

OFFICE OF SPECIAL MASTERS

Filed: August 3, 2005

R. DARRELL WEAVER, administrator of *
the estate of ASHLEY WEAVER, *

Petitioner, *

v. *

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

Respondent. *

No. 02-724V
Special Master
Margaret M. Sweeney

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

Julia W. McInerny, United States Department of Justice, Washington, D.C., for Respondent.

DECISION¹

SWEENEY, Special Master

On June 21, 2002, R. Darrell Weaver, as the parent and natural guardian of Ashley Weaver ("Ashley"), filed a petition² for compensation under the National Childhood Vaccine Injury Act ("Vaccine Act"). 42 U.S.C. § 300aa-1 to -34 (1991 & Supp. 2002). The timely-filed petition alleges that as a result of a series of three hepatitis B³ vaccinations Ashley received on

¹ The court encourages the parties to review Vaccine Rule 18, which affords each party 14 days to object to disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy."

² Subsequent to the filing of the petition, on April 4, 2003, petitioner filed a Motion to Amend Caption to reflect the fact that Mr. Weaver was the administrator of his daughter's estate.

³ The hepatitis B vaccine is "a noninfectious viral vaccine derived by recombination from hepatitis B surface antigen and cloned in yeast cells; administered intramuscularly for immunization of children and adolescents and of persons at increased risk for infection." Dorland's Illustrated Medical Dictionary 1999 (30th ed. 2003).

September 3, 1999, October 7, 1999, and March 30, 2000, Ashley was diagnosed with eye palsy⁴ and hemiparesis⁵ in July 2000. Subsequent to the filing of the petition, Ashley died.⁶ Unfortunately, Mr. Weaver has not offered any medical evidence to support his allegation that Ashley's eye palsy, hemiparesis, or death were caused in fact by the hepatitis B vaccinations. Sadly, because Mr. Weaver is unable to present expert medical testimony in support of the allegations set forth in the petition, the special master is compelled to deny his claim and dismiss the petition.

Background

Ashley was born on December 14, 1987.⁷ Pet. at 1. Prior to July 2000, Ashley was a happy and healthy child who was developing normally. Id. at 2. Ashley's pediatric records reveal typical childhood ailments, such as cold symptoms, ear infections, diarrhea, croup, vaginitis, constipation, tonsillitis, allergies, and dermatological issues. Pet. Ex. 4 at 2-32.

Ashley received her series of hepatitis B vaccinations on September 3, 1999, October 7, 1999, and March 30, 2000. Pet. at 2; Pet. Ex. 10 at 7.

After the hepatitis B vaccinations, petitioner noticed a change in Ashley's behavior. Pet. at 2. Ashley began to favor her left side and turn her head to see. Id.

⁴ Palsy is another term for paralysis. Dorland's Illustrated Medical Dictionary, supra note 3, at 1353. Based upon the medical records submitted in this case, eye palsy likely refers to the paralysis of the third cranial nerve, which supplies most of the eye muscles. Id. at 1237, 1241.

⁵ Hemiparesis is "muscular weakness or partial paralysis affecting one side of the body." Dorland's Illustrated Medical Dictionary, supra note 3, at 829.

⁶ Ashley's death is evidenced by petitioner's Motion to Amend Caption. See supra note 2. Petitioner has not submitted any documentation, medical or legal, directly verifying Ashley's death. However, summary laboratory test results submitted by Thomas R. Crow, M.D., contain the notation: "Expired-Oct 07, 02." Pet. Ex. 2 at 2-9.

Additionally, petitioner has not filed an amended petition alleging that Ashley's death was caused by the hepatitis B vaccinations. Nor has petitioner submitted evidence that Ashley's death is a sequela of her alleged vaccine-related injuries. In spite of the lack of an amended petition or supporting evidence, the court will consider the allegation of a vaccine-related death.

⁷ All references to the Petition shall be designated herein as "Pet. at ___." All references to the pertinent Petitioner's Exhibit shall be designated herein as "Pet. Ex. ___ at ___." An affidavit from petitioner was not submitted.

On May 8, 2000, Ashley's mother telephoned pediatrician E. Ronald Orr, M.D. Pet. Ex. 4 at 32. Ashley's mother reported that "Ashley has had recently some left eye deviation medially, has had discoordination of her left hand and has had a slacking gait in her left foot." Id. Dr. Orr scheduled an appointment for Ashley with neurologist Linda S. Orr, M.D. Id.

Ashley saw Dr. Linda Orr on May 11, 2000. Pet. Ex. 11 at 7-8. Dr. Orr reported that Ashley's mother noticed left foot dragging about three weeks prior and Ashley's father noticed left hand clumsiness about one month prior. Id. at 7. Further, Ashley had a two-to-three week history of double vision. Id. Dr. Orr ordered an MRI, which was performed that day. Id. at 6, 8. The MRI revealed an area of increased signal in the right temporal lobe and some minimal shift of the midline structures. Id. Dr. Orr's differential diagnosis included postviral cerebritis,⁸ acute demyelinating encephalomyelitis ("ADEM"),⁹ and herpes encephalitis.¹⁰ Id. at 8. Because there was no signal enhancement, Dr. Orr did not believe that Ashley had a tumor. Id. Dr. Orr referred Ashley to Children's Hospital in Oklahoma City so that Ashley would have access to infectious disease specialists. Id.

Ashley was admitted to Children's Hospital on May 12, 2000, under the care of Venusto H. San Joaquin, M.D. Pet. Ex. 1 at 46-49. Dr. San Joaquin ordered a variety of tests during Ashley's hospitalization, including a repeat MRI. Id. at 47-48. The MRI was essentially unchanged from the MRI performed on May 11, 2000. Id. at 48. The neurologists, neuroradiologists, and pediatricians involved in Ashley's care concluded that ADEM was a possible cause of the MRI findings and therefore initiated steroid treatment. Id. Ashley was discharged home with a steroid taper on May 20, 2000. Id. The discharge diagnosis was ADEM versus "a slow-growing, infiltrating intracranial tumor." Id. at 46.

⁸ Cerebritis refers to either (1) a brain abscess or (2) encephalitis. See William Ernoehazy, Jr., M.D., Brain Abscess, at <http://www.emedicine.com/emerg/topic67.htm> (last updated Aug. 10, 2004); Marjorie Lazoff, M.D., Encephalitis, at <http://www.emedicine.com/emerg/topic163.htm> (last updated Jan. 10, 2005). A brain abscess is "a localized collection of pus" that affects "the brain as a result of extension of an infection . . . from an adjacent area or through a bloodborne infection." Dorland's Illustrated Medical Dictionary, supra note 3, at 6. Encephalitis is the "inflammation of the brain." Id. at 608.

⁹ Encephalomyelitis is "inflammation involving both the brain and the spinal cord." Dorland's Illustrated Medical Dictionary, supra note 3, at 610. ADEM is "characterized by perivascular lymphocyte and mononuclear cell infiltration and demyelination . . ." Id.

¹⁰ Herpes encephalitis is "the most common form of acute encephalitis, caused by a herpesvirus and characterized by hemorrhagic necrosis of parts of the temporal and frontal lobes." Dorland's Illustrated Medical Dictionary, supra note 3, at 608.

On June 3, 2000, Ashley underwent another brain MRI at Children’s Hospital. Id. at 38-39. The MRI was found to be inconsistent with an encephalitis. Id. at 39. Instead, one possible diagnosis was a low grade tumor. Id.

In July 2000, Ashley was diagnosed with eye palsy and hemiparesis. Pet. at 2; see also Pet. Ex. 4 at 34; Pet. Ex. 14 at 1.

On July 21, 2000, Paul C. Francel, M.D., performed an MRI-guided brain biopsy to ascertain whether Ashley was suffering from a demyelinating disease, an infectious or encephalitic process, or a malignancy. Pet. Ex. 9 at 7-9. The biopsy revealed gliosis,¹¹ but no evidence of demyelination or inflammation. Id. at 13.

On August 29, 2000, Ashley was evaluated by E. S. Roach, M.D., at The University of Texas Southwestern Medical Center. Pet. Ex. 14 at 1-2. Dr. Roach reported that Ashley had markedly improved after a treatment with steroids. Id. at 1. Dr. Roach believed that Ashley had a “demyelinating syndrome akin to ADEM” and wondered whether the hepatitis B vaccinations could have served as the stimulus. Id. Dr. Roach doubted that the demyelination would recur. Id. at 2.

Dr. Roach’s diagnosis was at odds with the assessment of R. Michael Siatkowski, M.D., an ophthalmologist at The Dean A. McGee Eye Institute at the University of Oklahoma. Pet. Ex. 3 at 15-16. Dr. Siatkowski also examined Ashley on August 29, 2000, and diagnosed right third cranial nerve palsy and ocular torticollis.¹² Id. at 15. Dr. Siatkowski found ADEM to be an unlikely diagnosis due to the fact that Ashley’s condition had not significantly changed over the course of four months. Id. at 16.

On November 15, 2000, Dr. Siatkowski wrote a letter to Dr. Francel indicating that he had postponed the planned surgery to repair Ashley’s right third nerve palsy due to the potential for Ashley developing a sixth nerve palsy,¹³ which could improve Ashley’s ocular position. Id. at 4. Also on November 15, 2000, Ashley had another brain MRI that was most consistent with a tumor. Pet. Ex. 1 at 11.

¹¹ Gliosis is “an excess of astroglia in damaged areas of the central nervous system.” Dorland’s Illustrated Medical Dictionary, supra note 3, at 778. Astroglia is the collective name for astrocytes, which are “neuroglia cell[s] of ectodermal origin, characterized by fibrous, protoplasmic, or plasmatofibrous processes.” Id. at 169-70.

¹² Torticollis is “a contracted state of the cervical muscles.” Dorland’s Illustrated Medical Dictionary, supra note 3, at 1924.

¹³ The sixth cranial nerve supplies the lateral rectus muscle of the eye. Dorland’s Illustrated Medical Dictionary, supra note 3, at 1237.

Ashley apparently underwent surgery to remove a brain tumor in December 2000.¹⁴ See Pet. Ex. 1 at 206 (October 23, 2001 discharge summary from Children’s Hospital); Pet. Ex. 4 at 35 (April 13, 2001 record of Dr. E. Ronald Orr); Pet. Ex. 7 at 329 (December 22, 2000 record of Marc R. Hille, M.D.); see also Pet. Ex. 3 at 4 (December 14, 2000 handwritten note of Dr. Siatkowski regarding the grave prognosis of Ashley’s “gliomatosis cerebri anaplastic astrocytoma”¹⁵). The tumor was not completely removed. Pet. Ex. 1 at 206; Pet. Ex. 4 at 35.

Either prior to or as a result of the brain surgery, Ashley began to experience seizures and was placed on seizure medications. Pet. Ex. 4 at 35; Pet. Ex. 7 at 319-29. The seizures continued until sometime before May 22, 2001. Pet. Ex. 7 at 323.

On May 22, 2001, Ashley had a follow-up visit with Dr. Hille, who had been treating Ashley for her seizures. Id. at 323-24. Dr. Hille noted that Ashley had developed new medical problems over the last several weeks:

She has lost her hearing on one side. She has developed slurring of her speech and has had difficulty swallowing water. She is doing reasonably well with swallowing solid food. She has been napping more, that is, at least three hours a day, frequently more. She began having problems not wanting or being unable to hold her head up several weeks ago. This has evolved into chronic complaints of neck pain. . . . Her parents also noticed a spot that came up on her anterior chest on the right of midline.

Id. at 323. Dr. Hille also described Ashley’s current condition:

She is clearly much more debilitated. They had to bring her into the office in a wheelchair. Her coordination is rather poor. She continues to manifest weakness on the right side, more so in the arm. I think this is probably worse. Her extraocular movements are all impaired at this point. . . . Her gaze appears dysconjugate. Her speech is slurred. Her mass and strength appear decreased, more so on the right.

¹⁴ Even though many medical records refer to it, petitioner did not file any records regarding this surgery, apparently performed at The University of Texas M.D. Anderson Cancer Center.

¹⁵ Gliomatosis cerebri is “a rare variant of glioblastoma multiforme in which one hemisphere or the entire brain is infiltrated diffusely with anaplastic astrocytes.” Dorland’s Illustrated Medical Dictionary, supra note 3, at 777. Glioblastoma multiforme is “the most malignant type of astrocytoma, . . . one of the most common primary tumors of the brain.” Id. at 777. Astrocytoma is “a tumor composed of astrocytes.” Id. at 169. Anaplastic astrocytoma is “a malignant to highly malignant form of astrocytoma that often degenerates into a glioblastoma multiforme.” Id.

Id. Dr. Hille explained these symptoms as signs that Ashley’s tumor was progressing. Id. In private, Dr. Hille discussed Ashley’s prognosis with her parents. Id. at 324.

By July 6, 2001, Ashley was bedridden and unable to speak. Pet. Ex. 4 at 37. Ashley underwent the placement of a feeding tube on July 10, 2001. Pet. Ex. 7 at 285. Then, later that day, Ashley was admitted to Duncan Regional Hospital in Duncan, Oklahoma with left lower lobe pneumonia. Id. at 337-39. The pneumonia improved and Ashley was discharged home on July 13, 2001. Id. Upon discharge, Thomas R. Crow, M.D., noted that while Ashley would improve somewhat, her brain tumor would cause a progressive decline. Id. at 338-39.

On October 20, 2001, Ashley was readmitted to Children’s Hospital with a ten-day history of headache and vomiting. Pet. Ex. 1 at 206. Ashley responded to treatment and was discharged on October 23, 2001. Id. at 206-07.

On December 5, 2001, Ashley was admitted to Duncan Regional Hospital with acute status epilepticus.¹⁶ Pet. Ex. 7 at 194-95. The seizures were controlled and stabilized and Ashley was discharged home on December 8, 2001. Id. Dr. Crow noted upon discharge that Ashley showed “remarkable resilience” given her tumor but that her prognosis remained poor. Id. at 195.

Ashley had another bout of pneumonia that required hospitalization in January 2002. Id. at 114-15. Again, she improved and was discharged home. Id. Dr. Crow again emphasized Ashley’s remarkable life span. Id. at 115. On June 28, 2002, Ashley was admitted to Duncan Regional Hospital with left leg cellulitis,¹⁷ right middle lobe pneumonia, and fever. Id. at 6-8. Once again, Ashley responded to treatment and was discharged home on July 4, 2002. Id. at 5-8.

On September 3, 2002, Ashley was readmitted to Duncan Regional Hospital with bilateral pneumonia. Id. at 409-11. Unlike in the past, Ashley displayed a decreased level of consciousness. Id. at 409. A computed tomography scan (“CT scan”)¹⁸ revealed an intercerebral

¹⁶ Status epilepticus is “a continuous series of generalized tonic-clonic seizures without return to consciousness.” Dorland’s Illustrated Medical Dictionary, supra note 3, at 1756.

¹⁷ Cellulitis is “an acute, diffuse, spreading, edematous, suppurative inflammation of the deep subcutaneous tissues and sometimes muscle, sometimes with abscess formation.” Dorland’s Illustrated Medical Dictionary, supra note 3, at 328.

¹⁸ A CT scan is a “recording of internal body images at a predetermined plane by means of the tomograph.” Dorland’s Illustrated Medical Dictionary, supra note 3, at 1919. A tomograph is “an apparatus for moving an x-ray source in one direction as the film is moved in the opposite direction, thus showing in detail a predetermined plane of tissue while blurring or eliminating detail in other planes.” Id. In a CT scan, “the emergent x-ray beam is measured by a

hemorrhage into her tumor, causing compression and hydrocephalus.¹⁹ Id. Ashley was stabilized and discharged home on September 20, 2002. Id. at 409-11.

Ashley apparently died on October 7, 2002. See Pet. Ex. 2 at 2-9.

Respondent's Rule 4(b) Report and Respondent's Response to Petitioner's Motion for Judgment

Counsel for the respondent filed her Rule 4(b) Report on September 19, 2002, indicating that respondent could not evaluate the merits of petitioner's claim because the petition was not accompanied by medical records or a medical expert report. Resp't Rep. at 2. Therefore, respondent argued that petitioner was not entitled to compensation and that the case should be dismissed.

Then, in response to the medical records filed by petitioner on October 31, 2003, and petitioner's Motion for Judgment on the Record filed on March 25, 2005, respondent's counsel filed Respondent's Response to Petitioner's Motion for Judgment on May 26, 2005. Respondent's position is that despite several deficiencies in the record, including the lack of evidence of Ashley's apparent death and the lack of an amended petition alleging a vaccine-related death, the court can rule on petitioner's motion.²⁰ Resp't Resp. at 2-3. Respondent urges that the court deny compensation to petitioner, contending that the medical records do not support a causal connection between the hepatitis B vaccinations and Ashley's injuries and/or death. Id. at 14.

Petitioner's Counsel's Efforts to Retain a Medical Expert

On July 26, 2002, petitioner's counsel filed a status report indicating that petitioner had "elected to participate in the resolution process being created by the Hepatitis B Steering Committee and would ask that the Court include this case in those proceedings." Petitioner

scintillation counter; the electronic impulses are recorded on a magnetic disk and then are processed by a mini-computer for reconstruction display of the body in cross-section on a cathode ray tube." Id.

¹⁹ Hydrocephalus is "a condition marked by dilation of the cerebral ventricles, most often occurring secondarily to obstruction of the cerebrospinal fluid pathways . . . and accompanied by an accumulation of cerebrospinal fluid within the skull In children it . . . is typically characterized by . . . mental deterioration[] and convulsions." Dorland's Illustrated Medical Dictionary, *supra* note 3, at 870.

²⁰ Because no amended petition was filed, respondent was not obligated to take a position regarding the merits of a vaccine-related death claim.

further noted that he intended “to develop expert testimony in concert with other similar cases after the discovery phase of the proceedings is completed.”

At some point between July 26, 2002, and May 7, 2003, this case was grouped with other similar cases and placed into the Hepatitis B–Neurological Demyelinating Omnibus Proceeding (“Omnibus Proceeding”). The court conducted a hearing in the Omnibus Proceeding on October 13-15, 2004, with both sides presenting expert testimony. The record in the Omnibus Proceeding remains open. Because petitioner has requested a ruling on the record prior to the closing of the record in the Omnibus Proceeding, the court will not consider the evidence presented in the Omnibus Proceeding in this case.

The record in this case does not include an expert opinion supporting the contention that Ashley was injured or died as a result of her hepatitis B vaccinations.

The Vaccine Act

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if petitioner²¹ proves, by a preponderance of the evidence, all of the elements set forth in § 300aa-11(c)(1)²² of the Vaccine Act and that the illness or death is not due to factors unrelated to the administration

²¹ Section 11(b)(1) requires that: (1) only the “person who sustained a vaccine-related injury . . . or the legal representative of any person who died as the result of the administration of a [Table vaccine] . . .” can bring an action for vaccine injury-related claims (so long as the requirements of subsection (c)(1) are satisfied) and (2) that no previous civil action was filed in the same matter.

²² Mr. Weaver, in his apparent capacity as the administrator of his daughter’s estate, is the appropriate person to be substituted to maintain this action. In addition, subsection (c)(1) requires, *inter alia*, the following elements be satisfied: (1) that the vaccine in question is set forth in the Vaccine Injury Table; (2) that the vaccine was received in the United States or in its trust territories; (3) that the petitioner (or here, the person represented by petitioner) either sustained an injury as a result of the administration of a Table-designated vaccine for a period of more than six months after the administration of the vaccine, suffered illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, or died from the administration of the vaccine; and (4) that the petitioner or petitioner’s legal representative has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury. Here, petitioner was unable satisfy the third requirement. Specifically, Mr. Weaver was unable to offer the testimony of a qualified medical expert to support petitioner’s theory of liability. Thus, the lack of expert opinion evidence supporting the allegations of the petition defeats the underlying claim.

of the vaccine.²³ Section 300aa-11(c)(1)(C) describes the substantive elements petitioner must prove to recover in the Vaccine Program. In this case, petitioner can recover in one of two ways. First, petitioner can recover if he proves a Table injury; in other words, if he shows that Ashley received a vaccine listed in the Vaccine Injury Table (“Table”), 42 C.F.R. § 100.3(a), and suffered from an injury associated with that vaccine within the prescribed time period. 42 U.S.C. § 300aa-11(c)(1)(C)(i). Petitioner is unable to make this showing because eye palsy and hemiparesis are not Table injuries for the hepatitis B vaccine.²⁴ Instead, petitioner must proceed on an actual causation theory.

Under an actual causation theory or “off-Table” claim, § 300aa-11(c)(1)(C)(ii), petitioner must prove that Ashley’s eye palsy, hemiparesis, or death was caused in fact by her hepatitis B vaccinations. Congress explained what it intended by this causation requirement:

[T]he petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner.

H.R. Rep. No. 99-908, pt. 1, at 15 (1986). The United States Court of Appeals for the Federal Circuit amplified congressional intent:

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. Sec’y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted); Bunting v. Sec’y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991) (“A petitioner’s burden is not to show a generalized ‘cause and effect relationship’ with listed illnesses, but only to show causation in a particular case.”). As the Federal Circuit explained in Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999), two separate elements must be demonstrated by a preponderance of the evidence, namely, “that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Thus, both the Vaccine Act and the case law clearly require an expert medical opinion.

²³ Of course, the petition must also be filed within the statutory period. 42 U.S.C. § 300aa-16(a).

²⁴ Although, as noted above, no amended petition was filed, the court notes that death is not a Table injury for the hepatitis B vaccine.

Section 300aa-13(b)(1) specifically requires consideration of all relevant medical and scientific evidence presented to the court including:

(A) any diagnosis, conclusion, medical judgment, . . . regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

A review of the record now under consideration reveals no medical evidence²⁵ to support petitioner’s theory that Ashley suffered from eye palsy and hemiparesis, or died as a result of the administration of the hepatitis B vaccinations administered on September 3, 1999, October 7, 1999, and March 30, 1999. In fact, the record contains strong evidence that Ashley’s injuries and subsequent death were caused by her brain tumor.

The Vaccine Act specifically provides that “the special master or court may not make a finding [of eligibility and compensation] based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion.” 42 U.S.C. § 300aa-13(a)(1). Thus, because petitioner is unable to prove by a preponderance of the evidence the matters required in § 300aa-11(c)(1),²⁶ petitioner cannot carry the “heavy burden” required in off-Table cases to prove that Ashley’s eye palsy, hemiparesis, or death were more likely than not the result of the hepatitis B vaccinations at issue here. There is no doubt that Ashley’s family has endured great suffering; nevertheless, the statutory requirements have not been satisfied.

CONCLUSION

Because petitioner is unable to present medical records and/or expert testimony to support a theory of causation, the special master finds that petitioner has not and cannot meet his burden of proof to prove that the hepatitis B vaccinations of September 3, 1999, October 7, 1999, and March 30, 2000, caused Ashley’s eye palsy, hemiparesis, or death. Therefore, the special master finds that petitioner must be denied compensation under the Vaccine Program.

²⁵ Although the Federal Circuit made clear in Knudsen v. Secretary of HHS, 35 F.3d 543, 548-49 (Fed. Cir. 1994), that when proceeding under an off-Table theory, a petitioner is not required to identify and provide proof of the specific biological mechanism that caused the alleged vaccine injury, a reputable medical explanation of a logical sequence of cause and effect to support petitioner’s theory of liability is necessary.

²⁶ See 42 U.S.C. § 300aa-13(a).

Accordingly, this petition is DISMISSED with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment accordingly.

IT IS SO ORDERED.

Margaret M. Sweeney
Special Master