In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

August 3, 2000

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LESLIE BROWN, as the Legal Representative of her deceased daughter, LAUREN BROWN,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

No. 99-044V
Published

Curtis R. Webb, Twin Falls, ID, for petitioner.
David L. Terzian, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

On January 28, 1999, petitioner filed a petition on behalf of her daughter, Lauren Brown (hereinafter, "Lauren"), for compensation under the National Childhood Vaccine Injury Act of 1986[1] (hereinafter the "Vaccine Act" or the "Act"). Petitioner has satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that: (1) she has not previously collected an award or settlement of a civil action for damages arising from the vaccine injury and death; and (2) DPT, Hib, and polio vaccines were administered to Lauren in the United States.

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[1] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. §300aa-1 et seq. (West 1991), as amended by Title II of the Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of November 26, 1991 (105 Stat. 1102). For convenience, further references will be to the relevant subsection of 42 U.S.C.A. § 300aa.

Petitioner alleges that Lauren's vaccinations were a substantial factor in Lauren's contraction of hemolytic anemia, causing her death. Respondent denies causation.

The court held a hearing in this case on May 10, 2000. Testifying for petitioner was Dr. Ralph Shapiro. Testifying for respondent was Dr. Gregory H. Reaman. Both are specialists in pediatrics, oncology, and hematology.

FACTS

Lauren was born on September 23, 1996. She received her first DPT vaccination with HiB, OPV, and her second Hepatitis B vaccination on November 21, 1996 when she was two months old. Med. recs. at Ex. 2B. She received her second DPT vaccination with OPV and Hib on Thursday, January 30, 1997, at the age of four months. Med. recs. at Ex. 2B, p. 14. At the Cleveland Clinic Foundation, Lauren's pediatrician, Dr. G. Williams, wrote in his notes for that day's visit that Mrs. Brown was concerned that Lauren was not drinking enough formula. Med. recs. at Ex. 2B, p. 26.

Lauren returned to the clinic on Tuesday, February 4, 1997 and saw Dr. Erwin. Lauren was fussy and had a history of a fever of 101 degrees since the prior Tuesday, but it had dropped to 99 degrees since Thursday, January 30, 1997. She had a low fluid intake, but was awake and alert. She had mild nasal congestion. Her nares (nostrils) were patent. Dr. Erwin's impression was a urinary tract infection (UTI). She had not had any contact with sick people. She had been given her last dose of Tylenol the day before this visit. Med. recs. at Ex. 2D, p. 71.

Two days later, on February 7, 1997, at 3:20 a.m , the nurse on call received a telephone call from Mrs. Brown with Lauren screaming in the background. She stated that Lauren was

crying and irritable and was difficult to console. She was not taking her bottles well and her urine output was decreased. Her temperature was 99 degrees. Med. recs. at Ex. 2E, p. 81.

Lauren was brought into the Emergency Room (ER) at 4:08 a.m. that day and diagnosed with severe anemia. She had been listless for three hours and was grunting. There had been no improvement from her UTI one week previously. Her eating and drinking had declined. She was pale and blood was noted in her diaper. Med. recs. at Ex. 2E, p. 85.

The pediatric admission assessment at 6:00 a.m. that day was that Lauren's alertness had decreased. Med. recs. at Ex. 2E, p. 87. The PICU admission note was that Lauren presented to the ER at 4:00 a.m. with progressive lethargy, irritability, and poor fluid intake over the past morning. She had had a temperature of 101 degrees at home from February 2-4. She was seen on Feb. 4th at the pediatric clinic and was afebrile and appeared to have active urine. On examination, Lauren was unresponsive and did not withdraw to pain. Her bowel sounds were positive and she was very hypoactive. Med. recs. at Ex. 2E, pp. 87-88, 90.

On February 6, 1997, Lauren had a nephrology consultation. The doctor noted a lack of urine output for the prior three hours. The history given was that Lauren had been well until five days previous (or approximately Feb. 1st) and was seen Feb. 4th with a fever but looked alert and responsive. The examining doctor suspected a UTI. However, Lauren's culture was negative. She arrived in the ER at 4:00 a.m. that morning and was lethargic and shocky. She was aggressively resuscitated with fluid, blood, and albumin. A urine output was established and maintained until 11:30 a.m. when it ceased. Med. recs. at Ex. 2E, p. 92.

On physical examination, Lauren was puffy looking with oozing around her neck and the artery line in the section site (she was intubated and on a ventilator). The doctor's impression

was acute renal insufficiency. He thought the likely causes were shock and hemoglobinuria. He thought hemolytic uremic syndrome (HUS) was unlikely because of her initial platelet count. Med. recs. at Ex. 2E, p. 93.

On February 6, 1997, Lauren had a pediatric hematology/oncology consultation. The history given was that she had been a healthy infant until her four-month DPT on Thursday. She developed a low-grade fever that persisted and was seen on Tuesday and treated. The fever persisted yesterday. The infant was not feeling well and was lethargic. By 4:00 a.m., she was shocky. There was no evidence of a red cell disorder. Med. recs. at Ex. 2E, pp. 94-95.

Lauren died on February 7, 1997. The autopsy was limited to a cytogenic autopsy and states she had an acute febrile illness with severe hemolytic anemia. The cause of death was disseminated intravascular coagulation and multiple system organ failure due to autoimmune hemolytic anemia, etiology undetermined. She had cerebral edema with marked flattening of the convolutions of her cerebral hemispheres with concomitant narrowing of the sulci. Microscopically, she had severe, acute anoxic encephalopathy and subarachnoid hemorrhage. Her spinal cord showed anoxic myelopathy. Her spleen showed marked congestion and scattered small foci of necrosis. Her kidneys had numerous fibrin thrombi within glomerular capillaries, and acute tubular necrosis. Her adrenals had extensive acute hemorrhages. Med. recs. at Ex. 2F, pp. 202, 204; Ex. 3, pp. 4, 5, 9.

The death certificate states brain death due to shock and hemolytic anemia (Coombs positive), acute renal failure, and disseminated intravascular coagulation. Med. recs. at Ex. 2F, p. 208.

Written Submissions

Petitioner filed Mrs. Brown's affidavit (P. Ex. 1) stating that, after the January 30, 1997 vaccinations, Lauren had a fever that night of 104 degrees. She was ill on January 31, 1997 with a fever of 99 degrees, and did not respond, smile, play or fix visually. She did not hold the nipple as firmly as usual and did not drink as much as normal. She did not grip Mrs. Brown's finger tightly and would not bounce on her lap. Lauren had an unusually shrill cry the evening of January 31, 1997. On Saturday, February 1, 1997, Lauren had a low-grade fever, was unresponsive, cried more frequently, and was more difficult to console. She slept less at night but more during the day. On February 2, 1997, Lauren's crying and reduced responsiveness continued, but her crying continued to worsen. By February 2, 1997, Mrs. Brown could not always console her and Lauren cried herself to sleep. On February 3, 1997, Lauren's crying continued and got worse. Mrs. Brown called the on-duty nurse at the Cleveland Clinic the evening of Monday, February 3, 1997. On Tuesday, February 4, 1997, Lauren continued to have a low-grade fever, reduced responsiveness, and worse crying. Mrs. Brown took her to the Cleveland Clinic and Dr. Erwin diagnosed a UTI. On February 5, 1997, Lauren had not improved. Mrs. Brown called the Cleveland Clinic in the morning and at noon. Lauren was less responsive and drank less. She cried inconsolably and constantly. They went to the ER on Thursday, February 6th, and Lauren died on February 7th.

Petitioner submitted a number of medical articles (P. Exs. 6-9). The first article is "Acute Hemolytic Anemia Related to Diphtheria-Pertussis-Tetanus Vaccination."[2] P. Ex. 6. In the

[2] By B. Haneberg, et al., *Acta Pediatr Scand* 67:345-50 (1978).

article, the authors describe three children who received their second or third DPT and developed severe hemolytic anemia afterward. Direct antiglobulin tests were positive. The infant most severely affected also had reduced serum complement levels, indicative of an immunological mechanism for the hemolysis.[3] Further testing suggested that the antibodies to tetanus and diphtheria toxoids as well as to pertussis toxoids were antigenically bound to the erythrocytes (red blood cells). *In vitro* (test tube) experiments showed that tetanus and diphteria toxoids were easily bound to human erythrocytes, helping to explain the pathogenesis of the autohemolysis.

At the beginning of their article, the authors state that "infections and drugs have been implicated as causative factors" in acute hemolytic anemia. P. Ex. 6, p. 345. The first child was administered his second DPT at four months of age and, four days later, he was admitted to the hospital with severe anemia. The second child was administered her second DPT at almost seven months of age and was symptomatic two weeks later. The third child received his third DPT vaccination at the age of five and one-half months and his polio vaccine at nine months. He was very pale for weeks before being admitted to the hospital at the age of ten and one-half months. Id. at 346.

Blood testing showed that the vaccines, particularly the tetanus component of the vaccines, attached to these children's erythrocytes. Id. at 347. Poliovirus and cytomegalovirus, on the other hand, did not agglutinate the human erythrocytes. Further testing showed that in one

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[3] Hemolysis is "disruption of the integrity of the red cell membrane causing release of hemoglobin. Hemolysis may be caused by ... antibodies that cause complement-dependent lysis...." Immune hemolysis is "the lysis by complement of erythrocytes sensitized as a consequence of interaction with specific antibody to the erythrocytes." Dorland's Illustrated Medical Dictionary, 27th Edition (1988) at 749. Lysis means "dissolution" or "destruction." Id. at 967.

of the children, antibodies to diphtheria, pertussis, and tetanus were antigenically bound to the erythrocytes. Id. at 348. The authors conclude that in the cases of the first two children, their second DPT vaccinations were possible causative agents of their hemolysis. Id. The authors opine that their tests showing that diphtheria and tetanus vaccines have an affinity to human erythrocytes could explain the initial step in the pathogenesis of the hemolysis. Id. at 348-49. "Positive results of antiglobulin tests in all our patients indicate that the hemolysis most likely was the result of an immunological reaction." Id. at 349. "[T]he hemolytic disease can be explained by the action of antibodies against the [DPT] vaccine components that were already attached to the surface of the erythrocytes." Id.

Petitioner's Exs. 7, 8, and 9 are abstracts relating acute hemolytic anemia to polio vaccine or hepatitis B vaccines, for Exs. 7 and 8, respectively, and to both DPT and polio vaccines for Ex. 9.[4] In Ex. 9, a four-month-old girl had received DPT and oral polio vaccines one month prior to admission. The authors found the case interesting because DPT preceded the girl's acute hemolytic anemia.

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[4] By G. Pilotti, "Thrombopenia and Acute Hemolytic Anemia in the Course of Poliomyelitis Vaccination," *Minerva Pediatr* 27:637-39 (1975) (in Italian); C. Liminana, et al., "Immune Hemolytic Anemia and Thrombocytopenic Purpura After Recombinant Hepatitis B Vaccine Administration (3)," *Medicinia Clinica* 113:39 (1999) (in Spanish); and L. Olcay, et al., "A Warm Antibody Mediated Acute Hemolytic Anemia with Reticulocytopenia in a Four-Month-Old Girl Requiring Immunosuppressive Therapy," *Turk J Pediatr* 41:239-44 (1999) (in English).

TESTIMONY

Dr. Ralph Shapiro testified for petitioner.[5] Tr. at 6. He is board-certified in pediatrics and in the pediatric subspecialty of hematology and oncology. Tr. at 7. Dr. Shapiro testified that he has two practices, one dealing with clinical immunology and the other, primary care pediatrics. Tr. at 6. He received his bachelor's degree in microbiology summa cum laude. *Id.* He also received a pediatric immunology fellowship. *Id.* His opinion is that Lauren's immune response was triggered by Tetramune (DPT and HiB) and polio vaccines and it is impossible to know which vaccine triggered her response of immune hemolytic anemia. Tr. at 8. Lauren may have developed an antibody after her first series of vaccinations and, then, after her second series of vaccinations, she had an anamnestic response, that is, her immune reaction worsened to the same antigens. Tr. at 9.

Lauren had a high fever and irritability after her vaccinations, and then developed a low-grade fever which persisted. *Id.* She was initially alert. Tr. at 10. But when her urine was tested on February 4, 1997, it showed hemoglobin, indicative of an aggressive breakdown of her red blood cells. Tr. at 10-11. Dr. Shapiro does not believe Lauren had a urinary tract infection when she was seen by the doctor on February 4th because the urine culture never grew out a bacterial infection. Tr. at 11. There were three to five white cells in Lauren's urine, but that can occur with hemolytic anemia. *Id.* The one plus hemoglobin in her urine should not have been there.

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[5] He is Director of the Midwest Immunology Clinic. He does manuscript reviews for 12 professional journals including the *American Journal of Pediatric Hematology/Oncology*. He has written 29 articles for peer-reviewed journals and nine articles for non-peer-reviewed journals. He has written three book chapters, including "Hematologic and Oncologic Complications of Immunodeficiencies...." He has participated in 86 oral and poster presentations at meetings. P. Ex. 5.

Id. Most often, if one has a urinary infection, the urine culture grows out bacteria. Tr. at 12. Dr. Shapiro does not believe Lauren had nasal congestion either as a source of infection because her nostrils were clear and there were no secretions. *Id.* One can have mild nasal congestion without infection. *Id.* The autopsy did not show any specific evidence for infection. *Id.*

Lauren went into severe disseminated intravascular coagulation and shock. Tr. at 12-13. The vaccinations triggered an immune response which increased over several days with response peaks. Tr. at 13. The red blood cells were probably breaking at a certain rate until the heart could take it any longer. *Id.* Hemolysis is the breakdown of red blood cells. Tr. at 14. Anemia happens as the hemoglobin in the body drops. *Id.* Lauren had autoimmune hemolytic anemia. Tr. at 14-15.

In discussing the article that is petitioner's exhibit 6, Dr. Shapiro stated that diphtheria, pertussis, and tetanus antibodies were stuck on the surface of the children's red blood cells. Tr. at 16. A warm antibody IgG suggests an antibody response that occurred earlier but did not hurt Lauren. Tr. at 17. By the time she received her second set of vaccines, she was already sensitized. *Id.* Lauren's reaction was extremely unusual. *Id.* Viral infections also cause immune hemolytic anemia, but Lauren did not have any symptoms of flu. Tr. at 18. On December 2, 1996, prior to her second set of vaccinations, Lauren had a 12.7 hemoglobin, which is great for a child her age. Tr. at 19.

Dr. Shapiro stated that the timing of her illness is consistent with immune hemolytic anemia. Tr. at 20. Within 24 hours of vaccinations, she had an antibody response. Tr. at 21. The immune response to the proteins on the vaccine sticks to the red blood cells. *Id.* High doses of penicillin can also cause immune hemolytic anemia. *Id.* Antibody is attached to the protein.

Tr. at 21-22. Usually hemolysis is self-limited, over one to six weeks, and goes away. Tr. at 22. Lauren was not diagnosed appropriately on February 4th and her hemoglobin subsequently dropped to a lethal point at the hospital. Tr. at 23.

Dr. Shapiro practices immunology two half-days a week. Tr. at 24. He currently has two patients with immune hemolytic anemia. *Id.* They have ongoing immune deficiencies. *Id.* He practices hematology as part of his immune practice. *Id.* He is a primary care pediatrician three days a week and has experience with urinary tract and upper respiratory infections. Tr. at 25. Immune hemolytic anemia is uncommon. Tr. at 26. He has not seen immune hemolytic anemia after vaccination, but he once consulted on a case of breaking red blood cells after vaccination, but he does not remember which vaccine. Tr. at 25-26.

In the hemophagocytic process, the antibodies eat the red blood cells and destroy them. Tr. at 26. Lauren would fit into all four articles that petitioners filed except in severity. Tr. at 36. Her first immune response would have produced IgM. Tr. at 37. Shortly, this would become IgG antibodies. *Id.* The importance of petitioner's exhibit 6 is not the specific antibody that was made, but the showing of an example of an immune response triggered by vaccines that could cause hemolysis. Tr. at 64. Each time an immune response happens, it is different. *Id.* The exhibit's relevance is not the specific antibody made, but that immune response to vaccines can trigger reactions that cause hemolysis. *Id.* Lymphocytes stick to something which does not belong in the body. *Id.* Which lymphocytes are encountering which part of a protein differs each time. Tr. at 64-65. Thus, the types of antibodies produced with a vaccination one time may be a little different the next time. *Id.*

Dr. Gregory H. Reaman testified for respondent. Tr. at 45. He is board-certified in pediatrics and in the pediatric subspecialty of hematology and oncology. Tr. at 46. He is Director of Medical Specialty Services and Chief of the Department of Hematology/Oncology at Children's National Medical Center as well as Professor of Pediatrics at The George Washington University School of Medicine and Health Sciences. Tr. at 46-47.[6]

Dr. Reaman has treated autoimmune hemolytic anemia (AHA) many times. Tr. at 48. The cause of AHA is not specifically known, but recent viral infections, not vaccinations, have been related to it. Tr. at 48-49. In his opinion, Lauren had AHA because of a viral illness or an undetermined etiology. Tr. at 49. Dr. Reaman distinguished Lauren's case from petitioner's exhibit 6 because the authors of that article demonstrated a mechanism for hemolytic anemia not for autoimmune hemolytic anemia. Tr. at 49-50. Lauren had a warm reacting panagglutinin to the autoantigen on her red blood cells. Tr. at 50. Lauren's IgG response was part of her AHA, not due to her response to her vaccinations. Tr. at 70. Dr. Reaman thinks that Lauren's urine culture on February 4, 1997 means nothing because it is normal to have some red blood cells in the urine. Tr. at 81.

Dr. Reaman stated that the basis for his opinion that Lauren had a viral illness is that she had fever, irritability, decreased oral intake, and nasal congestion. Tr. at 51. He ascribes her temperature of 104 degrees on the evening of the vaccinations to a viral illness. Tr. at 52. He

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[6] He is a reviewer for a number of journals, and on the editorial board of other medical journals, including the *Journal of Pediatric Hematology/Oncology*. He has written 122 articles, most of which dealing with pediatric cancer, expecially leukemia. He co-authored a chapter on hematologic disorders for a text on pediatric critical care. He has 13 manuscripts in press, 17 manuscripts submitted, and 116 presentations at meetings, mostly again dealing with pediatric cancer, especially leukemia. R. Ex. B

also attributes her low-grade fever to the viral illness. *Id.* That she had nasal congestion means she had secretions. Tr. at 53. He is not sure that she had a urinary tract infection, although not all UTIs have a positive culture. Tr. at 57-58. She had abnormalities in her urine consistent with a UTI. Tr. at 58. A one plus hemoglobin in her urine is consistent with an inflammatory response to infection. *Id.* Hemolysis is usually not intravascular. *Id.* Perhaps there was a problem with the way Lauren's urine was obtained. Tr. at 59.

Dr. Reaman opined that the fever was not the result of hemolysis, but of infection. Tr. at 66. We do not vaccinate infected infants because we will not get as good an antibody response. Tr. at 66-67. Her IgG, showing warm panagglutinin, has nothing to do with her first series of immunizations. Tr. at 70. Lauren had destruction of her red blood cells in her liver and spleen. Tr. at 81. AHA is not a destruction of red blood cells within the blood vessels. *Id.* Therefore, the red blood cells do not break down in the blood and hemoglobin does not get excreted in the urine as in the article that is petitioner's exhibit 6. *Id.*

Dr. Reaman does not know when Lauren's AHA began. Tr. at 82. He thinks either shock or infection could have caused her disseminated intravascular coagulation (DIC), but Dr. Shapiro states that on autopsy, none of Lauren's organs showed evidence for infection. Tr. at 83. Dr. Shapiro thinks that shock caused Lauren's DIC. Tr. at 84. Dr. Reaman does not think the absence of infections in Lauren's organs is significant. *Id.* If there were bacterial pneumonia, it would probably have been seen, but not finding evidence of infection in the organs does not prove there was no infection. Tr. at 83. Dr. Shapiro responded that there were no lymphocytic infiltrates in her tissues or ballooning of liver or lung cells. Tr. at 83-84.

Dr. Shapiro stated that since we do not know specifically what the antibody was against in Lauren's case, we do not know if she had autoimmune hemolytic anemia or just immune hemolytic anemia. Tr. at 89-90. Dr. Reaman, on the other hand, is comfortable saying that Lauren had AHA and it was probably caused by a viral infection. Tr. at 91. The report from the Red Cross[7] shows that the serum antibodies were warm autoantibodies, a panagglutinin. *Id.* This indicates AHA. *Id.* What makes AHA is antibody against oneself. *Id.* Dr. Shapiro agreed that the antibody the Red Cross found was an autoantibody, but he does not know if there were additional antibodies on Lauren's cells that caused the destruction because the Red Cross was looking at transfused cells. Tr. at 92.

Dr. Reaman responded that these were not transfused cells. *Id.* This was an antibody in her serum against normal red blood cells. *Id.* They were red blood cell antigens. *Id.* She was RH positive at birth, but these were RH negative cells. *Id.* Dr. Shapiro said we have not identified to what the antibody is sticking. *Id.* All we know is that it sticks to panels of red blood cells broadly. *Id.* Lauren's antibody was not against DPT or oral polio. Tr. at 93. It was an antibody to her constitutive red blood cells. *Id.* Dr. Shapiro believes that the vaccine triggered an immune response producing this antibody. Tr. at 95. Viruses in other situations have been known to trigger the same kind of response. *Id.* Lauren did get a virus: polio virus from the polio vaccine. *Id.* Dr. Reaman does not believe that oral polio vaccine causes a viral infection, at least not in normal people. Tr. at 96. It can induce a viral infection in

[7] Filed by the court's leave on July 28, 2000.

immunodeficient people. *Id.* We do not know if Lauren was immunologically deficient. Tr. at 97.

Referring to petitioner's other exhibits (7-9), Dr. Reaman thought exhibit 7 was too short to determine what it was describing and exhibit 8 was irrelevant because it involved hepatitis B. Tr. at 85. In exhibit 9, the Turkish article, the onset interval of one month between vaccination and illness was too long for the vaccination to be a trigger. Tr. at 86. Dr. Reaman presumes that Lauren's viral infection caused her AHA, even though the mechanism is unknown. Tr. at 88-89. Vaccinations do cause hemolytic anemia, as petitioner's exhibit 6 shows, but have not been causally related to AHA. Tr. at 89. Autoimmune hemolytic anemia is an aberrant situation because one is making antibodies to one's own red blood cells. Tr. at 106-07. Dr. Reaman does not know if AHA is a response to anything. Tr. at 107. One can respond aberrantly to any immunological challenge. Tr. at 107-08.

Lauren's AHA was definitely caused by a recent or intercurrent viral infection which occurred in close temporal relation to her death. Tr. at 109-10. By the term recent, Dr. Reaman refers either to the end of January or early February, that is, several days to a month. Tr. at 110. Lauren did not have a diagnosis of an upper respiratory infection on February 4, 1997. Tr. at 111. Dr. Reaman admitted that vaccinations can cause fever. *Id.* Usually DPT causes a fever. *Id.* He also believes that a urinary tract infection did not cause Lauren's AHA. Tr. at 112.

DISCUSSION

Petitioner is proceeding on a theory of causation in fact. To satisfy her burden of proving causation in fact, petitioner must offer "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, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149.

Petitioner must not only show that but for the vaccines Lauren would not have had the injury, but also that the vaccines were a substantial factor in bringing about her injury and death. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

In essence, the special master is looking for a reputable medical explanation of a logical sequence of cause and effect (Grant, supra, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, supra, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen:

> Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.
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> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

Although the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), listed various criteria for federal district court judges to follow in their role as gatekeeper for the admission of scientific and medical evidence, such criteria are merely aides in evaluation, rather than prescriptions, for the Office of Special Masters. Even in federal district courts, "Daubert's list of specific factors neither necessarily nor exclusively applies . . . in every case . . . [and its] list of factors was meant to be helpful, not definitive." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141, 151 (1999).

In the Office of Special Masters, even the Federal Rules of Evidence are not required.[8] Invariably, consistent with the legislative intent in creating the Vaccine Program, the special masters admit most evidence. But see, Domeny v. Secretary, HHS, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999), aff'd, (Fed. Cl. May 25, 1999) (unpublished), aff'd, No. 99-5130 (Fed. Cir. Apr. 11, 2000) (rejecting proffer of dentist's testimony for diagnosis of a neuropathy).

As the Federal Circuit stated in Knudsen, supra, 35 F.3d at 548, "Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules." Thus, the task before the undersigned is not to delineate how petitioner's evidence does or does not satisfy the Daubert litany of support in peer-reviewed medical literature, concurrence among a majority of physicians in the field of hematology, and

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[8] CFC Rules, Vaccine Rule 8(b) Evidence. "In receiving evidence, the special master will not be bound by common law or statutory rules of evidence. The special master will consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties."

confirmative testing of methodology. Rather, the task is to determine medical probability based on the evidence before the undersigned in this particular case.

The undersigned has two highly qualified experts here who agree that Lauren had hemolytic anemia, but differ as to whether it was immune or autoimmune. Dr. Shapiro opined that her vaccinations on January 30, 1997 caused her immune hemolytic anemia, and that had the doctor at the Cleveland Clinic recognized on February 4, 1997 that her one plus hemoglobin in her urine was highly unusual, perhaps she could have been treated earlier and survived. On the other hand, Dr. Reaman opined that Lauren's fever the night of the vaccinations was due to a viral illness, not her vaccinations, and that her subsequent lowered fluid intake, irritability, and low-grade fever were also due to her viral illness. Additionally, he opined that when Lauren saw the doctor on February 4, 1997 with nasal congestion, that was also due to a viral illness, even though the doctor diagnosed her with a urinary tract infection, not an upper respiratory infection, and prescribed an antibiotic. Dr. Reaman did not think that her one plus hemoglobin in her urine meant anything significant.

Dr. Shapiro thought petitioner's exhibit 6, dealing with three children who had acute hemolytic anemia as a consequence of an immunological reaction to their DPT vaccinations, was right on point with Lauren's case because it indicates that DPT can cause an immune process resulting in hemolysis. Dr. Reaman disagreed, saying that petitioner's exhibit 6 did not deal with autoimmune hemolytic anemia, just hemolytic anemia, and therefore, was inapplicable to Lauren's case because she had AHA. The authors tested blood cells in the blood vessels, not in the liver and spleen, which are the loci for the activity of AHA.

The court agrees with Dr. Shapiro that the significance of petitioner's exhibit 6 is that DPT can cause the hemolytic process in vaccinees resulting in anemia. The Federal Circuit in Knudsen states that requiring "identification and proof of *specific* biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." 35 F.3d at 549 (emphasis added).

The court does not find Dr. Reaman's explanation of Lauren's condition persuasive. First, Dr. Reaman admits that fever post-DPT is quite common. For him to posit that Lauren's 104-degree fever the evening of her five vaccinations (DPT, HiB, polio) was due to a viral illness, and not to the DPT, is not persuasive. Mrs. Brown did complain to the doctor on the day of vaccinations that Lauren's fluid intake had decreased but, without more, it is difficult to reach Dr. Reaman's conclusion that this was the beginning of a viral illness. Even if it were, that would make this case similar to Herkert v. Secretary, HHS, 2000 WL 141263 (Fed. Cl. Jan. 19, 2000), No. 97-518V, in which the undersigned held that an acellular DPT was a substantial factor (as was cytomegalovirus) in causing a child's transverse myelitis.

Second, Dr. Reaman links all of Lauren's other symptoms–her subsequent lowered fluid intake, persistent low grade fever, irritability–to the same viral illness. She did not see a physician again for six days, yet Dr. Reaman posits that her mild nasal congestion when she saw the doctor on February 4, 1997 was another symptom of this pre-existing viral illness. Surely, the treating pediatrician could have diagnosed an upper respiratory infection based on all of the above symptoms if he had believed that is what Lauren had.[9] He obviously did not believe that

[9] The undersigned might add that if one includes the behavior that Mrs. Brown described in her affidavit (unresponsiveness, failure to smile, play, or fix visually, not holding the nipple

is what she had. He thought she had a urinary tract infection (which Dr. Reaman does not disagree with, but Dr. Shapiro does).

The court is most impressed with the continuity of symptoms from the time of vaccinations until Lauren's demise. It calls to mind the "relatively uninterrupted progression from vaccination... to death" that the Honorable Eric G. Bruggink discussed in a hypotonic-hyporesponsive death case. Allen v. Secretary, HHS, 24 Cl. Ct. 295, 296 (1991), appeal dismissed, No. 92-5028 (Fed. Cir. Feb. 19, 1992).

There is also legal precedent to hold that vaccines cause hemolytic anemia. See Elsperger v. Secretary, HHS, No. 90-3850, 1991 WL 255131 (Spec. Mstr. Cl. Ct. 1991) (respondent conceded petitioner's DT vaccine caused his hemolytic anemia). See also, Gall v. Secretary, HHS, No. 91-1641V (1999 WL 1179611 (Spec. Mstr. Fed. Cl. 1999) (DPT caused hemophagocytic lymphohistiocytosis [HLH] or familial hemophagocytic lymphohistiocytosis [FHL]). Contra, Cohen v. Secretary, HHS, No. 94-0353V, 1998 WL 408784 (Spec. Mstr. Fed. Cl. 1998).

The court finds petitioner's exhibit 6 supportive in the manner Dr. Shapiro stated: it shows that DPT can cause an immunological process resulting in acute hemolytic anemia. Dr. Reaman dispensed with the significance of petitioner's exhibit 6 because he said it does not deal with autoimmune hemolytic anemia. Dr. Reaman emphasized that tetanus and diphtheria antibodies adhering to red blood cells in the vessels differs from antibodies present in the spleen and liver in AHA. But the undersigned does not view the exhibit as unpersuasive because of that

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firmly, not gripping Mrs. Brown's finger tightly, not bouncing on her mother's lap, unusual shrill cry, inconsolability), one is most certainly not in the realm of a viral illness or a mere cold.

difference. As Dr. Shapiro testified, there are many immunologic processes resulting from vaccinations and this exhibit describes just one which resulted in acute hemolytic anemia. The authors themselves state that an immunological mechanism led to the children's anemia. That DPT vaccine caused acute hemolytic anemia in the three children described in the exhibit is supportive of Dr. Shapiro's opinion of causation in fact in this case.

The lack of epidemiologic evidence to show that vaccinations such as DPT, HiB, and/or polio cause AHA is not detrimental to petitioner's case. In Knudsen, supra, the Federal Circuit stated that evidence showing that viral infections more often cause encephalopathies than do vaccines was not proof in an individual case that a virus and not the vaccine was the cause of encephalopathy:

> The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and 0not caused by the DTP vaccine.

35 F.3d at 550.

The fact that Lauren's disease process is consistent with Dr. Shapiro's understanding of immune hemolytic anemia due to vaccination, buttressed by petitioner's exhibit 6 showing the manifestation of an immunologic process leading to acute hemolytic anemia as a consequence of DPT vaccination, is sufficient for petitioner to prevail in her case. She has provided a prima facie case of causation in fact that any or all of the vaccinations Lauren received January 30, 1997 caused in fact her acute hemolytic anemia and death. The statute provides that she receive $250,000.00 in compensation.

CONCLUSION

Petitioner is entitled to $250,000.00. A check shall be made payable to petitioner for this sum.

IT IS SO ORDERED.

Aug. 3, 2000
DATE

Laura D. Millman
Laura D. Millman
Special Master