27, 1993); Martin v. Secretary of HHS, 1995 WL 695023, No. 2725V (Fed. Cl. Spec. Mstr. Nov. 8, 1995); Carrico v. Secretary of HHS, 1996 WL 422146, No. 90-3712V (Fed. Cl. Spec. Mstr. July 12, 1996). However, in support of Dr. Halsey’s statement, to this court’s knowledge, petitioners in any Vaccine Program case have not yet produced any medical literature which persuasively links the measles vaccine to SSPE.

Inesita's SSPE and eventual death is a tragic case. The records and testimony show that Inesita's parents were loving and devoted parents, dedicated to giving Inesita the best care possible. The Vaccine Program, however, was designed by Congress to compensate only those individuals who can demonstrate either a Table Injury or a causal link between their injuries and a listed vaccination. Petitioners have failed to do so here. The court sympathizes with petitioners but cannot rule in their favor.

This petition is hereby dismissed. The Clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master