In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. [redacted]V
October 23, 2009
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To be Published

JOHN and JANE DOE/51, as the Legal Representatives of their minor child, BABY DOE,	*	
Petitioners,	*	
v.	*	Entitlement; no logical sequence of cause and effect between a transient encephalopathy and failure to thrive, speech delay, fine motor delay, and social integration problems
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Andrew D. Downing, Tulsa, OK, for petitioners.
Michael P. Milmoe, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

[1] Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. Because of the personal nature of the material discussed as well as petitioners' prior motion to redact the transcript, the undersigned sua sponte redacts this decision as of this date.

Petitioners filed a petition on January 8, 2008, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that their daughter Baby Doe (hereinafter, "Baby Doe") suffered multiple seizures and paralysis in her lower extremities within one hour of receiving acellular DTP, HiB, and hepatitis B vaccines. Petition, p. 1. During a July 2, 2008 telephonic status conference, petitioners' counsel stated that petitioners were alleging encephalopathy, but not a Table encephalopathy.

A hearing was held on November 20, 2008. Testifying for petitioners were Mrs. Doe, treating pediatrician Dr. Marc A. Hultquist, registered nurse Blanche D. Coleman, expert pediatric neurologist Dr. G. Steven Miller, expert internist Dr. Richard Hastings, and Mr. Doe. Testifying for respondent was expert pediatric neurologist Dr. Michael E. Cohen.

The issue here is sequelae and whether there is a logical sequence of cause and effect between a transient encephalopathy due to fever and pain from four vaccinations, and failure to thrive, speech delay, fine motor delay, and social integration problems. Respondent admits that Baby Doe had a reaction to her vaccinations, but asserts it was brief. Petitioners allege a much more serious reaction with permanent sequelae. Petitioners changed their allegation from vaccine-caused seizures to causation in fact encephalopathy with permanent sequelae.

FACTS

Baby Doe was born on August 17, 2004. She was a large baby and Mrs. Doe had polyhydramnios.[2] Mrs. Doe asked for induction because she and her family were moving in the very near future. The baby was found to have weighed 8 pounds two weeks earlier. Med. recs.

[2] Polyhydramnios is an excess of amniotic fluid. Dorland's Illustrated Medical Dictionary, 31st ed. (2003) at 1480.

at Ex. 2, p. 10. After induction failed, Baby Doe was born by Caesarean and Mrs. Doe was voluntarily sterilized. *Id.* Mrs. Doe had a history of having previously lost a fetus. Med. recs. at Ex. 2, p. 14. She had three other children (all boys) who were two, four, and six years old.

On October 27, 2004, Baby Doe was taken to the family practice at Reynolds Army Community Hospital in Ft. Sill, OK, and saw Dr. David R. Anderson. Med. recs. at Ex. 4, p. 85. She was 23 ½ inches tall and weighed 5.5 kg. or 12 and 1/4 pounds. *Id.* She had a history of atrial septal defect.[3] *Id.* She was two months and 10 days old, and late two weeks for her two-month well baby visit. *Id.* A take-home sheet for the Two Month Well Baby Check up states that Baby Doe weighed 12.1 pounds, was 23 ½" tall, and had a head circumference of 15 ½." Med. recs. at Ex. 5, p. 87.

On January 12, 2005, when Baby Doe was four months old, she received her second series of acellular DPT, HiB, hepatitis B, and inactivated polio vaccines. Med. recs. at Ex. 4, p. 84 (this page is a record of the vaccinations that Dr. Marc A. Hultquist filed as part of a VAERS[4] report; petitioners did not file the four-month well-baby visit record).

On January 13, 2005, at 11:13 a.m., Mr. and Mrs. Doe took Baby Doe to Reynolds Army Hospital Emergency Room where she saw Dr. Lawrence Kaplan. Med. recs. at Ex. 5, p. 92. The complaint was possible reaction to shots. *Id.* Baby Doe had received her immunizations the day before and, the prior night, developed fever and was given Tylenol. The fever remained. She

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[3] Atrial septal defect is a congenital cardiac anomaly "in which there is persistent patency of the atrial septum due to failure of fusion between either the septum secundum or the septum primum and the endocardial cushions." Dorland's Illustrated Medical Dictionary, 31st ed. (203) at 479-80.

[4] VAERS stands for Vaccine Adverse Event Reporting System.

was noted not to be moving her lower extremities at the hips. She had a temperature of 101.2° in the ER. *Id.* Mrs. Doe gave the history to Dr. Kaplan. The staff made three failed attempts to insert an IV. *Id.* Baby Doe was referred to Dr. Marc A. Hultquist, a pediatrician, in the emergency room who decided to admit her to the hospital. Med. recs. at Ex. 5, p. 91.

Dr. Hultquist wrote a History and Physical on January 13, 2005 at 2:47 p.m. Med. recs. at Ex. 5, p. 90. The admitting diagnosis was occult bacteremia. Baby Doe had been well until the day before when she received her second series of vaccinations. She tolerated the first series okay when she was two months old. An hour after arriving home from the prior day's vaccinations, she had reduced leg movements. That evening, she had a fever of 100.3.° Mrs. Doe telephoned the emergency room that evening which tried to reassure her and she stayed home. *Id.* This morning, Mrs. Doe brought Baby Doe to the ER where they recognized that she had reduced movement of her legs. Mrs. Doe said that Baby Doe usually was sucking on her toes and rolling around, but she stopped doing those things after the vaccinations. Baby Doe vomited once the prior night and was not feeding as well as normally. She had only one wet diaper that day. One of Baby Doe's brothers was having headaches without a sore throat, fever, or runny nose. In addition, he was frequently urinating and Mrs. Doe described the urine as cloudy. *Id.* The family moved from Colorado about four weeks after Baby Doe's birth. *Id.*

Baby Doe had 101° temperature in the emergency room. Med. recs. at Ex. 5, p. 91. She weighed 7 kg. or 15.4 pounds which was approximately the 75th percentile for her age. Dr. Hultquist physically examined Baby Doe. She had a normal suck. Her upper extremities were normal with free range of motion. Her lower extremities mostly lay in a normal anatomical position, slightly bent and mostly extended. Baby Doe would draw up her legs if prompted. If

Baby Doe's legs were lifted up, she would sometimes show more active range of motion. She did not seem overly irritable with the hip exam, which showed no obvious hip clicks or gross movement. She did become fussier with the lower extremity exam. There was no obvious clonus or other abnormalities. Neurologically, she had good suck reflex and good tone in the upper extremities. She seemed to have good tone in the lower extremities but was not always actively fighting the exam. *Id.*

Dr. Hultquist planned to admit her to the hospital and put her on Rocephin,[5] IV fluids for support. He considered whether she might have Guillain-Barré syndrome "but it seems fairly soon after the immunizations to manifest itself." *Id.* Baby Doe had an ultrasound of her hips which ruled out any possible septic arthritis. *Id.* and med. recs. at Ex. 5, p. 99.

A CT scan of Baby Doe's head on January 14, 2005 was normal. Med. recs. at Ex. 5, p. 101.

Baby Doe's head circumference was in the 50th percentile, measuring 16 and 1/8 inches. Med. recs. at Ex. 5, p. 102. Her length was 27 inches which put her above the 95th percentile. *Id.* Her weight was 7.04 kg. (or 15 ½ pounds) which put her in the 90th percentile. *Id.*

Two hours after Dr. Hultquist met Baby Doe in the emergency room, he admitted her to a ward at 2:44 p.m. Med. recs. at Ex. 5, p. 104. Dr. Michael F. Davis, Dr. Hultquist's partner, took over care of Baby Doe. Med. recs. at Ex. 5, p. 110.

A Pediatric Admission Assessment dated January 13, 2005 states that Baby Doe's behavior was appropriate. Med. recs. at Ex. 5, p. 105. She was calm with her mother and father.

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[5] Rocephin is ceftriaxone sodium, an antibiotic. Dorland's Illustrated Medical Dictionary, 31st ed. (2003) at 1639, 315.

She cried in the treatment room for venipunctures and the feeding tube. *Id.* She had loose stools, and had used five to seven diapers in the last 24 hours. Baby Doe's normal diet was breast milk four times daily and fruits and rice twice daily. Her temperature was 98.° *Id.* Mrs. Doe was very concerned about further vaccinations. Med. recs. at Ex. 5, p. 107.

A Past Medical/Social History form dated January 13, 2005 states that Baby Doe was eating breast milk, rice cereal, and fruits before her hospitalization. Med. recs. at Ex. 5, p. 117. Her primary care manager was Dr. Ortiz. *Id.*

A patient problem list dated January 13, 2005 notes that Baby Doe had dehydration related to her fever and decreased appetite as evidenced by tearless crying. The goal was to hydrate her. Med. recs. at Ex. 5, p. 228.

On January 13, 2005, a patient assessment review of systems sheet notes for 8:00 p.m. that Baby Doe was awake and active, and that her mother said she was moving her lower extremities in spurts. Med. recs. at Ex. 5, p. 127. Baby Doe's lungs were clear bilaterally to auscultation. She had a nasogastral tube for 40 cc of Pedialyte[6] and was breast feeding. She had one wet diaper. *Id.*

The Progress Notes for January 13, 2005 state that Baby Doe was admitted from the ER and had immunizations on January 12, 2005 at noon. Her parents state that 30 minutes later, she started running a temperature and became lethargic. Today, Baby Doe was not moving her lower extremities. A feeding tube was inserted with Pedialyte for rehydration purposes. Med. recs. at Ex. 5, p. 108.

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[6] Pedialyte is a mixture of potassium, sodium, and chloride (electrolytes) as well as glucose and water to help the body absorb liquid during episodes of diarrhea and vomiting. www.pedialyte.com.

At 5:40 a.m., Baby Doe's temperature was 100.9.° She was wrapped in a blanket from home. When the blanket was removed, her temperature was rechecked at 6:30 a.m. and was 101.1.° She received Tylenol and Dr. Hultquist was notified. Med. recs. at Ex. 5, p. 113.

Later on, Baby Doe was sleeping in the crib. Her color was normal and her respiration easy and even. Baby Doe woke easily to her mother's voice. Baby Doe was drooling and her mother reported that her teeth were coming in. Her anterior and posterior fontanelles were soft and flat. Her skin was warm and dry. *Id.* Baby Doe turned her head toward the direction of noises both to the right and left side without difficulty. She reached out to grab objects without difficulty. She had equal grip strength bilaterally and moved her left leg without difficulty. Her right leg had less movement than her left leg. She had equal palmar grasp bilaterally. She moved her toes bilaterally without difficulty. The right leg was in a relaxed position. Baby Doe smiled at her mother and made cooing sounds. *Id.*

The next note states that Baby Doe had three soiled diapers throughout the nursing shift. Two diapers contained wet urine and one was soiled with feces. Baby Doe had 12 oz of Pedialyte and two intermittent breast feedings. She was awake and active. Med. recs. at Ex. 5, p. 108. When tactilely stimulated, Baby Doe's right leg was limber. Med. recs. at Ex. 5, p. 108-09. She allowed the right leg to be picked up and dropped without reaction. When the right leg was touched, she responded by wiggling her toes. Her arms were turned into her chest and her hands curled up on the tip of her chest. Baby Doe recoiled her left leg somewhat to her body. She did reach out for her mother and toys. Her mother stated that Baby Doe was not acting herself and was very stiff. She was very concerned about Baby Doe's condition. Dr. Hultquist was notified. Baby Doe's temperature was 99.8° at 1:30, and 100.9° at 1:50. Dr. Hultquist was

notified and Tylenol was ordered. Dr. Hultquist spoke to Mrs. Doe for about 40 minutes and then to the nurse concerning Baby Doe's care and condition. Med. recs. at Ex. 5, p. 109.

On January 14, 2005, a patient activities flow sheet notes that Baby Doe breastfed well and completely at breakfast, lunch, and dinner for a total of 86 minutes spent breast feeding. Med. recs. at Ex. 5, p. 128. Her temperatures that day were 99.4,° 100.9,° 101.1,° 99.9,° 98.9,° 99.8,° and 98.2.° *Id.*

A patient assessment review of systems for January 14, 2005 states that Baby Doe was awake and alert with her eyes open. Med. recs. at Ex. 5, p. 129. Her anterior and posterior fontanelles were soft and flat. She moved her head toward the direction of noises without difficulty and moved her left leg without difficulty. Her right leg moved less. She reached out for things with an equal grip and an equal palmar grasp, and moved her right foot and toes on her right foot without difficulty. *Id.* Baby Doe had no nausea or vomiting and tolerated breast feeding. She had a wet diaper. She moved her lower extremities without difficulty. She turned her head to the right and left without difficulty. She had normal activity with her left leg and less movement with her right leg. Baby Doe smiled at her mother and made cooing noises. She did not have flaccidity. *Id.*

On January 14, 2005, the Progress Notes continue with Dr. Davis's notation that he saw Baby Doe and she was awake and alert. Med. recs. at Ex. 5, p. 110. She breastfed well overnight without vomiting or diarrhea. She received Rocephin. Dr. Davis examined Baby Doe and noted reactive responses in her upper and lower extremities. He suspected she had a reaction to her immunizations or a viral illness. He recommended ad lib breast feeding and removal of the nasogastric tube. She would use Tylenol for fever at or above 101.° *Id.*

On January 14, 2005, no rigidity was noted at that time. Mrs. Doe was at the crib side with the call light in reach. Baby Doe's axillary temperature was 98.7°. Mrs. Doe was breast feeding Baby Doe at that time. Later on, Baby Doe's axillary temperature was 99.7° which was reported to Dr. Davis. Med. recs. at Ex. 5, p. 112. Dr. Davis said he would be in for a thorough assessment. Later, Baby Doe's axillary temperature was 99.4° and she was moving her right leg more than earlier that morning. The nurse would continue to monitor. *Id.* Later on, Baby Doe was drooling and fussy. She got more fussy with touching of the right leg. She received Tylenol. The mother held Baby Doe in an upright position. Baby Doe had no difficulty swallowing and had good head control. Baby Doe had a loose and brown stool which was noted as normal for breast feeding. She had urinated in her first diaper that morning before having the bowel movement. It was clear in quantity and in a sufficient amount. The stool came with the second diaper. No odor was noted with both diapers. *Id.* Later, the nasogastric tube was discontinued. Baby Doe was consolable. She had no respiratory distress or fever. Later on, the mother was sponge bathing Baby Doe. No distress was noted. *Id.*

On January 14, 2005, a pediatric nutritional screen was filled out for Baby Doe. Mec. recs. at Ex. 3, p. 78. Baby Doe weighed 7.04 kg[7] (or 15 ½ pounds) which put her in the 90th percentile for weight. She measured 27 inches, which put her above the 95th percentile for height. *Id.* Under the category "nausea/vomiting/diarrhea," the person filling out the form wrote "no." *Id.* The person whose signature looks like Athos Ruchnevan, wrote that Baby Doe had a fair appetite. She had no chewing/swallowing or suck/swallow coordination problems. *Id.* For

[7] A kilogram equals 2.204623 pounds. Dorland's Illlustrated Medical Dictionary, 31st ed. (2003) at 979. Baby Doe's weight of 7.04 kg equals 15 ½ pounds on January 13, 2005.

diagnosis, he put rule out sepsis. Baby Doe's diet at home was breast feeding. Baby Doe was a low nutrition risk. She was to be re-screened in seven days. *Id.*

On January 15, 2005, the patient activities flow sheet showed temperature of 98° at 2:00 a.m., 98.1° at 6:00 a.m., and 97.5° at 10:00 a.m. Med. recs. at Ex. 5, p. 130. Baby Doe breastfed well for breakfast and lunch. *Id.*

The patient assessment review of systems states Baby Doe's anterior and posterior fontanelles were soft and flat. She turned her head toward noises right and left without difficulty. She had equal right and left hand grips and palmar grasps. She had multiple wet diapers. Baby Doe moved her extremities without difficulty up and down. She had a mild rash on her neck and upper back. She was smiling and making cooing sounds. Med. recs. at Ex. 5, p. 131.

On January 15, 2005, at 8:30, the baby was sleeping quietly, breathing easily and evenly, with normal color. The mother was at crib side with the call light in reach. The mother denied any needs or distress. Med. recs. at Ex. 5, p. 111.

Dr. Davis returned at 11:30 a.m. and wrote that Baby Doe did well overnight without fever. She fed well. Her mother reported that Baby Doe had improved activity and was not in acute distress. *Id.* Baby Doe had a mottled erythematous rash on her trunk and neck. He suspected a viral syndrome or a normal reaction to her immunizations with muscle soreness. He recommended that Baby Doe be discharged to her home. *Id.*

A summary sheet for January 15, 2005 states that the principal diagnosis for Baby Doe was "reaction to diphtheria and tetanus toxoids with acellular pertussis (DTaP) and inactive

poliovirus (IPV) immunizations versus viral syndrome." Med. recs. at Ex. 5, p. 88. The second page of this form states reaction to DTaP and IPV immunizations. Med. recs. at Ex. 5, p. 89.

On January 18, 2005, Dr. Hultquist saw Baby Doe for a follow up to her adverse reaction to vaccine. Med. recs. at Ex. 5, p. 132. Baby Doe's temperature was 96,° her height was 61 cm, her weight was 7.08 kg (15.6 pounds) or .04 more kg than when she was discharged from the hospital three days before. *Id.* Baby Doe was not rolling over yet, but she was moving her extremities much better. Previously, she had not raised her legs and acted as if she refused to move them. Dr. Hultquist found that Baby Doe had no systemic symptoms. *Id.* The source of Dr. Hultquist's information was Mrs. Doe. Baby Doe had not had fever for two days. She had no neurological symptoms. *Id.* Dr. Hultquist wrote that Baby Doe was awake, alert, oriented, appeared well-developed, well-nourished, well-hydrated, healthy, active, and in no acute distress. Med. recs. at Ex. 5, p. 133. Dr. Hultquist tested all of Baby Doe's systems: head, eyes, ears, nose, oral cavity, pharynx, neck, lymph nodes, lungs, cardiovascular, back abdomen, rectum, skin, hair, musculoskeletal, and neurological, and found them all normal. *Id.* Dr. Hultquist's assessment was fever as symptom: "Adverse reaction to immunizations is the most likely explanation for her fever and not moving her legs." Med. recs. at Ex. A, p. 211. Dr. Hultquist spoke to Mrs. Doe about immunizations and she said she would feel much more comfortable waiting until one year for further vaccination. Dr. Hultquist suggested that the vaccinations could be administered one at a time so that Mrs. Doe would be more likely to know what the problem was. He discussed with Mrs. Doe that there was a possibility that Baby Doe

could have had a urinary tract infection. White blood cells showed up on testing of Baby Doe's urine which could indicate pyuria.[8] *Id.*

On January 21, 2005, at 5:00 p.m., Dr. Hultquist filled out a Vaccine Adverse Event Reporting System (VAERS) form. Med. recs. at Ex. 4, p. 81. The vaccine was administered by Blanche Coleman on January 12, 2005 at 3:00 p.m. Within an hour, Baby Doe became fussy and then developed a fever up to 103.°[9] She stopped using her legs voluntarily whereas she normally put her feet in her mouth. She was not even flexing her hips much. *Id.* A head CT scan was reported as normal. Dr. Hultquist wrote on the VAERS form that Baby Doe recovered. *Id.* Baby Doe had received DPaT and inactivated polio virus vaccines in her left leg intramuscularly and Hib and Hepatitis B vaccines (Comvax) in her right leg intramuscularly. These were her second series of vaccinations. Med. recs. at Ex. 4, p. 82. Baby Doe had a pre-existing atrial septal defect. *Id.* On an additional page, Dr. Hultquist wrote that Baby Doe did not have a life threatening illness and had recovered. For "current illness," he wrote "None." Med. recs. at Ex. 4, p. 84. Baby Doe's former symptoms were agitation, fever, hypokinesia,[10] and abnormal pain. *Id.*

Baby Doe did not see a doctor again for six months.

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[8] Pyuria is "the presence of pus in the urine." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1555.

[9] Dr. Hultquist testified that even though Baby Doe's temperature before she was brought to the hospital on January 13, 2005 was listed in the ER notes as 100.3 degrees, he remembered that Mrs. Doe had told him that it was 103 degrees and put that temperature on the VAERS form..

[10] Hypokinesia is "abnormally decreased mobility; abnormally decreased motor function or activity." Dorland's Illustrated Medical Dictionary, 31st ed. (2003) at 895.

On July 20, 2005, Mrs. Doe brought Baby Doe, at the age of 11 months, to see Dr. Janice L. Gibbons, another pediatrician at Reynolds. This was in lieu of her six-month well baby check-up. Med. recs. at Ex. 5, p. 134. Mrs. Doe told Dr. Gibbons that Baby Doe had a severe adverse reaction to her four-month vaccinations with a fever to 104.5° and flaccid paralysis. She told Dr. Gibbons that Baby Doe had been hospitalized for four days. *Id.* Mrs. Doe said that Baby Doe had no difficulty feeding. She was breast fed. Baby Doe's weight on July 20, 2005 was in the 5th percentile, her height in the 50th percentile, and her head circumference in the 75th percentile. Dr. Gibbons diagnosed Baby Doe with failure to gain weight and failure to thrive[11] as well as poor growth. *Id.* On examination, Baby Doe appeared alert, well-hydrated, and healthy. Her fontanelle was not bulging, sunken, or tense. *Id.* Dr. Gibbons tested all of Baby Doe's systems and found them normal. Med. recs. at Ex. 5, p. 135. Her muscle tone was normal. Per Baby Doe's milestone assessment, Mrs. Doe told Dr. Gibbons that, at nine months, Baby Doe fed herself with her fingers, responded to her own name, had an ability to sit independently, crawl/creep, pull to a standing position, and play patty-cake, and she was shy with strangers. *Id.* At two months, Baby Doe held her head steady in an upright position. Dr. Gibbons reviewed the immunization schedule with Mrs. Doe since Baby Doe had had only her two- and four-month immunizations. She also discussed with Mrs. Doe using vitamins, solid foods, a cup, finger foods, proper milk quantity, and her concerns about Baby Doe's eating, teething, and Mrs. Doe's talking to Baby Doe, as well as the importance of cuddling her. *Id.* Dr. Gibbons noted that Baby Doe was at the 90th percentile for weight at four months and was now in the 5th percentile. *Id.*

[11] Failure to thrive is "a condition in which an infant's weight gain and growth are far below usual levels for age." Stedman's Medical Dictionary, 27th ed. (2000) at 646.

Dr. Gibbons sent Baby Doe for lab tests on the next day and wanted to see Baby Doe in two weeks for a weight check. She wanted Mrs. Doe to keep a log of all Baby Doe's intake. (No intake log was filed in this case.) Med. recs. at Ex. 5, p. 136. Dr. Gibbons spent 30 minutes with Mrs. Doe and Baby Doe, 50% of that time used to counsel Mrs. Doe. *Id.*

On July 20, 2005, at 4:46 p.m., Dr. Gibbons requested a nutritional consult from Tara S. Wamsley. Dr. Gibbons asked Ms Wamsley to evaluate Baby Doe's diet and to counsel Mrs. Doe because of Baby Doe's failure to thrive. Baby Doe had fallen from the 90th percentile in weight to the 5th percentile over six months.

On July 21, 2005, Baby Doe saw registered nurse Dellas Glynn because she fell and had a red bruise on the top of her head. Med. recs. at Ex. 5, p. 138. Mrs. Doe told Nurse Glynn that Baby Doe had been playing at the activity table in the waiting room, fell forward, and bumped her head. She cried but was easily consoled. *Id.* Baby Doe was awake, alert, active, and in no acute distress. She had a contusion on the top of her head with no breakage of skin or drainage. *Id.* Nurse Glynn discussed closer monitoring of Baby Doe and said to apply ice to the site as soon as she arrived home. Med. recs. at Ex. 5, p. 139.

On July 22, 2005, Dr. Hultquist phoned Mrs. Doe to discuss the lab test results. Med. recs. at Ex, 5, p. 140. Baby Doe had a high TSH[12] reading of 5.48 (normal range is 0.49-4.67) which deals with thyroid. *Id.* Dr. Hultquist told Mrs. Doe that the results looked okay and did not point to anything specific. She told Dr. Hultquist that she had two first cousins with cystic fibrosis. Dr. Hultquist arranged for a CF test and asked Mrs. Doe to switch Baby Doe to

[12] TSH stands for thyroid-stimulating hormone. Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1958.

Nutramigen for the time being and to mix three scoops with 5 oz of formula. He asked her to return the next week. Med. recs. at Ex. 5, p. 141. Mrs. Doe did not bring Baby Doe back the next week as Dr. Hultquist (and previously Dr. Gibbons) requested, but waited until two months later bring Baby Doe back.

On July 28, 2005, Dr. Mohammad G. Soud responded to Mrs. Doe's telephone call regarding a question about the formula. Baby Doe had not been drinking the Nutramigen for three days. Mrs. Doe was giving her stored breast milk. Dr. Soud told Mrs. Doe to mix ½ the breast milk and ½ the Nutramigen for a day, and then 1/4 of the breast milk and 3/4 of the Nutramigen for another day until she ran out of breast milk. Then she should give Baby Doe only Nutramigen. If Baby Doe refused it, they would start Baby Doe on another formula. Mrs. Doe reported that Baby Doe was not acting sick at all. Med. recs. at Ex. 5, p. 143.

On August 1, 2005, Dr. Janice Gibbons telephoned Mrs. Doe because Baby Doe needed a weight follow-up and Mrs. Doe had not brought Baby Doe in as the doctors had requested. Med. recs. at Ex. 5, p. 144. She called Mrs. Doe to check on Baby Doe and see when they could come in for a weight check. No one was home and she left a message to call the clinic. *Id.* It took seven and one-half weeks for Mrs. Doe to return Dr. Gibbons' phone call. On September 22, 2005, she left a phone message for Dr. Hultquist. Med. recs. at Ex. 5, p. 145. She came in for a clinic visit on September 23, 2005. *Id.*

On September 23, 2005, two months after her last visit, Baby Doe saw Dr. Hultquist. Med. recs. at Ex. 5, p. 146. Both of Baby Doe's parents accompanied Baby Doe to this examination. Baby Doe's height was 72 cm and her weight 8.56 kg. or 18.8 pounds. Baby Doe was one year and one month old. She had no systemic symptoms. *Id.* Baby Doe's father was on

active duty and would be deploying in two months. *Id.* Dr. Hultquist did a complete physical examination of Baby Doe. She had diarrhea throughout the day which was watery, but not bloody. Med. recs. at Ex. 5, p. 147. She had no neurological symptoms, was awake, alert, appeared well-nourished, well-hydrated, healthy, active, and in no acute distress. *Id.* Her neck had no demonstrated decrease in suppleness. Dr. Hultquist told Baby Doe's parents that he wanted Baby Doe brought back the next week before he ordered lab tests. He wanted to consider the proper course of action. He had an x-ray done of Baby Doe's abdomen to rule out an obstructive pattern that might suggest bowel stenosis. Dr. Hultquist's impression was that Baby Doe had chronic diarrhea. He wanted to rule out an obstructive pattern that might suggest bowel stenosis. *Id.* Mrs. Doe did not bring Baby Doe back one week later as Dr. Hultquist requested. Instead, she waited one month to return.

One month later, on October 20, 2005, Baby Doe saw Dr. Hultquist. Her weight was 8.98 kg. or 19.7 pounds. Med. recs. at Ex, 5, p. 149. Mrs. Doe and her mother were present with Baby Doe. Med. recs. at Ex. 5, p. 150. The purpose of the visit was to follow-up with Baby Doe's failure to thrive. Mrs. Doe was concerned that the Pediatric Clinic thought she was neglecting Baby Doe specifically because of Baby Doe's diagnosis of failure to thrive. Dr. Hultquist explained to Mrs. Doe and her mother that he did really not have any concern about her neglecting Baby Doe. He just wanted to make sure that they were not missing a problem that could be corrected. Med. recs. at Ex. 5, p. 149. Mrs. Doe and her mother told Dr. Hultquist that Baby Doe had a normal appetite, no vomiting, no abdominal pain, and no diarrhea. Her stools had been firming up over the prior several months. Med. recs. at Ex. 5, p. 150. She had no neurological symptoms. She was awake, alert, well-developed, well-nourished, well-hydrated,

healthy appearing, active, and in no acute distress. Dr. Hultquist said they would repeat the TSH, CBC (complete blood count), chem 7, and C.P. tests. They were also going to order a test for cystic fibrosis, and continue to monitor Baby Doe. *Id.*

On October 21, 2005, Mrs. Doe telephoned Dr. Hultquist to find out where she was supposed to go for the tests. Med. recs. at Ex. 5, p. 152.

On October 25, 2005, Mrs. Doe brought a stool sample in for the labs ordered. Med. recs. at Ex. 5, p. 151.

In October 2005, at the age of 14 months, Baby Doe's weight was between the 10th and the 25th percentiles. Med. recs. at Ex. 5, p. 102. There are no medical notes for November.

On December 6, 2005, Dr. Hultquist telephoned Mrs. Doe to have her bring Baby Doe in for a blood draw for DNA analysis for cystic fibrosis. Med. recs. at Ex, 5, p. 153.

On December 21, 2005, Dr. Jack H. Lich reported that Baby Doe's test result was positive for her being a carrier of cystic fibrosis. Med. recs. at Ex. 5, p. 155.

On December 29, 2005, Dr. Hultquist referred Baby Doe to the pediatric gastroenterology clinic. Med. recs. at Ex. 5, p. 153.

On January 9, 2006, Dr. Hultquist was advised that Mrs. Doe had telephoned. Baby Doe was seen in the ER and Mrs. Doe was told to call for a follow-up appointment. Baby Doe was tested for respiratory synctycial virus and the test result was negative. Med. recs. at Ex. 5, p. 156. Baby Doe had a chest x-ray done at the ER on January 9, 2006 at 1:22 a.m. because of shortness of breath and congestion. Med. recs. at Ex. 5, p. 157. Her heart and lungs were normal. Her pleural spaces were dry. *Id.*

On January 10, 2006, Dr. Hultquist noted in the records that he attempted to contact Mrs. Doe three times and got a message that the number was disconnected. *Id.*

On January 11, 2006, Mrs. Doe called Dr. Hultquist. Med. recs. at Ex. 5, p. 159. Dr. Hultquist notes that Baby Doe was still having some coughing. He scheduled her to see Dr. Gibbons on January 12, 2006. Med. recs. at Ex. 5, p. 160.

On January 12, 2006, Baby Doe saw Dr. Gibbons for her cough. Med. recs. at Ex. 5, p. 161. Her weight was 9.58 kg. or 21.12 pounds. She was one year and four months old. Baby Doe had had a cough for four days and was seen in the emergency department three days earlier. She was started on Albuterol and Zithromax. Her symptoms improved slightly, but she still had a mild cough at night. Albuterol did not seem to be helping. Mrs. Doe was concerned because Baby Doe was undergoing a work-up for cystic fibrosis due to her failure to thrive. Her initial sweat test was negative, but her cystic fibrosis carrier screen was positive. *Id.* Baby Doe had a cough but no wheezing, fever, earache, nasal discharge, nasal passage blockage, chest pain, or discomfort. Med. recs. at Ex. 5, p. 162. Her appetite was not decreased and she had no vomiting or abdominal pain. She had rhinorrhea. She had normal movement of all extremities. *Id.* Dr. Gibbons diagnosed Baby Doe with a cough and told Mrs. Doe to go ahead with cystic fibrosis testing since this appeared to be just a viral upper respiratory infection and cough. They would continue to follow Baby Doe for failure to thrive and cystic fibrosis results. Med. recs. at Ex. 5, p. 163. Baby Doe was put on Robitussin. *Id.*

On February 6, 2006, Mrs. Doe brought Baby Doe and her three-year-old son Aidan to a Targeted Case management person named Lorna Thompson to get a referral for Baby Doe to Sooner Start for services. Med. recs. at p. 217. Mrs. Doe was familiar with the program because

Aidan was enrolled and received services almost a year previously. *Id.* Mrs. Doe told Ms. Thompson that Baby Doe had recently been diagnosed with failure to thrive because she could not maintain her weight. Mrs. Doe stated that at four months of age, Baby Doe had an adverse reaction to vaccination that caused seizures, breathing problems, and other physical complications. Ms. Thompson recalled that event as Mrs. Doe told her and Connie Blose that she thought Baby Doe was going to die from the reaction. Mrs. Doe stated that Rene's development began to deteriorate slowly from the reaction to now. Mrs. Doe stated that Baby Doe was in a constant state of agitation and cried all the time and could not be separated from Mrs. Doe. *Id.* Mrs. Doe stated that the problems with Baby Doe caused a separation between her and her husband prior to his deployment to Iraq. Mr. Doe was returning in a few weeks for a two-week stay and she was apprehensive about his return. They were undergoing counseling from her minister at church. Ms. Thompson provided Mrs. Doe with OASIS for respite for five hours per week of free day care to the family for Baby Doe but Mrs. Doe said that Baby Doe had had no further immunizations and day care would not take her. Ms. Thompson provided Mrs. Doe with a website of the Oklahoma Family Network to seek some parent to parent mentorship. She scheduled an initial family interview for February 8, 2006 in the Brewer home. *Id.* Baby Doe's three brothers are Blake (born in 1998), Code (born in 2000), and Aidan (born in 2002). Med. recs. at p. 226.

An undated Referral/Family Interview on an Oklahoma form states that Baby Doe at four months had an adverse reaction to vaccination consisting of respiratory problems, seizures, depressed system, and a nearly fatal reaction. Med. recs. at p. 227. She had been experiencing deteriorating health since that time. She had a current diagnosis at 12 months of age of failure to

thrive. She had negative results for celiac disease and a normal MRI. She was negative for cystic fibrosis but positive for a cystic fibrosis gene. *Id.* All her blood tests and bone scans were negative. Her current weight was 20 pounds 4 ounces. *Id.* Follow-up actions noted constant crying/irritability, lack of language, and excessive clinginess to Mrs. Doe. Med. recs. at p. 229.

On February 8, 2006, Lora Thompson from SoonerStart Early Intervention paid a visit to Baby Doe and Mrs. Doe. Med. recs. at p. 281. Baby Doe was very clinging of her mother. She cried most of the visit when her mother was not attending her. Lorna Thompson, resource coordinator, discussed respite care, continued counseling with Mrs. Doe's minister, scheduling an audio screening, a possible medical follow-up for blood tests to determine Baby Doe's lead and mercury levels, and a repeat CT scan and MRI. Med. recs. at p. 282. Baby Doe was constantly irritable when awake. She slept at various times during the day for 90 minutes or more. Med. recs. at p. 289.

On February 9, 2006, Mrs. Doe filled out an 18 Month Questionnaire (ASQ stands for Ages and Stages Questionnaire). Med. recs. at p. 230. Lorna Thompson assisted her. SoonerStart was the administering program or provider. *Id.* Baby Doe did not have any words at all and was not processing commands. She followed simple directions with gestures. Med. recs. at p. 231. Baby Doe could walk, climb, and pick up an object from the floor. Med. recs. at p. 232. Mrs. Doe thought Baby Doe walked, ran, and climbed like other toddlers. Med. recs. at p. 233. Baby Doe had failure to thrive of no known cause. She had mental impairment due to vaccinations. Med. recs. at p. 234. Baby Doe looked at her mother when she talked to her. Med. recs. at p. 237. Baby Doe sometimes laughed or smiled when her mother played with her. Baby Doe's body was relaxed most of the time. When upset, Baby Doe could calm down within

15 minutes most of the time. *Id.* Sometimes, Baby Doe had tantrums for long periods of time. *Id.* Baby Doe rarely or never had eating problems. Med. recs. at p. 238. Baby Doe engaged sometimes in repetitive spinning. *Id.* She had some loose stools. *Id.* Mrs. Doe wrote that most people felt that Baby Doe was slow in development and growth. She was an average 9-12 month old. Med. recs. at p. 240. She had no concerns about Baby Doe's sleeping. She loved to sleep. *Id.* Mrs. Doe was concerned about Baby Doe's failure to thrive. Baby Doe was easily aggravated by noisy toys, movement, touching of her body. She hated massage, lotion rubs, and touching of her back. She did not like grass or dirt on her hands. She loved the slide but hated the trampoline. *Id.* What Mrs. Doe liked most about Baby Doe was that she could dress her in pink. Baby Doe was laid back and quiet. *Id.*

On February 10, 2006, SoonerStart Early Intervention had a scheduled appointment with Baby Doe and Mrs. Doe at the health department to do a hearing screening. She had passed on the right side, but would not allow screening on that side. She had a flat tympanic membrane on the left. Temple K. Stewart recommended referral to a physician. Med. recs. at p. 262.

On February 15, 2006, the SoonerStart Early Intervention program had a discussion with Mrs. Doe who was concerned with Baby Doe's irritability and chronic crying. Med. recs. at p. 280.

On February 23, 2006, Baby Doe saw a pediatric gastroenterologist. (There is a slash and initials on a handwritten page that is difficult to read.) The doctor wrote that Baby Doe weighed 23 pounds. Sgt. Doe had been in Iraq since November. Mrs. Doe stated she first noted Baby Doe dropping weight when she was five months old. Mrs. Doe told the doctor that Baby Doe had seizures after her immunizations and paralysis, and poor growth since. Baby Doe

weighed 21 pounds on January 10, 2006. Mrs. Doe attributed lack of growth to the immunizations. At 12 months, Baby Doe had fallen off the growth curve. She was breastfed for 12 months, given Nutramigen up to 15 months, had a weight above the 5th percentile, then was fed whole milk. Currently, Baby Doe was taking whole milk, one Carnation instant breakfast shake, and eating solids. She had periods of loose stools, six to seven times a day. Baby Doe had a delay in speech. Med. recs. at Ex. 5, p. 164.

On February 28, 2006, SoonerStart Early Intervention per Kris Fanning visited Baby Doe and Mrs. Doe. Mrs. Doe was concerned with Baby Doe's speech. Ms. Fanning suggested pointing and naming pictures in books. Med. recs. at Ex. C, p. 261.

On March 6, 2006, SoonerStart Early Intervention per Kris Fanning visited Baby Doe and Mrs. Doe for a scheduled visit. Med. recs. at Ex. C, p. 259. Baby Doe had two areas (sound and speech) that qualified her for the early intervention program. In addition, she had the automatic diagnosis of failure to thrive. Med. recs. at Ex. C, p. 260. Resources coordinator Lorna Thompson monitored the provision of services and found that Baby Doe was friendly, cooperative and easily moved from task to task. Baby Doe had a very calm demeanor and approached the evaluators and initiated some contact with her brother Aidan's playmate Andy. Mrs. Doe reported that this was new behavior. Mrs. Doe declined any need for additional resources or information about resources at this time. Med. recs. at Ex. C, p. 279. Baby Doe was asleep when the evaluation team arrived but woke up shortly thereafter. She was eager to participate in most activities. Med. recs. at Ex. C, p. 298.

Also on March 6, 2006, Baby Doe took a vision screening test which she passed. Med. recs. at Ex. C, p. 305. She could fix and follow. Med. recs. at Ex. C, pp. 305, 306.

On March 28, 2006, SoonerStart Early Intervention per Kris Fanning visited Baby Doe and Mrs. Doe for a scheduled visit. Mrs. Doe said that Baby Doe was babbling more and saying "mama" all the time. Med. recs. at Ex. C, p. 269.

On April 5, 2006, Baby Doe saw nutritionist Wamsley. Med. recs. at Ex. 5, p. 165. The purpose of the visit was to give Mrs. Doe nutritional education secondary to Baby Doe's failure to thrive. Baby Doe's height was 31 inches (10^{th} to 25^{th} percentile) and her weight 23 pounds (10^{th} to 25^{th} percentile), putting Baby Doe in the 50^{th} to 75^{th} percentile for height and weight together. *Id.* Mrs. Doe reported that Baby Doe had an appointment with the pediatric gastroenterologist the next day. Baby Doe was one year and seven months old. She was not taking dietary supplements. Mrs. Doe said she sometimes gave Baby Doe half a Flintstones's vitamin. Mrs. Doe reported that she gave Baby Doe 4 oz of juice at breakfast and a scrambled egg, toast with butter or sometimes jelly. On the way to the gym, she had a baggy for Baby Doe of Life Cereal, 8 oz. cup of whole milk and a lunch of a McDonald's cheeseburger with some French fries and some sips of Sprite. At 4:00 p.m., she gave Baby Doe grapes. She had 4 oz. of tea. At dinner, she had ½ cup to 1 cup of Hamburger Helper with green beans, 8 oz of milk, and a 4 oz shake of Carnation Good Start mixed with whole milk, chocolate syrup, and a scoop of ice cream. Baby Doe usually ate five to seven eggs a week scrambled with milk and cheese added. Baby Doe drank 14 cups of whole milk a week. Mrs. Doe said she had Baby Doe on a high-fat diet and gave Baby Doe olives, avocados, butter, sour cream, cream cheese, and unlimited chips if she wanted. Baby Doe had either salty foods or Mrs. Doe added salt to her foods in cooking. Baby Doe received an ice cream shake at bedtime and unlimited candy if she wanted. Mrs. Doe reported no eating behavior pitfalls. Nutritionist Wamsley reported no symptoms concerning

nutrition, metabolism, and development and Mrs. Doe reported no concerns about Baby Doe's eating behavior. *Id.* Mrs. Doe reported that Baby Doe was very active. *Id.* Nutritionist Wamsley gave Mrs. Doe handouts: "A Food Guide for the First Five Years," "Food Tips When You Need to Eat More," "More Food Tips When You Need to Increase Protein in Your Diet," "High Calorie Drink Recipes," and pages from "Eating Hints for Cancer Patients-Before, During, and After Treatment" to increase calories and protein. Med. recs. at Ex. 5, p. 166. Nutritionist Walmsley told Mrs. Doe to follow-up in one month or sooner if there were problems. They spent 40 minutes together. Nutritionist Walmsley noted that Baby Doe was receiving adequate kilocalorie intake as evidenced by her weight/length being at the 50th percentile. Nutritionist Walmsley also noted that Baby Doe's diagnosis of failure to thrive was possibly related to her past inadequate kilocalorie intake as evidenced from Mrs. Doe's reports of Baby Doe's weight falling in percentile. Baby Doe's estimated kilocalorie needs were 1,000 kilocalories per day. Her estimated protein needs were 12 grams per day. Nutritionist Walmsley discussed with Mrs. Doe meal planning guidelines for 12-24 months old, the recommended number of servings per day and serving sizes for each food group, the potential for choking hazards, increasing the quality of food versus increasing the quantity of meal/snack times, tips to increase kilocalorie and fat throughout the day, and feeding Baby Doe consistently throughout the day, i.e., every three hours. Mrs. Doe was to focus on feeding Baby Doe consistently throughout the day (every three hours) and increasing the quality of the food, not the quantity (add kilocalories/fat/protein to each meal versus increasing the amount of food), using tips from the appointment and the handouts. *Id.*

On April 6, 2006, Baby Doe saw Dr. David S. Jones, a pediatric gastroenterologist. Med. recs. at Ex. 5, p. 167. Mrs. Doe told Dr. Jones that Baby Doe had a normal appetite, and no hyperphagia, dysphagia, gagging, belching, vomiting, bloating, abdominal pain, regurgitation, jaundice, flatus, constipation, or rectal bleeding. Baby Doe was not slow to finish meals. She did have diarrhea. *Id.* Mrs. Doe told Dr. Jones that she first noticed Baby Doe dropping off the growth curve at five months. She said that Baby Doe had seizures and neurologic compromise after her immunizations. *Id.* She said that Baby Doe had had poor growth since. Med. recs. at Ex. 5, p. 168. Baby Doe was breastfed for 12 months, then on Nutramigen until she was 15 months old, then fed whole milk. She was currently drinking 16 oz of whole milk daily, one Carnation shake (4 oz), and eating solids. She had periods of loose stools six to seven times per day that lasted about one to two weeks, and then she had normal bowel movements once a day that were pasty. *Id.* Mrs. Doe reported that Baby Doe had seizures and paralysis after her immunization. She had speech delay and received early intervention. Baby Doe did not tire easily. She had no motor disturbances and no sensory disturbances. *Id.* Baby Doe did not speak during Dr. Jones's examination. Med. recs. at Ex. 5, p. 169. A motor exam revealed no dysfunction. Her balance, gait, stance, and reflexes were normal. Her growth parameters were normal. She had a mutation in the cystic fibrosis TR gene and was a carrier. She had a low TSH sensitivity. *Id.* Dr. Jones concluded that Baby Doe's failure to thrive was currently resolved. Med. recs. at Ex. 5, p. 171. There was no clinical or laboratory evidence of a gastrointestinal malabsorption. She was growing well after decelerating on the growth curve after previous

immunizations. He would repeat the TSH given her history of low TSH. Hyperthyroidism[13] could affect Baby Doe's growth. He would continue the current dietary recommendations. Baby Doe had intermittent diarrhea. Dr. Jones suspected toddler's diarrhea.[14] He would repeat the celiac panel with total IgA as a previous celiac panel was sent without total IgA. He would also send her stool for giardia antigen. Baby Doe had delayed milestones in speech and he recommended developmental pediatric referral as soon as possible. He spent 60 minutes with Baby Doe and Mrs. Doe. *Id.*

On April 8, 2006, Mrs. Doe failed to show up for an appointment with the nutritionist Wamsley who noted that there was no answer at home previously on December 28, 2005. On April 4, 2006, Mrs. Doe's home number was out of service. Med. recs. at Ex. 5, p. 137.

On May 8, 2006, SoonerStart Early Intervention had a scheduled visit with Baby Doe and Mrs. Doe which did not occur because the family cancelled without giving a reason. Med. recs. at Ex. C, p. 265.

On May 22, 2006, SoonerStart Early Intervention had a scheduled visit with Baby Doe and Mrs. Doe. They worked on communication. Mrs. Doe discussed day care because she planned to return to work in August. Med. recs. at Ex. C, p. 266.

On June 13, 2006, SoonerStart Early Intervention had a scheduled visit with Baby Doe and Mrs. Doe which did not occur because no one was home. Med. recs. at Ex. C, p. 264.

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[13] Hyperthyroidism means an overactive thyroid, one of whose characteristics is weight loss. Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 889.

[14] Toddler's diarrhea is "recurrent loose stools usually seen in otherwise healthy, normally growing children between the ages of 1 and 3 years, and occurring in daytime; often due to excessive fluid intake." Stedman's Medical Dictionary, 27th ed. (2000) at 494.

On June 26, 2006, SoonerStart Early Intervention had a scheduled visit with Baby Doe, her brothers Aidan, Blake and Code, and Mrs. Doe. Baby Doe was babbling more and said "no." The intervenor Kris Fanning encouraged Mrs. Doe to try various thicknesses of liquids with straws. Baby Doe managed the straw very well and also an open cup. She was able to blow bubbles and said no several times. Med. recs. at Ex. C, p. 258.

On July 25, 2006, SoonerStart Early Intervention had a scheduled visit with Baby Doe, her brothers Blake, Code, and Aidan, and Mrs. Doe. Mrs. Doe said Baby Doe had been crying and was fussy. The visit concentrated on verbalizing. Med. recs. at Ex. C, p. 256.

On August 1, 2006, SoonerStart Early Intervention had a scheduled visit with Baby Doe and Mrs. Doe . Baby Doe was beginning more intonations. Med. recs. at Ex. C, p. 255.

On August 3, 2006, a Progress Note for SoonerStart Targeted Care Management states that Mrs. Doe and her children had moved in with Mrs. Doe's mother approximately two weeks before in order to save money to buy a house in the future when Mr. Doe returned from Iraq. Med. recs. at Ex. C, p. 275. A release was signed for Early Head Start. Baby Doe was calmer and less agitated than on previous visits. Med. recs. at Ex. C, p. 273. Baby Doe no longer had an active diagnosis of failure to thrive. She was still delayed in development. The main concerns were communication and cognition. Med. recs. at Ex. C, p. 291. Baby Doe was less agitated but still clingy to adults in the home. She was not using words but was beginning to point for needed items. *Id.*

On August 4, 2006, at 10:13 a.m., Mrs. Doe phoned Dr. Hultquist because she was concerned about Baby Doe receiving vaccinations in order to enter day care. She said Baby Doe cannot take immunizations. Med. recs. at Ex. 5, p. 174. An assistant called Mrs. Doe at 1:44

p.m. but there was no answer. Dr. Hultquist called at 3:46 p.m., but there was no answer. The same assistant called at 4:23 p.m. but there was no answer. On August 7, 2006, the assistant spoke to Mrs. Doe who stated she needed a letter stating Baby Doe could not receive immunizations and it was all right for her to attend day care. On August 9, 2006, Dr. Hultquist completed the letter. Mrs. Doe was told to come for a medical release of information and then to turn that sheet into him for further action. *Id.* Dr. Hultquist's letter states that she had a dramatic change in growth correlated with her reaction to her vaccines. He agreed to suspend further immunizations until he and the staff could better understand the role of the immunizations and rule out other problems. Med. recs. at Ex. 7, p. 204.

On August 9, 2006, Dr. Hultquist wrote in his notes that Baby Doe had a reaction to her four-month vaccinations with a dramatic change in growth. Med. recs. at Ex. 7, p. 204.

On August 14, 2006, SoonerStart Early Intervention Program had a scheduled visit with Baby Doe and Mrs. Doe. Baby Doe was vocalizing more. Med. recs. at Ex. C, p. 254.

On September 20, 2006, SoonerStart Early Intervention Program had a scheduled visit with Baby Doe and Mrs. Doe, and went over animal sounds in a book and the signs for readiness to toilet train. Med. recs. at Ex. C, p. 252.

On October 4, 2006, SoonerStart Early Intervention Program had a scheduled visit with Baby Doe and Mrs. Doe but it did not occur because Mrs. Doe thought it was for the day before and Baby Doe was napping. Med. recs. at Ex. C, p. 251.

On October 18, 2006, SoonerStart Early Intervention Program had a service visit with Baby Doe, Mrs. Doe, and the three brothers Blake, Code, and Aidan. Med. recs. at Ex. C, p. 250. Baby Doe was saying words. Today they were playing peek-a-boo and Baby Doe would

say boo. *Id.* Baby Doe was using about 10 words spontaneously. She was signing some words, pointing to what she wanted, and would imitate words. Med. recs. at Ex. C, p. 293.

On November 1, 2006, SoonerStart Early Intervention Program had a scheduled visit for Baby Doe and Mrs. Doe, but no one was home. The visit was rescheduled. Med. recs. at Ex. C, p. 249.

On November 20, 2006, Baby Doe saw Shelly L. Morgan for a rash on Baby Doe's buttocks. Med. recs. at Ex. 5, p. 175. Baby Doe was two years three months old and weighed 12.95 kg. or 28 ½ pounds. *Id.* She had a normal appetite. Baby Doe's parents were informed that the rash was probably MRSA. Med. recs. at Ex. 5, p. 176.

On December 11, 2006, SoonerStart Early Intervention Program Med. recs. at Ex. C, p. 246. Baby Doe's friend Skylar was there and she had been enjoying Skylar's staying with them. *Id.*

On December 20, 2006, SoonerStart Early Intervention Program had a scheduled service provided to Baby Doe for one hour. Med. recs. at Ex. C, p. 245. Baby Doe was doing great with toilet training had hardly had any accidents. *Id.* Baby Doe had made great progress. She was imitating almost everything and was spontaneously using lots of single words as well as a few combinations of words. *Id.*

On January 3, 2007, SoonerStart Early Intervention Program had a scheduled service date which Mrs. Doe and Baby Doe did not show up for. No one was home. A message was left for Mrs. Doe that the service was rescheduled for January 17, 2007 at 11:30 a.m. Med. recs. at Ex. C, p. 244.

On February 7, 2007, Kris Fanning of SoonerStart Early Intervention Program informed her supervisors that the Does were pleased with Baby Doe's results and wished to exit the program at this time. Med. recs. at Ex. C, p. 270. They had no concerns. All goals had been accomplished. Med. recs. at Ex. C, p. 288. There were no concerns on nutrition screening. Med. recs. at Ex. C, pp. 299, 302. Baby Doe did not want to participate in a cognitive task, but engaged well with all other tasks. Mrs. Doe said this was typical for Baby Doe. Med. recs. at Ex. C, p. 301. Baby Doe was not at the exact age level. Med. recs. at Ex. C, p. 302. SoonerStart Early Intervention Program closed Baby Doe's chart at Mrs. Doe's request. *Id.*

On August 31, 2007, Baby Doe saw Community Health Nurse Jacquetta J. Chaney to obtain a Special Needs Accommodation Process or SNAP because of her speech delay. Baby Doe's parents requested she receive no further immunizations. Past medical history showed Baby Doe met the requirements for SNAP. Med. recs. at Ex. 5, p. 177.

On September 26, 2007, Baby Doe returned to see Community Health Nurse Chaney for evaluation in Child/Youth Service activities. Med. recs. at Ex. 5, p. 178. She was three years and one month, at the 18-month level for comprehension, and small for her age. *Id.*

On October 5, 2007, Speech Pathologist Connie Blose of Head Start screened Baby Doe. Baby Doe did not know colors or numbers and could not repeat any sentences. Med. recs. at Ex. 8, p. 205.

On October 30, 2007, Baby Doe saw Dr. John J. Apost for possible strep throat. Med. recs. at Ex. 5, p. 180. She had a temperature of 99.1.° Her height was 95 cm and her weight 13.75 kg or 30.3 pounds. She had a sore on her mouth. *Id.* She had had a fever for two days and decreased oral intake. However, she was making tears in the clinic. She had had diarrhea

for seven days. Mrs. Doe was concerned because she had heard of another child who had lesions on the tongue, developed staphylococcal toxic shock syndrome (which Dr. Apost questioned), and died. Med. recs. at Ex. 5, p. 181. Baby Doe was not having frequent illnesses. Her pediatric history was normal. Baby Doe did not have any white patches in her mouth. *Id.* Dr. Apost diagnosed Baby Doe with tonsillitis. Dr. Apost educated Mrs. Doe about staphylococcal toxic shock syndrome and Baby Doe's condition. Med. recs. at Ex. 5, p. 82.

The next day, on October 31, 2007, Cara E. Dailey spoke with Mrs. Doe at 2:11 p.m. because Baby Doe was breaking out and had facial and tongue swelling. Med. recs. at Ex. 5, p. 186.

On October 31, 2007, at 3:49 p.m., Baby Doe was back to see Dr. Apost for vomiting, diarrhea, and a swollen tongue. Med. recs. at Ex. 5, p. 183. Although Baby Doe was prescribed Augmentin for tonsillar erythema the day before, Mrs. Doe felt Baby Doe did not do any better. Her tongue had gotten worse and she refused to drink. Baby Doe's temperature was 98.3° and her weight was 13.35 kg or 29.4 pounds. She had decreased urine output but cried with tears. She was active, alert, responsive and not in distress. She had no systemic symptoms and her fever was low grade. *Id.* Baby Doe had multiple lesions on the sides of her tongue consistent with Vincent's stomatitis.[15] The back of her throat and posterior pharynx were erythematous. Med. recs. at Ex. 5, p. 184. Dr. Apost's diagnosis was stomatitis - multiple lesions on the side of the tongue consistent with enteroviral infection and dehydration. He admitted Baby Doe to the

[15] Vincent's stomatitis is "acute necrotizing ulcerative gingivitis." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1765. "Gingivae" are the gums. *Id.* at 768.

hospital for fluids. They would do a blood culture, comprehensive metabolic panel, urinalysis, and x-ray of the neck. Med. recs. at Ex. 5, p. 185.

On November 1, 2007, Dr. Mark S. Craig noted that Baby Doe had an oral intake of 150 ml over 14 hours and a small amount of jello. She received 260 ml of intravenous fluid. Med. recs. at Ex. 5, p. 188. Her temperature ranged from 96.9°-98° and her weight was 13 kg or 28.6 pounds. Baby Doe had had two weeks of diarrhea, one week of vomiting and fever, and four days of glossitis.[16] She had been seen in clinic with no tears to crying. (This note conflicts with Dr. Apost's records that Baby Doe did have tears with crying, which would mean that when she was in the clinic, she was not dehydrated.) Mrs. Doe gave Dr. Craig the history. *Id.* Baby Doe handled her secretions well and could swallow. Med. recs. at Ex. 5, p. 189. Dr. Craig concluded Baby Doe's glossitis was most likely of viral origin. She appeared clinically dehydrated on initial exam. Intravenous fluids would continue. Med. recs. at Ex. 5, p. 190.

Also on November 1, 2007, the nutritionist Andrea E. Fleenor set up a new diet for which she was educating Mrs. Doe. Med. recs. at Ex. 5, p. 192. Baby Doe weighed 13.35 kg or 29.4 pounds and was 39 inches in height. *Id.* Baby Doe was three years two months old, screened as a high nutritional risk, and was in the 5th percentile for BMI/age. Med. recs. at Ex. 5, p. 193. She had had a decreased appetite for six days. Nutritionist Fleenor spoke to Mrs. Doe who told her Baby Doe had lost four pounds in the last two weeks due to decreased intake. She had decreased appetite and diarrhea. She had difficulty swallowing secondary to glossitis. Mrs. Doe stated that Baby Doe usually liked all foods. Nutritionist Fleenor stated that Baby Doe's

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[16] Glossitis is "inflammation of the tongue." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 781.

weight/age and height/age were within normal limits. The goal of the therapy was to meet 75% of Baby Doe's nutritional needs to prevent further weight loss and promote normal growth. She recommended boosting milk shakes and/or pudding with all trays. *Id.*

On November 1, 2007, Dr. Craig returned and the Does told him Baby Doe was doing very well and they would like to take her home. Med. recs. at Ex. 5, p. 197. Baby Doe looked well-hydrated and had improved "drastically." She was discharged home. Med. recs. at Ex. 5, p. 198.

On November 7, 2007, Baby Doe saw Dr. Apost for a follow-up. Med. recs. at Ex. 5, p. 200. Baby Doe was doing well. The plaques on the sides of her mouth had resolved. She was afebrile, active, alert, well-hydrated, not in distress, and doing well at home. Med. recs. at Ex. 5, p. 201. Forms were completed and returned to Mrs. Doe about immunization exemptions. Med. recs. at Ex. 5, p. 202.

On January 10, 2008, Baby Doe saw Dr. Hultquist. Med. recs. at p. 213. There was concern about developmental delay due to an immunization she received at four months. Med. recs. at p. 214. The day she had the immunization, she developed a fever of 104.5.° (Obviously, Dr. Hultquist's notation is based on Mrs. Doe's history to him and not on the medical records he and others wrote at the time.) She was not spontaneously moving her legs, but she would withdraw from pain. She was not seen again until one year of age. At that visit, the clinic learned that she was not growing well. She was breastfed up to 13 months. She started baby foods at about five to six months and solid foods near a year. Mrs. Doe described Baby Doe as a good eater. She used formula after 13 months because Baby Doe was not growing well. *Id.* Baby Doe was a year behind in her gross development. Mrs. Doe's main

concern was speech. Head Start had some concerns about Baby Doe's ability to complete simple puzzles. *Id.* Baby Doe was three years and four months old. She could ride a tricycle but not sing a song. She could use pronouns appropriately. *Id.* Baby Doe's receptive skills seemed normal, but her speech was unintelligible in a lot of situations. Med. recs. at p. 216.

On March 14, 2008, petitioners took Baby Doe at the age of three years, six months, for speech evaluation. Med. recs. at Ex. 12, p. 319. Baby Doe had moderate phonological impairment. The recommendation was once a week therapy. *Id.* Mrs. Doe told speech pathologist Sarah Kay that there had not been any significant medical problems and Baby Doe did not have any specific medical diagnoses. She has seen a pediatrician but no other specialists. *Id.* Mrs. Doe had no concerns about vision or hearing. *Id.* Her developmental history was that Baby Doe was a fussy baby who liked to be held. Mrs. Doe stated that Baby Doe was able to roll over at five months, crawl at 9 months, sit alone at 12 months, and walk at 15 months. Med. recs. at Ex. 12, p. 320. She did not speak her first word until she was two years old. Mrs. Doe regarded Baby Doe's development as slow. Baby Doe could attend to one activity for 10-15 minutes. She did not show frequent re-changes. She was easily frustrated. She played with toys appropriately and was able to share toys. *Id.* Mrs. Doe stated there was a family history of speech difficulty. Baby Doe physically pointed to make her wants and needs known. She could make many different sounds and use gestures. She said many words but only one word at a time. When someone could not figure out what she was asking for, Baby Doe would typically cry and then cry again. Mrs. Doe felt that Baby Doe understood almost everything said to her. Mrs. Doe did not feel that speech and language development stopped for any period of time. She had no concerns about feeding or swallowing. Mrs. Doe told Ms. Kay that Baby Doe had failure to

thrive as an infant when she had her five-month vaccinations. Baby Doe ate soft foods, pureed foods, crunchy foods, and meat. She could use a regular cup, spoon, and straw. She liked vegetables. She could self-feed. *Id.* Ms. Kay felt that Baby Doe's language skills were at age appropriate levels at that time, but she should continued to be monitored secondary to a phonologic impairment. Med. recs. at Ex. 12, p. 321. Baby Doe had a total occurrence of major phonological deviations, placing her in the high-moderate range for phonological impairment. She had difficulty producing consonant sequences. If untreated, this phonological impairment could further impact her language skills. *Id.* Baby Doe's voice, fluency, and oral motor control appeared within functional limits for conversation. There were no concerns for feeding or swallowing, according to Mrs. Doe. *Id.*

On March 20, 2008, Baby Doe received an occupational therapy pediatric initial evaluation from occupational therapist Chandra Landers. Med. recs. at Ex. 13, p. 323. Mrs. Doe gave a history that within 10 minutes of Baby Doe's four-month immunizations, she became limp and unresponsive. Mrs. Doe reported she rushed her to the emergency room where she had a temperature of 105 degrees and suffered two seizures. Mrs. Doe reported that for at least three weeks, Baby Doe was not responsive but had to have a feeding tube placed. After about three weeks, Baby Doe apparently began to nurse again but had still very limited responsiveness. Mrs. Doe reported that the doctors ran a lot of tests on her and ruled out Guillain-Barré, which they thought initially possible. Initially diagnosed with failure to thrive, Baby Doe had caught up with her size and no longer had that diagnosis. She is a carrier of cystic fibrosis. Mrs. Doe was in contact with the Vaccinations and Immunizations Compensation Program. Mrs. Doe reported that some speech, sensory, and fine motor problems began to show up recently. Mrs. Doe

reported that Baby Doe's teachers at Head Start are concerned that she did not complete activities on the same level as other children. Currently, Baby Doe was diagnosed only with developmental delay and took only daily vitamins. *Id.* Baby Doe was attending a half-day of Head Start and had some difficulty communicating with the other children there because of her speech problem, but she played a lot with one little girl there. *Id.* Baby Doe walked independently and sat in a chair at the table for the entire evaluation. She attempted all activities although, on a few occasions, she said, "I can't." Toward the end of the session, she requested many times to leave. She followed directions well for her age. *Id.*

Baby Doe had normal tone and functional range of motion in her upper extremities. Med. recs. at Ex. 13, p. 324. Mrs. Doe stated Baby Doe could use utensils appropriately and feed herself. She cannot do buttons, snaps, and zippers. She will not hold a bagel with cream cheese or a peanut butter and jelly sandwich because they will get on her hands, but she will eat them if someone else holds them. She will not play with water and sand at Head Start and will not get into a bathtub with bubbles. She covers her ears in public places except for the grocery store. She will not let her mother touch her ears even to change her earrings. *Id.* Therapist Landers assessed Baby Doe with some delays in fine motor skills, including visual, motor, and grasping skills. Med. recs. at Ex. 13, p. 325. Some grasping limitations might be due partially to sensory tactile defensiveness. She could benefit from occupational therapy once a week. *Id.*

On July 28, 2008, Baby Doe saw Dr. Laurie A. Kukas, an osteopath specializing in developmental pediatrics. Ex. 23, p. 406. Baby Doe was three years and 11 months old. Mrs. Doe gave Dr. Kukas a history that Baby Doe had a 104-105° temperature within one hour of her immunizations and developed an encephalopathy with flaccid paralysis of her legs and loss of

body control, including her ability to suck and breast feed. Mrs. Doe said Baby Doe required tube feedings during her three-day hospitalization. Baby Doe gradually improved but was irritable, oversensitive to sounds, touch, and taste, and difficult to console until 13-18 months old. *Id.* By 13 months of age, Baby Doe had regained most of her gross motor skills but had limited speech. She was diagnosed with failure to thrive because her weight dropped from the 50th percentile to the 5th percentile. Mrs. Doe wondered to Dr. Kukas if Baby Doe had signs of possible autistic disorder because of obsessive-compulsive behaviors including handwashing 15-20 times a day, putting bears in a certain place at bedtime, freaking out if a cut bleeds, difficulty with professional photos, difficulty with certain food textures, hearing subtle sounds no one else hears, covering her ears and crying when there are loud sounds, preferring soft easy foods to chew or easy crunch foods, pocketing food in her cheeks, and waking during the night to sleep with her parents. *Id.* Mrs. Doe said that after the immunizations, there was a time when Baby Doe would no longer interact with her family, was lethargic, and looked as if she were in a daze. Ex. 23, p. 407. Baby Doe crawled on her hands and knees after 12-13 months. She did not walk alone until 15-16 months. Her problem-solving and following directions were very good. *Id.*

Baby Doe's brothers are 6, 8, and 10 years old. The six-year-old brother is enrolled in T-1 for immaturity in adaptive and emotional skills. He frequently fights with Baby Doe over toys. *Id.* Baby Doe's father was often away when Baby Doe was 3-25 months old. Another deployment was expected in May 2009. Mr. Doe was a straight A, Honor Roll student. Mrs. Doe was a B-C student. She is attending college classes and will be doing phlebotomy. *Id.* Baby Doe weighed 33.2 pounds and was 39 inches tall. Ex. 23, p. 408. Her physical and neurological examinations did not identify specific abnormalities that explain her developmental

delays. Oral motor control of her tongue and lips were delayed for her age. Her resting muscle tone was low normal to mildly hypotonic. *Id.* Dr. Kukas received petitioners' expert pediatric neurologist Dr. Miller's report diagnosing Baby Doe with encephalopathy from a severe reaction to her second set of immunizations. Ex. 23, p. 407. Dr. Kukas diagnosed Baby Doe with residual developmental delays and encephalopathy-related adverse reactions to her second set of vaccinations, developmental delays (communication, social, adaptive, fine motor, and self help), possible hyperacusis (over-sensitive hearing) which could be due to abnormal central auditory processing, mild generalized hypotonia and poor body awareness, sensory processing dysfunction, developmental coordination disorder, sleep disturbance, mood swings, mild temper tantrums, social and separation anxiety, and obsessive-compulsive traits. Ex. 23, p. 408. Dr. Kukas opined that Baby Doe does not seem to have autistic disorder. Ex. 23, p. 409. She recommended that Baby Doe receive an intense multidisciplinary treatment plan combining private and public school services. *Id.* She suggested that Baby Doe's primary pediatrician conduct tests to rule out anemia, thyroid, genetic, and other conditions if Baby Doe did not start to improve. She also suggested a brain MRI or PET scan or SPECT scan when Baby Doe is older to define better "the areas of her brain that were affected during the vaccine adverse reaction." *Id.* To get Baby Doe to sleep better, Dr. Kukas suggested to Mrs. Doe that the television be turned off one hour before bedtime and Baby Doe stop taking a sippy cup to bed. She suggested low doses of melatonin with a protein or complex carbohydrate snack 30 minutes before bedtime. She suggested soft music and/or white noise to be used the entire night if needed. Mrs. Doe should continue to monitor Baby Doe's sleep for awakenings, nightmares, and/or restlessness and snoring with pauses and/or gasps. She should discuss her observations

with her pediatrician to see if Baby Doe needed a sleep study or ENT consultation to see if her enlarged tonsils and/or adenoids needed to be removed. *Id.* Dr. Kukas suggested Mrs. Doe add Omega 3, 6, and 9 and vitamin B complex to Baby Doe's diet. She suggested the Coromega brand. Dr. Kukas suggested oral motor strategies to wake up Baby Doe's mouth before meals. She gave Mrs. Doe a sheet of mouth/tongue movement games to do in the mirror with Baby Doe. She suggested occupational therapy services with emphasis on sensory and vestibular strategies. She also suggested speech-language therapy, and formal vision examination. *Id.* Even though Baby Doe has normal hearing, Dr. Kukas suggested additional audiology evaluations. Ex. 23, p. 410. She also suggested gradually reducing electronics (television, video games, computer games) to one hour per day and preferably only 30 minutes at a time followed by an active break and other play or chores. *Id.*

On September 25, 2008, Baby Doe at the age of four years, one month, saw occupational therapist Aileen Sadler for an initial evaluation. Med. recs. at Ex. 22, p. 400. The history Ms. Sadler wrote was that an hour and one-half after receiving her immunizations, Baby Doe had a temperature of 105.° She was lethargic and her legs did not appear to be moving. Mrs. Doe rushed Baby Doe to the emergency room where she was admitted to the hospital and developed feeding difficulties. Mrs. Doe said Baby Doe was given breast milk by NG tube. She told Ms. Sadler that Baby Doe had had a seizure during the first night. Mrs. Doe told Ms. Sadler that in the following months, Baby Doe cried and was like a colicky baby all the time. *Id.*

Ms. Sadler tested Baby Doe's fine motor skills and found her able to manipulate a variety of materials. She could not button large buttons. *Id.* She was able to walk and run without difficulty. Ex. 22, p. 401. She disliked tactile input. Ex. 22, p. 402. Baby Doe displayed

excellent attention for a child her age. She engaged easily in activities and followed directions without difficulty. Ex. 22, p. 403. Overall, her fine motor skills were developing well for a child her age. Her grasp appeared weak for her age. She had difficulties in social situations, becoming anxious in new and unfamiliar situations. *Id.* Ms. Sadler recommended occupational therapy to address Baby Doe's grasping skills and pre-writing skills. She also needed a sensory diet. *Id.*

On October 1, 2008, Baby Doe saw Dr. Kukas again. Ex. 23, p. 412. Dr. Kukas gave a teacher packet to Mrs. Doe for Baby Doe's teacher to fill out after six weeks of the new school year. Baby Doe's current Head Start teacher, Ms. Anderson, completed the forms and returned them on October 12, 2007. Ms. Anderson reported that Baby Doe had difficulties with speech, fine motor, and following directions, but was good at learning songs. After a few days, Baby Doe made friends easily and got along well with others. *Id.*

Additional Submitted Material

Filed as Ex. A for petitioners (this is petitioners's second Ex. A) and given page number 212, is a statement dated August 28, 2007 from Mrs. Doe with the heading "VICP Claim" and addressed "To Whom It May Concern." Mrs. Doe states that within 25 minutes of her four-month vaccinations, Baby Doe was not responding neurologically, was running a very high fever, and her lower extremities were paralyzed. She was in the emergency room within one hour of her vaccinations where was she evaluated and admitted to the hospital. She was given medication to control her fever and anaphylaxis. Mrs. Doe states Baby Doe "had some kind of disorder of her brain and body." *Id.* After her release from the hospital, Baby Doe could no

longer sit up on her own, make eye contact, or respond to voices or touch, according to Mrs. Doe. She had constant irritability and failure to thrive.

Mrs. Doe submitted an affidavit dated January 3, 2008, filed as exhibit 1. She states that Baby Doe at birth was in the 95th percentile for length and the 90th percentile for weight. Ex. 1, p. 1. Mrs. Doe also states that one hour after her four-month vaccinations, Baby Doe "had a high fever and stopped responding neurologically." Ex. 1, p. 2. She continues, "Baby Doe was experiencing paralysis in her lower extremities, and suffered a seizure." *Id.* She took Baby Doe to the emergency room at Reynolds Army Hospital.

Mrs. Doe continues in her affidavit that for her three days in the hospital, Baby Doe continued to have fever, lethargy, paralysis of her legs, additional seizures, and incessant crying. *Id.* She states, "She also continued to display a decreased level of consciousness." *Id.* Mrs. Doe states that after her discharge from the hospital, Baby Doe could no longer sit up on her own, make eye contact, or respond to voices, touch, or other stimuli. She also went from the 90th percentile in weight to below the fifth percentile in weight in just a few months. She was diagnosed with failure to thrive and has had continual diarrhea and developmental delays. *Id.*

Mrs. Doe states that when Baby Doe was one year old, she was still wearing clothing for a three-month old and weighed only 18 pounds. She still did not make facial gestures or verbal noises other than to express a constant irritability. *Id.*

Petitioners filed as exhibit 15 the 20-page expert report dated March 28, 2008 of Dr. Richard A. Hastings, an internist. He also examined Baby Doe on March 28, 2008. Ex. 15, pp. 337, 338. Mrs. Doe told Dr. Hastings that 10-15 minutes after her vaccinations, Baby Doe was feverish, lethargic, with limp extremities, her eyes were partially closed, and she was not

responding normally. Ex. 15, p. 340. Mrs. Doe told Dr. Hastings that Baby Doe had fever up to 105.° Ex. 15, p. 341. She said Baby Doe appeared to be in substantial pain as touching her arms or legs caused her to cry and withdraw. *Id.* X-rays of Baby Doe's brain and legs, and ultrasound of her hips were normal. Mrs. Doe told Dr. Hastings that Baby Doe had some overtly abnormal movement disorders the first night in the hospital which resembled a seizure. *Id.* On the third day, Baby Doe was discharged from the hospital with increasing movement of her lower extremities. Dr. Hultquist evaluated her on January 18, 2005. In a subsequent note, Dr. Hultquist wrote that Baby Doe had 104.5 fever and flaccid paralysis. Examinations on July 20, 2005 confirmed that Baby Doe was in the 5th percentile for weight and the 50th percentile for height. *Id.* Dr. Hultquist recommended nutritional consultation. Ex. 15, p. 342. Dr. Hultquist's opinion was that "the clinical demise" of Baby Doe was a direct result of her adverse immunization reaction. *Id.* Since then, Baby Doe has regained her physical growth development in height and weight by use of an aggressive nutritional support program. Ex. 15, p. 343. On examination, Baby Doe was reluctant to use speech. Ex. 15, p. 346. Dr. Hastings concludes that Baby Doe "experienced a generalized muscular injury in the form of upper and lower extremity motor flaccidity with paralysis within the first 24 hours" after vaccination. Ex. 15, p. 347. He opines she had a change in mental status with decreased levels of consciousness and cognitive function within the first 12-24 hours after vaccination. *Id.* He also opines that Baby Doe had a seizure within the first 24 hours after vaccination in conjunction with her "high fever." *Id.* Dr. Hastings attributes Baby Doe's failure to thrive to her vaccine injury as well as her developmental delays in physical function milestones and in speech, cognition, and fine motor movement function. Ex. 15, p. 348. Dr. Hastings concludes that Baby Doe's vaccine injury

involved her "central nervous system, brain and neurological systems." *Id.* He states Baby Doe had an encephalopathy with rapid onset after her vaccinations. Ex. 15, p. 350. He opines that the vaccines injured Baby Doe's brain and nervous system. Ex. 15, p. 351. He states that the combination of decreased level of consciousness with cognitive decline and seizures in association with flaccid paralysis confirms that her central nervous system and brain were adversely impacted by her vaccine reaction. Ex. 15, p. 352. Dr. Hastings states that encephalopathy involves altered levels of consciousness and focal or generalized seizures and depression of motor (muscle) units. *Id.* He states that Baby Doe's reduction in her level of consciousness and her paralysis demonstrate that "her central nervous system and brain were being traumatized by an encephalopathic process." *Id.* As for sequelae, Dr. Hastings says that individuals can completely recover or can have persistent adverse clinical features. *Id.* He opines that Baby Doe suffered neurologic injury as a direct result of her adverse reaction, resulting in failure to thrive, developmental delays physically and in speech and fine motor skills. Ex. 15, p. 353. However, he notes that Baby Doe had substantial clinical improvement in her growth delays and physical milestone delays with the exception of fine motor movement and speech. *Id.* He opines that Baby Doe had an immune-stimulated inflammatory encephalopathy and/or an allergic-mediated inflammatory encephalopathy. *Id.* Baby Doe is too young to assess the extent of her level of learning impairment. Ex. 15, p. 354. Dr. Hastings is an osteopath. Ex. 16, p. 1. His Ph.D. thesis was on preimplantation development in the rabbit embryo and he has written three articles on this topic. Ex. 16, p. 361. He has also written about placentas of myomorph rodents and thrombolysis in myocardial infection. *Id.* Dr. Hastings has published seven articles. *Id.*

Petitioners filed the affidavit dated July 23, 2008 of Sheela McKenney, MSW, LCSW, as exhibit 17. Ms. McKenney is Mrs. Doe's mother. Ex. 17, p. 1. Ms. McKenney is a licensed clinical social worker with a Masters in social work. She works for Sterling Medical to provide mental health services at Ft. Sill. She states Baby Doe was suffering from a clear neurological impairment after her vaccine reaction. *Id.* (Ms. McKeeney was in Colorado at the time.)

Petitioners filed the affidavit dated July 23, 2008 of Dr. Marc A. Hultquist, who was chief of pediatrics at Reynolds Army Community Hospital on January 13, 2005 when Baby Doe was brought into the emergency room with a fever and reduced movement in her legs. Ex. 18, p. 1. He ordered a feeding tube to ensure adequate hydration. Multiple tests were ordered to determine why Baby Doe had reduced movement in her legs. Baby Doe's condition stabilized and she was discharged from the hospital January 15, 2005. *Id.* He saw Baby Doe on January 18, 2005 for a follow-up and noted her extremities moved better. Ex. 18, p. 2. When Baby Doe was next seen in the pediatric clinic on July 20, 2005, she had a marked reduction in growth, going from the 90th % to 5th % in weight "in just a few months." [This was actually six months later.] *Id.* He finds it medically plausible that Baby Doe's adverse vaccine reaction resulted in significant and sustained neurological injury. *Id.* Dr. Hultquist submitted an inquiry about Baby Doe to the Vaccine Healthcare Centers Network which is a military support group. *Id.* They responded that Baby Doe had an adverse reaction and should notify the Vaccine Injury Compensation Fund. He notified the family about this. Ex. 18, p. 366.

Petitioners filed as exhibit 19 the expert report of Dr. G. Steve Miller, a pediatric neurologist. He also examined Baby Doe. Ex. 19, p. 1. Baby Doe had an encephalopathy as a result of her vaccine reaction. *Id.* He opines that Baby Doe had a high fever, loss of motor tone,

especially in the lower extremities, a diminished level of consciousness, and seizure. *Id.* He obtained the history from Baby Doe's parents in his clinic note. Ex. 19, p. 368. Baby Doe was breastfed until 15 months of age. *Id.* An hour after Baby Doe's vaccinations, she had 105° fever. Baby Doe's legs were not moving and she was lethargic. Her arms seemed fine. She moved her hands and arms normally. She did not make eye contact and stared straight ahead as if in a daydream. Baby Doe continued to be lethargic. She did not nurse or cry. *Id.* Her legs were extended and she would not hold anything. Ex. 19, p. 369. The first night, Mrs. Doe reported that Baby Doe had what appeared to be a seizure with not shutting her eyes and her eyes rolling around involuntarily with eyelid twitching lasting a minute or so. Mrs. Doe told Dr. Miller that the nurse thought this might have been a seizure. During the second and third days, Baby Doe began moving her legs, beginning with her right toes, then right leg, her left toes, and left leg. Mrs. Doe said Baby Doe was not cooing or smiling. Mrs. Doe said Baby Doe was not feeding in the hospital so breast milk was given by NG tube. *Id.* After her discharge, Baby Doe was spacey as if she were not there. The parents felt this was not the same baby. She would not focus. She just cried. For four to six months, Baby Doe was like a colicky baby all the time. At 13 months of age, she was brought back to the pediatric clinic, but she had no interest in eating or trying new foods. She began sitting alone at 14 to 15 months and walked at 15 to 16 months. She had two words by two years of age. The parents described Baby Doe as anti-social and withdrawn. *Id.* Neurological examination showed Baby Doe to be alert and oriented to person, place, and situation. Ex. 19, p. 370. Muscle mass, strength, and tone were normal. Reflexes were normal and symmetric. Gross and fine motor coordination were intact. Sensory examination was grossly intact. *Id.* Baby Doe passed all gross motor skills tasks up to the six-

year level. She had only one failure in the personal/social skills test. In the fine motor adaptive skills, she had only one failure. In language skills, she had three failures. Only 40% of her speech was understandable. Her failures were in defining opposites, five words, and understanding four prepositions. Baby Doe's results suggest normal development. However, Dr. Miller said the Denver Developmental Screening Test does not measure expressive speech or articulation very well. *Id.*

Dr. Miller also wrote a Record Review, dated August 4, 2008. Ex. 19, p. 371. He writes (although this is not written in any contemporaneous record) that Baby Doe had a fever of 105° within one hour of her four-month vaccinations. She was lethargic, unresponsive, and her extremities, particularly her legs, were limp. He states, "It is reported that Baby Doe suffered a seizure. However, there is no actual description." (There is also no actual record until Mrs. Doe much later added a seizure to the history of Baby Doe's symptomatology and in other histories she gave to providers, added a seizure before she went to Reynolds Army Community Hospital and stated she had multiple seizures in the hospital. There is no contemporaneous record of any seizure.) *Id.* In the emergency room, the upper extremities were normal with free range of motion with the lower extremities mostly lying in a normal anatomical position. Ex. 19, p. 372. Dr. Miller states that after discharge from the hospital, Baby Doe would not make eye contact or respond to voices or touch. (This is not in any contemporaneous medical record, not in Dr. Hultquist's record of January 18, 2005, and not in Dr. Gibbons' record of July 20, 2005 after Baby Doe spent six months without adequate nutrition.) Mrs. Doe had nutritional consultation. *Id.* Dr. Miller's professional focus is on seizures and anticonvulsants. Ex. 20, pp. 377-78. He

has written two published articles, one on epilepsy and the other on pediatric migraine. Ex. 20, p. 378.

Petitioners filed the GlaxoSmithKline Prescribing Information for Infanrix (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed). Ex. 21, pp. 379, 399. Included in contraindications to administration of pertussis-containing vaccine is:

> Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous dose of a pertussis-containing vaccine that is not attributable to another cause....

Ex. 21, p. 383.

Under the heading "Warnings" is advice to consider carefully vaccination with Infanrix if a prior vaccination containing acellular pertussis was followed by a temperature of 105° F within 48 hours not due to another identifiable cause. Ex. 21, p. 383. The information states that occurrence of fever increases with successive doses of Infanrix. Ex. 21, p. 386.

Under Table 1. Adverse Events (%) Occurring Within the 3 Days Following Vaccination of Italian Infants with Either Infanrix or Whole-Cell DTP at 2, 4, and 6 Months of Age, for those infants who received Infanrix, under the subheading "Systemic" are the following data: 7.1% (first dose), 7.9% (second dose), and 9.0% (third dose) had **fever up to 100.4°** F; 36.3% (first dose), 34.9% (second dose), and 28.8% (third dose) had **irritability**; 34.9% of infants (first dose), 18.8% (second dose), and 11.4% (third dose) had **drowsiness**; 16.5% (first dose), 13.9% (second dose), and 11.5% (third dose) had **loss of appetite**; and 5.8% (first dose), 4.1% (second dose), and 3.3% (third dose) had **vomiting**. *Id.* Under the subheading "Local" are the following data: 4.7% (first dose), 4.0% (second dose), and 5.2% (third dose) had **tenderness** within three days of vaccination. *Id.*

Under Table 2, which focused on US infants at 2, 4, and 6 months of age similarly vaccinated with Infanrix, under the subheading "Systemic" are the following data: 0.5% (first dose), 0.7% of infants (second dose), and 5.1% (third dose) had **fever up to 101° F**; 3.9% (first dose), 3.5% (second dose), and 4.1% (third dose) had **fussiness**; 26.3% (first dose), 16.4% (second dose), and 12.9% (third dose) had **drowsiness**; 8.1% (first dose), 7.7% (second dose), and 6.6% (third dose) had **poor appetite**; 6.6% (first dose), 3.7% (second dose), and 3.8% (third dose) had **vomiting**. Ex. 21, p. 387. "Fussiness" was defined as moderate or severe, i.e., prolonged crying and refusal to play or persistent crying that could not be comforted. *Id.* Under the subheading "Local" are the following data: 2.7% (first dose), 2.0% (second dose), and 1.5% (third dose) had **pain** within three days of vaccination. *Id.* "Pain" was defined as moderate or severe, i.e., the infant cried or protested to touch or cried when the leg was moved. *Id.*

Under Table 3, which focused on adverse events occurring within three days following vaccination with Infanrix in US infants at 2, 4, and 6, months of age where all the doses were Infanrix, under the subheading "Systemic" are the following data: 0.0% (first dose), 0.9% (second dose), and 3.5% (third dose) had **fever up to 101.1° F**; 7.5% (first dose), 6.0% (second dose), and 9.6% (third dose) had **anorexia**; 5.8% (first dose), 6.8% (second dose), and 3.5% (third dose) had **vomiting**; 37.5% (first dose), 19.7% (second dose), and 13.2% (third dose) had **drowsiness**; 3.3% (first dose), 7.7% (second dose), and 8.8% (third dose) had **fussiness**. Under the subheading "Local" are the following data: 5.0% (first dose), 6.1% (second dose), and 0.9% (third dose) had **pain**. Ex. 21, p. 388.

Under Table 4, which focused on adverse events occurring within three days following vaccination with Infanrix in German infants at 3, 4, and 5 months of age where all the doses

were Infanrix, under the subheading "Systemic" are the following data: 6.3% (first dose), 8.3% (second dose), and13.3% (third dose) had **fever up to 100.4° F**; 0.0% (first dose), 0.1% (second dose), and 0.1% (third dose) had **fever up to 103.1° F**; 8.0% (first dose), 7.4% (second dose), and 6.5% (third dose) had **loss of appetite**; 4.3% (first dose), 3.9% (second dose), and 3.4% (third dose) had **vomiting**; 10.3% (first dose), 9.5% (second dose), and 8.6% (third dose) had **restlessness**; 6.0% (first dose), 4.9% (second dose), and 4.0% had **diarrhea**. Ex. 21, p. 389. Under the subheading "Local" are the following data: 2.0% (first dose), 2.6% (second dose), and 3.7% (third dose) had **pain**. *Id.*

Under Table 7, which reflected a double blind study of severe adverse events occurring within 48 hours after Infanrix vaccination in Italian infants at 2, 4, and 6 months of age, 5 children (for a rate of 0.36/1000 doses) had a **fever up to 104° F**. Ex. 21, p. 393.

In an ongoing U.S. coadministration safety study, Infanrix was given together with 7-valent pneumococcal and HiB conjugate vaccines, hepatitis B recombinant vaccine, and inactivated poliovirus vaccine at 2, 4, and 6 months of age. Following the first dose at 2 months of age, **fever up to 100.4° F, 101.3° F, 102.2° F, and 103.1° F** occurring within four days was reported in 19.8%, 4.5%, 0.3%, and 0.0% respectively of 333 infants. The frequency of **irritability/fussiness, drowsiness, and loss of appetite** was 61.5%, 54%, and 27.8%, respectively. Ex. 21, pp. 393-94. Fewer than 20 reports of encephalopathy were received in worldwide voluntary reports of adverse events since market introduction of Infanrix. Ex. 19, p. 394.

Respondent filed the expert opinion of Dr. Michael Cohen, a pediatric neurologist. Ex. A (this is not petitioners' two exhibits marked A). Dr. Cohen states that Baby Doe's current

overall developmental delay seems quite minimal. She has no evidence of a static or progressive encephalopathy. Ex. A, p. 2. Rather than an encephalopathy, Baby Doe developed transient fever because of the immunization. Her failure to move her legs resulted from a local reaction to her vaccinations and not from damage to her central or peripheral nervous system. She had quick resolution of the problem and no chronic or long standing neurologic residua. Baby Doe's overall intelligence seems normal. Dr. Cohen was unaware of any vaccination-induced injury that specifically targets speech. Speech disorders are commonly seen in children. He believed that Baby Doe had neither an acute nor chronic encephalopathy and did not have any residual deficit from her immunizations. She had a local reaction without adverse long-term consequences. He does not attribute failure to thrive to vaccinations. Ex. A, p. 3. Dr. Cohen is Chairman of the Department of Neurology at the State University of New York at Buffalo. Ex. B, p. 1. He has written 79 articles, co-authored three books, and written 17 book chapters. Ex. B, pp. 16-24.

TESTIMONY

Petitioners had seven witnesses. Their first was Mrs. Doe. Tr. at 36. Baby Doe is the youngest of her four children. Tr. at 37, 38. The older siblings are boys. *Id.* They are six years older, four years older, and two years older than Baby Doe. Tr. at 37. Baby Doe did not have any reaction to her two-month vaccinations. Tr. at 39. Baby Doe received her second set of immunizations on January 12, 2005 when she was five months old. *Id.* At the January 12th visit, Baby Doe was in the 95th percentile for height and weight and developing normally. Tr. at 40. Nurse Blanche D. Coleman administered the vaccinations. Tr. at 41. Baby Doe had two vaccinations on each thigh with four bandaids. *Id.* Mrs. Doe is trained as an EMT. Tr. at 42.

Baby Doe's vaccine sites did not have any redness or swelling. *Id.* For the first 30 minutes, she did not have any reaction to the vaccines. *Id.*

Mrs. Doe took her home and Baby Doe was asleep in the car seat. Tr. at 43. She put her in her crib still in the car seat. *Id.* Mrs. Doe thought it odd that she was still sleeping after an hour. *Id.* When she tried to rouse Baby Doe, she was still asleep. Tr. at 44. Baby Doe had high heat coming out of her. Her legs were flaccid. She was whiney, irritable, and lethargic. *Id.* Her legs were just hanging instead of retracting. *Id.* Whenever she touched Baby Doe, Baby Doe would whine, moan, and arch her back. *Id.* Baby Doe did not focus on her mother. Tr. at 45.

Mrs. Doe called the hospital which informed her that fevers were normal. *Id.* Baby Doe's temperature was 103 degrees under her arm. Tr. at 46. Mrs. Doe gave Baby Doe Motrin but it did not lower her fever completely, just to 101 degrees. Tr. at 47. It then went back up. *Id.* The injections sites were not red or swollen. Tr. at 48. Baby Doe whined all night and did not feed. *Id.* Mrs. Doe took her to the emergency room on January 13th. *Id.* She told Dr. Hultquist in the emergency room that Baby Doe's temperature was 103 degrees at home, although the record states 100.3 degrees. Tr. at 49-50. In the emergency room, Baby Doe's temperature was 101 degrees after four doses of Motrin. Tr. at 50.

Baby Doe was admitted to the hospital on January 13, 2005 and stayed three days. Tr. at 52. Mrs. Doe testified Baby Doe had no movement of her legs and was not responding to her mother normally. Mrs. Doe testified that Baby Doe did not want to nurse. The hospital placed an NG tube in her nose to feed her. *Id.* At night, while Mrs. Doe was holding Baby Doe, Baby Doe looked the opposite direction of where her mother was. Tr. at 53. Her mother looked down and her eyes were twitching rapidly. Mrs. Doe laid her in her crib and got the nurse. This

seemed to Mrs. Doe to be a seizure. *Id.* The eyes were going side to side for a few seconds. *Id.* When she and the nurse came back, Baby Doe was lethargic but not twitching. *Id.*

Mrs. Doe had the impression that all of Baby Doe was in pain. Tr. at 55. Her arms were fine, but she was just sleepy. *Id.* Her legs did start to get movement back in time and she started to nurse. Tr. at 56.

Mrs. Doe testified that Baby Doe was not completely back to normal when discharged from the hospital. *Id.* She was diagnosed with adverse reaction to her immunizations. *Id.* At home, Baby Doe was blank and without expression. She was not the same child. Tr. at 57. She would no longer try to find her brothers who had entered a room and would not grab her mother's nose or ears when she talked to her. *Id.* She slept and ate normally. Mrs. Doe was not concerned because she did not have any life threatening problems. *Id.* She assumed Baby Doe's recovery would take time. Tr. at 58. No one told her to see a neurologist. *Id.* Baby Doe still seemed to have muscle weakness. *Id.* She was not sitting up or rolling over. Before the vaccinations, she was sitting up on her own. *Id.* Baby Doe did not like being bathed. She was very irritable when jostled, clothed, or changed. She would instantly arch her back and scream. Tr. at 60. The vaccine sites looked normal. *Id.*

Baby Doe seemed to look through her mother. Tr. at 61. She did not have any more fever. *Id.* The reason Mrs. Doe did not take her back to the hospital is that Baby Doe was not having a life threatening problem. She was breathing, eating, and did not have a temperature. There was no medically emergent reason for her to take Baby Doe back in. She was not in a coma. "She was just not the same child that I had taken to the hospital that day in January." Tr. at 62. Mrs. Doe did not want to take her back to the doctor for months because she did not want

Baby Doe to receive any more vaccinations. *Id.* She thought the law required Baby Doe to have immunizations and she did not want to bring Baby Doe back to have her receive immunizations again. *Id.* Immunizations would be standard procedure. *Id.*

Three days after Baby Doe was discharged from the hospital, she did see Dr. Hultquist on January 18, 2005. *Id.* Dr. Hultquist examined Baby Doe. Tr. at 65. Mrs. Doe stated that physically Baby Doe was healthy, but mentally she was not. Tr. at 66.

Baby Doe next saw the pediatrician six months later on July 20, 2005. *Id.* Baby Doe was 11 months old and still breast feeding, but had difficulty gaining weight. Tr. at 67. Baby Doe was also eating baby cereal. Her mother does not understand why Baby Doe did not gain weight. *Id.* Baby Doe was in the fifth percentile in weight but she was healthy. *Id.* Mrs. Doe testified that Baby Doe was not neurologically the same or normal developmentally. Tr. at 68. Although the record states Baby Doe was pulling herself up to standing, Mrs. Doe stated this was not true. *Id.* She was not sitting up on her own at 11 months. Tr. at 70. Over approximately a year, the failure to thrive aspect of Baby Doe's condition began to resolve. Tr. at 71. At 20 months of age, she had gotten to the 50^{th} to 75^{th} percentile in weight. Tr. at 72. Baby Doe was very immature in speaking. Tr. at 73. By 20 months, Baby Doe was walking. Tr. at 74. She was physically healthy. *Id.* The doctors recommended a developmental pediatric referral for Baby Doe's delayed speaking. Tr. at 74-75. But Mrs. Doe did not get the referral to the developmental pediatrician until July 2008. Tr. at 75.

Mrs. Doe described Baby Doe's problems. Baby Doe is understandable only in about 40-50% of her speech. Tr. at 76. She has been diagnosed with an oral muscle control issue and articulation disorder. *Id.* She also has fine motor skill problems such as holding a pencil,

crayons, and scissors. Tr. at 77. Her hands get tired very quickly. *Id.* Baby Doe's peers treat her differently. *Id.* Baby Doe attaches herself to her teachers and to an adult for security. Tr. at 78. Baby Doe's muscle tone is normal. *Id.* She is very active and keeps up with her brothers. *Id.* Baby Doe has sensory difficulties in that she does not like any marker on her hand or the commotion at field trips or the zoo. Tr. at 79.

Mrs. Doe stated that she considered Baby Doe's not moving her legs in the hospital to be paralysis. Tr. at 91. Baby Doe slowly regained movement by the third day. *Id.* Mrs. Doe had basic training as an emergency medical technician (EMT). Tr. at 93. She was a certified nursing assistant. Tr. at 94. When Baby Doe was examined on the day after admission, on January 14th, the record states she was moving her lower extremities without difficulty, but Mrs. Doe denied that she was completely normal and back to the point she had been pre-vaccination. Tr. at 95, 96. The record states that Baby Doe smiled at her mother, but Mrs. Doe denied that this was true. Tr. at 96. Mrs. Doe stated that Baby Doe was awake and had her eyes open, but she was not moving around. *Id.* Although the record states that Baby Doe was cooing, her mother stated that this was incorrect. Baby Doe was whining. *Id.* Mrs. Doe said it was a whine, a sign, a moan and Baby Doe was not blowing bubbles or babbling or cooing. Tr. at 97. On the evening of admission, January 13th, the record states Baby Doe was awake and active. *Id.* However, Mrs. Doe denied this. She stated that Baby Doe's only activity was arching her back and irritability. Mrs. Doe testified that Baby Doe would not even nurse and was not moving about. *Id.*

The record for January 13th states that Baby Doe had good suck reflex and good tone in her upper extremities. Tr. at 98-99. Mrs. Doe denied that Baby Doe had good suck on the night

of her hospital admission. Mrs. Doe stated Baby Doe had an NG tube inserted because she was not breast feeding enough. Tr. at 99. Mrs. Doe testified that by January 14th, Baby Doe would latch on with the NG tube, but the hospital still had to feed her. She stated that Baby Doe was using her mother's breast as a pacifier. *Id.*

The hospital records state for January 14th and 15th that Baby Doe tolerated breast feeding well. Tr. at 100. But Mrs. Doe said when she mentioned Baby Doe breastfed well, she meant that Baby Doe latched on. Mrs. Doe testified that since Baby Doe was getting her nourishment through an NG tube, she was not nursing to eat. *Id.*

The January 13th Medical Record Pediatric Admission Assessment states Baby Doe's behavior was appropriate, she was calm with her mother and father, and she cried in the treatment room during venipunctures and insertion of the feeding tube. Tr. at 101. Mrs. Doe denied that Baby Doe's behavior was appropriate that day:

> She [Baby Doe] appeared calm to the person who made these reports because when I was holding her she was either probably sleeping is my guess. ... She did cry for her venipuncture, and she did–but she did not act on a normal level to the child that I brought in and I knew.

Tr. at 101-02.

Baby Doe is not followed today by a neurologist. Tr. at 102. Dr. Kukas is her developmental pediatrician. *Id.*

When Mrs. Doe brought Baby Doe to see Dr. Hultquist three days after discharge from the hospital for a follow-up, she did not tell him that she had concerns about Baby Doe's behavior. *Id.* Her explanation for not telling Dr. Hultquist her concerns was:

> I did not because it was obvious to us both that she was recovering, and I wouldn't have expected a child who had had an adverse

> reaction, who had been hospitalized for three days, who had been battling these fevers, to come home and be 100 percent herself. I had expected there to be some recovering time, so three days later I was just following up on his orders to come back.

Tr. at 102-03.

The appointment lasted only 15 minutes and Dr. Hultquist did not express any concerns. Tr. at 103. He did examine Baby Doe. *Id.* Dr. Hultquist told her if there were any concerns with Baby Doe's feeding or fevers to bring her back. Tr. at 104. Mrs. Doe did not bring her back to the doctor because Baby Doe was healthy, had a blood pressure, was breathing, and did not have a fever. *Id.* Mrs. Doe stated Baby Doe was healthy. *Id.* Mrs. Doe stated she did not know that she could bring Baby Doe back for check-ups even if she was not going to be immunized. She just assumed she did not even need to go to well-baby check-ups if Baby Doe were not going to be immunized any more. *Id.*

Mrs. Doe listed the activities Baby Doe could not do after vaccination that she could do before vaccination: sit up with her Boppy pillow; grab her toes and chew on them; and reach for her toys. *Id.* Baby Doe was just a ball of personality before the vaccination. Tr. at 104-05. "The baby that I brought home did recover. She did start to move. She did gain, but she was not mentally the same child that she was before." Tr. at 105. Mrs. Doe's sole reason for bringing Baby Doe to a doctor when Baby Doe was 11 months old was that she was concerned. *Id.* Mrs. Doe took Baby Doe to Dr. Gibbons on July 20, 2005 complaining of failure to gain weight, failure to thrive, and poor growth. Tr. at 106.

Dr. Marc A. Hultquist testified next for petitioners. Tr. at 113. He is in the Fire Center Brigade, a combined troop medical clinic, taking care of soldiers at Reynolds Army Community Hospital. Tr. at 113-14. In January 2005, he was chief of the pediatric clinic at Reynolds. Tr. at

114. He was on duty at the emergency room on January 13, 2005 when Baby Doe was brought in with a documented fever. *Id.* She had reduced movement in her lower extremities. Tr. at 115. She had recently received her four-month immunizations. *Id.* Mrs. Doe told him that Baby Doe had changed within several hours after she received her immunizations, including a fever. She described Baby Doe as not acting like herself, not moving her lower extremities, and not eating as well. *Id.*

Dr. Hultquist and the ER staff noticed on January 13, 2005 that Baby Doe's intake was down and on his physical examination of Baby Doe, he noticed she was not spontaneously moving her lower extremities. Baby Doe would withdraw to pain stimuli in her lower extremities. Tr. at 116. They did some standard blood tests and a urinalysis as well as an ultrasound of her hips. *Id.* The urine culture was negative. The ultrasound was normal. *Id.* The nursing staff could not obtain a blood sample so no blood culture was done. Tr. at 117.

Dr. Hultquist does not believe that Baby Doe had a localized reaction to the vaccinations in her lower extremities because there was no sign of an infection or significant redness outside the normal response to a vaccination. *Id.* He believes Baby Doe's reaction was systemic which, to him, means both lower extremities symmetrically were involved. *Id.* He would have expected that if it were a simple localized reaction at the vaccination sites, Baby Doe would have had more spontaneous movement than she displayed. Tr. at 118. He did not try to elicit pain at her thighs but at the bottom of her feet. *Id.* He thought Baby Doe might have Guillain-Barré Syndrome or some neurological problem. *Id.*

The leading diagnosis was that Baby Doe had an adverse reaction to her vaccinations. Tr. at 118-19. It affected her systemically. "To say whether or not there was an infection

specifically in the brain, we can't really say that for sure. The CAT scan came back normal." Tr. at 119. But, Baby Doe's cognition and alertness were affected. Her ability to eat was diminished. *Id.*

A few days after Baby Doe's discharge from the hospital, Dr. Hultquist submitted a VAERS report. *Id.* He decided on August 9, 2006 to suspend Baby Doe's immunizations because of her adverse reaction. Tr. at 120. Mrs. Doe told him when she brought Baby Doe to the ER on January 13, 2005 that Baby Doe had had 103 degree fever. Tr. at 122. The note in the hospital record of 100.3 degree temperature was a typographical error. *Id.* She had 101 degrees in the emergency room. Tr. at 123.

During Baby Doe's hospitalization, he entertained a diagnosis of possible viral illness or bacteremia. Tr. at 124. No specific testing was done for a viral illness. They could not culture the blood for bacteria because they could not obtain a blood sample. *Id.* The urine culture came back negative. *Id.*

On January 18, 2005, Dr. Hultquist saw Baby Doe for a follow-up three days after her hospital discharge. Tr. at 126. Baby Doe was regaining some of the motion that her mother had witnessed prior to her vaccinations but was not at baseline yet. Tr. at 127-28. That was Baby Doe's last visit until July 20, 2005 when she saw Dr. Gibbons. Tr. at 128. In January, Baby Doe had weighed 7.08 kilograms. In July, her weight was 7.7 kilograms. A kilogram is 2.2 pounds. On the growth chart, they noted she had not maintained the same normal curve. She was in the fifth percentile in weight in July but she had been a larger baby than that. *Id.*

Mrs. Doe told him that the reason she did not bring Baby Doe in for six months was that she was concerned that doctors would try to pressure her to continue Baby Doe's immunizations and she was scared. Tr. at 129-30.

Baby Doe has shown developmental delay over the years. Tr. at 130. She has not reached her normal potential for age. *Id.* She can walk and run like most children her age, but her speech and fine motor skills are affected. *Id.*

Dr. Hultquist thinks "it's reasonable to deduce that the event that she had in January is the nidus for the reason why we see the delay that we have at her age now or at the present time." Tr. at 131. He reported Baby Doe's case and some other case to the Vaccine Healthcare Centers Network, an organization created by the Department of Defense to answer questions regarding immunizations. Tr. at 131. They recommended that he report this for the family for compensation as the case was consistent with an adverse reaction. Tr. at 132. When Dr. Hultquist submitted the VAERS report, he thought that was what he was doing. *Id.*

Dr. Hultquist never recommended to Mrs. Doe that she take Baby Doe to a pediatric neurologist. Tr. at 133. He did not see her and did not know Baby Doe's progress was delayed until Dr. Gibbons saw her later and then the focus was on her failure to thrive since she was not gaining weight. *Id.* Dr. Gibbons is another pediatrician. Tr. at 134. I

In subsequent medical visits, when the box next to neurological system is checked "normal," that may be true for the problem focused on that visit, but it was not true for Baby Doe overall since she had speech problems. Tr. at 143. When Baby Doe was one year and seven months, she was noted to have delayed milestones with language and speech and a

recommendation was made for her to see a developmental pediatrician. Tr. at 145. She saw a pediatric gastroenterologist, Dr. Jones, for her failure to thrive. Tr. at 145-46.

Dr. Hultquist's impression is that Mrs. Doe was always concerned about Baby Doe. Tr. at 148. He felt that Mrs. Doe recognized changes in Baby Doe although he said that, sometimes, he could not validate the extent of what Mrs. Doe saw. *Id.* He did not always have the same degree of concern that she had. *Id.* The undersigned asked:

> THE COURT: What was it that you couldn't validate that [Mrs. Doe] complained to you about in Baby Doe?
> THE WITNESS: For instance, when she first reported when the child came in in the emergency room, and I've seen through the chart people have documented flaccid paralysis. Well, in my mind there was not flaccid paralysis. She was able to generate a response to pain stimuli. Not a reflect [reflex], but a response, so it was something that she actually pulled away from. That would be an example of a discrepancy [between what Mrs. Doe says and medical opinion in the records]. I wouldn't necessarily – it hasn't bothered me, that difference, because the mother is a layperson. She's not a doctor. So I felt like her reporting has been very consistent. I just wouldn't report necessarily the same degree of concern that mothers always display.

Tr. at 148-49.

Dr. Hultquist did not recall whether Mrs. Doe ever told him that Baby Doe's eyes had moved horizontally rapidly for a few seconds the first night she was in the hospital. Tr. at 149-50. Dr. Hultquist is board-certified in pediatrics. Tr. at 152. He has had a change in status since the time he saw Baby Doe and now sees 19- and 20-year-olds as well as soldiers in their forties and fifties. Tr. at 152-53. He became the chief of the Reynolds pediatric clinic in May 2005 and served in that capacity until August 2008. Tr. at 153-54. They had 3,000 patients impaneled to them and saw 18 to 23 patients a day. Tr. at 154. There were about 45 to 65 babies delivered each month that they were caring for. *Id.*

Dr. Hultquist remembers Baby Doe because making a diagnosis of adverse reaction to an immunization is not something he does very often. Tr. at 156. In fact, Baby Doe is probably the only patient he saw who had an adverse vaccine reaction. *Id.* He has submitted two or three vaccine immunization adverse reports when he was at Reynolds, "and none are more significant as what Baby Doe had gone through." *Id.*

He did not take any viral samples and does not believe Baby Doe had a viral infection. Tr. at 156-57. Dr. Hultquist stated:

> In this case I couldn't come up with a good explanation for why she had the event that she did other than the immunization. She had a response within just a few hours, a coincidental viral infection which is sometimes an explanation for other children, but just doesn't seem to have played out with her. She had a dramatic, like I said, response, and her recovery was quite quick. I don't mean that she recovered completely, but she went to the point where she wasn't eating and we helped her sustain her fluids with an oral gastric tube to being discharged and being able to maintain herself on her own in just a few days. ... Her drop and her recovery just seemed to be a lot more dramatic than the normal course of an infection.

Tr. at 156-57.

Dr. Hultquist saw Baby Doe in the emergency room and had her admitted to the hospital where he handed her care to Dr. Davis, his partner and another pediatrician. Tr. at 159. Baby Doe was in the hospital for three days. Dr. Hultquist read a note from Dr. Davis's handwriting: "Child did well overnight. No fever. Child fed well. Mother reports improved activity. No acute distress. Vital signs stable. General assessment: awake and alert, nontoxic. She had a rash on her trunk and neck. He suspected a viral syndrome, normal reaction to immunizations. Muscle soreness. Discharge to home." Tr. at 160-61. He and Dr. Davis never discussed Baby

Doe after he handed her care to Dr. Davis. Tr. at 162. Dr. Hultquist ended up seeing Baby Doe during the three-day follow-up. *Id.*

Dr. Davis stated in his notes under "Assessment" that Baby Doe had full range of motion and he noticed responses in her upper and lower extremities. Tr. at 162-63. His suspicion that Baby Doe had a normal reaction to her immunizations disagrees with Dr. Hultquist's diagnosis. Tr. at 163. Dr. Hultquist believes that Baby Doe had an encephalopathy:

> Well, I believe – at the time I did not feel like she was having an encephalopathic event or brain swelling, but I think that her decreased awareness or the global effect that she had could be consistently interpreted as an encephalopathy.

Id. When asked to define "encephalopathy," Dr. Hultquist said:

> Well, I would be looking for brain swelling, but just because we didn't see brain swelling on that CAT scan doesn't mean that an event wasn't having an impact on her globally on her brain.

Id. An EEG was not done. Tr. at 164.

Dr. Hultquist based his diagnosis on Baby Doe's symptoms such as alertness and ability to eat being affected. Tr. at 166-67. He also thinks the effect on her lower legs was a sign of a systemic event. Tr. at 167. He did not have enough testing to know if that happened from something going on in the brain. *Id.* Baby Doe was given a nasogastric tube for rehydration when attempts to use an IV failed. Tr. at 168. He would have expected her to have a lower level of fluids due to her temperature and reduced feeding but they were not seeing that lower fluid effect at that point. *Id.* He thinks Baby Doe was behind in fluids but did not have clinical signs of it. Tr. at 169.

Dr. Hultquist is not saying that Baby Doe's inability to move her legs was due to brain swelling or pressure. Tr. at 174. He continued:

> I'm trying to say I think there was an adverse reaction in the sense that maybe antibodies – you know, you can't have an allergic reaction if you've never been exposed to something before, so if this was the first time she had received the immunizations at two months of life I couldn't even really entertain an adverse reaction because she wouldn't have been exposed to these things before. But in this case she had been exposed to these immunizations at her two month period, and now you've got antibodies that can make a response. They can make a violent and very quick response.

Tr. at 174-75. He continued:

> I'm saying that the antibody response may have somehow affected the brain. Again, I'm not trying to say you had brain swelling, encephalopathy. I'm just saying that are these symptoms similar to encephalopathy in that globally she's somehow affected? Yes, but not in the sense that you would have every system affected.

Tr. at 175.

Dr. Hultquist said that whatever effect happened occurred immediately. Tr. at 176. He called it some type of allergic reaction. *Id.* He said:

> Again, I don't want to mislead you and try to tell you that she had an encephalopathic event in which you might see a bacterial meningitis because I don't think that she had an infection going on. I think she has an internal response, and through that internal response you were seeing the manifestations. And that's why I think she got better so quickly because it was the body turning on and turning off its reaction more so than – it wasn't the chemical attacking her body. ... From the immunization. But it was her body's response to the chemical that was introduced that was producing the global effect.

Tr. at 176-77. Dr. Hultquist felt that because both of Baby Doe's legs responded, she was having more of a systemic reaction. Tr. at 178.

Dr. Hultquist read from the inpatient note in the medical records that Baby Doe turned her head both left and right toward the direction of noises without difficulty and reached out to

grasp objects without difficulty. She had equal strength bilaterally to grasp and moved her left leg without difficulty. She moved her right leg less than her left leg. Tr. at 180. She had equal palmar grasp bilaterally to her feet and moved her toes bilaterally without difficulty. Her right leg was relaxed. She smiled at her mother and made cooing sounds. *Id.* He called these reassuring signs that they would use as supporting evidence to send the child home from the hospital. Tr. at 181.

The medical records for January 14th note that Baby Doe breastfed for breakfast, lunch, and dinner and then that she tolerated breast feeding well, but do not say how much milk she got. Tr. at 182. Baby Doe was discharged on January 15th. Tr. at 183. What impressed Dr. Hultquist was how quickly things occurred and how quickly things got better. Tr. at 183-84. He admitted that the nursing note stated Baby Doe was awake and active. Tr. at 184. The next day, Baby Doe is noted to be awake, alert, with her eyes open bilaterally. *Id.* Mrs. Doe said Baby Doe was moving her legs in spurts, although Dr. Hultquist testified that she was not moving her legs. Tr. at 184-85. The notes also say that Baby Doe moved her lower extremities without difficulty. Dr. Hultquist took issue with the qualifications of the nurses because they were not pediatric-trained. Tr. at 185.

Dr. Hultquist does not know what was the cause of the rash on Baby Doe's neck and chest, but he thinks the rash was the reason that his partner Dr. Davis concluded that Baby Doe had a viral syndrome. Tr. at 186. It was a valid reason at the time. Tr. at 187.

Because the nurses' notes are handwritten, Dr. Hultquist does not have any doubt that this is what the nurses saw, unlike the computer-generated notes. *Id.* Dr. Hultquist has the same training in neurology as any other pediatrician. *Id.*

Dr. Hultquist stated that when he was admitting Baby Doe into the hospital from the emergency room, he did not believe she was having a vaccine reaction although Mrs. Doe did. Tr. at 188. He did not think Baby Doe had flaccid paralysis. There was still tone in the way Baby Doe held her legs although she was not moving them spontaneously. She did have strength to withdraw to pain. Tr. at 189. Baby Doe's decreased leg motion could have been due to a muscular reason or a neurological one. Tr. at 189-90. He was more concerned about bacteremia, i.e., a septic hip. Tr. at 190. He was also considering whether Baby Doe had Guillain-Barré Syndrome. Tr. at 191. He was also considering a urinary tract infection. *Id.* Dr. Hultquist continued regarding his later opinion that the vaccination was responsible for Baby Doe's later speech delay and fine motor difficulties:

> You know, you're asking me today can I prove a cause and effect. No, I can't, but in my opinion I have no better explanation, and the most probable cause of her deficits today go back to a child who had a significant event that affected her in a couple ways globally with a systemic reaction validated by the fever that it's very probable. I don't have any other evidence to be able to show you that it's other. When you have to use a diagnosis of exclusion, you know, at some point you have to draw a line in how many more tests you're going to run on a child. When she starts to improve over the course of 24 hours, you're not going to order more tests. You're going to let the child get better and quit poking and prodding and everything.

Tr. at 192.

Dr. Hultquist saw Baby Doe three days after her hospital discharge. Tr. at 192-93. Baby Doe had full range of motion without swelling or induration. Tr. at 193. Dr. Hultquist clicked on the boxes stated Baby Doe was awake, alert, oriented, in no acute distress, and appeared healthy and well-hydrated. *Id.* On January 18th, Dr. Hultquist believed that Baby Doe had an adverse reaction to her vaccination but no neurological symptoms. Tr. at 194.

Any time someone injects a needle into tissue, there is obviously incurring damage. But he never had to admit a child for a localized reaction to a vaccine. Tr. at 196. Dr. Hultquist does not know which of Baby Doe's multiple vaccines caused her injury. However, the polio or the pertussis historically caused a lot of fevers. *Id.* He would pick the pertussis as the cause. *Id.* He had very little contact with Baby Doe after January 18th. Tr. at 198.

Blanche D. Coleman testified next for petitioner. Tr. at 201. She is a licensed practical nurse at Reynolds Army Community Hospital. *Id.* She has worked at the immunization and allergy clinic at Reynolds for 27 years. Tr. at 202-03. The procedure at Reynolds for immunization is that: (1) children under the age of two have to be seen by the Reynolds doctor for a well baby appointment, (2) the doctor orders the vaccinations, and then (3) the children come to the immunization clinic to get their shot. Tr. at 203. At the immunization clinic, they look at the doctor's orders and then they go through the sheets for particular vaccines with the mother to make sure that the baby has not had any problems with any previous vaccinations or other medications or has any allergies. *Id.*

Nurse Coleman administered the vaccinations to Baby Doe on January 12, 2005. Tr. at 204. Baby Doe received her second acellular DPT, her second Comvax (HiB and hepatitis B), and inactivated polio vaccines. Tr. at 204-05. Mrs. Doe contacted Nurse Coleman when Baby Doe was in the emergency room. Tr. at 205. Nurse Coleman had checked Baby Doe during the 15-20 minutes post-vaccination before she left the immunization clinic after receiving the vaccines and there was no localized reaction at the injection sites. Tr. at 206, 208.

Dr. G. Steven Miller testified next for petitioners. Tr. at 209. He is a pediatric neurologist. Tr. at 210. He performed an evaluation of Baby Doe. Tr. at 211. His opinion is

that Baby Doe had an adverse reaction to her January 12, 2005 vaccinations. Tr. at 213. He would select the pertussis vaccine as the most likely cause of her encephalopathy. *Id.* The basis for his opinion is Baby Doe had fever within hours of her immunization. *Id.* In addition, the physicians in the hospital did a number of tests which displays their concern. Tr. at 214. Mrs. Doe noted that Baby Doe was lethargic, without eye contact, and stared straight ahead, as if she were in a daydream state. *Id.* He believes that Baby Doe's acute encephalopathy was followed by a chronic encephalopathy, whose residua is her speech delay, fine motor delay, and sensory integration problems. Tr. at 215.

Dr. Miller thinks a fever of 103° is significant. Tr. at 216. She was able to sit up with side support before vaccination, but after the vaccination, could not. *Id.* Dr. Miller stated that encephalopathy was injury or damage to the brain. Tr. at 217. The vaccines induced Baby Doe's encephalopathy leading to her residua. Tr. at 217-18. He does not agree with respondent's expert Dr. Cohen's opinion that Baby Doe had a transient fever in reaction to her vaccinations and her failure to move her legs was due to a localized reaction at the site of the injections. Tr. at 218. Dr. Miller does not think there are any facts to support Dr. Cohen's opinion. *Id.* There was no mention in the hospital records of any swelling or induration of Baby Doe's legs. Tr. at 219.

Someone can have a vaccine-induced encephalopathy without a local reaction at the vaccine site. *Id.* Dr. Miller believes that Baby Doe's neurological impairment continues. *Id.*

Dr. Miller obtained a history of what happened to Baby Doe from the parents and looked at some of the medical records prior to seeing Baby Doe. Tr. at 221. His notation that Baby Doe had 105° temperature came from the parents and not from the medical records. Tr. at 222. Some

of the information that the parents gave him is corroborated in the medical records and some of it is not corroborated in the medical records. *Id.* What was not corroborated in the medical records was how Baby Doe was subsequent to the immunizations, such as when they returned home, on the fifth day, she cried constantly and arched her back, that this was not the same baby, that she had no focus and just cried, and that from four to six months, she cried all the time like a colicky baby. *Id.* This information was not documented in the medical records. Tr. at 223. He explained Baby Doe's parents not seeking medical assistance for Baby Doe by their fear of her having more vaccinations. *Id.*

Dr. Miller believes that Baby Doe became encephalopathic within one hour of being vaccinated. Tr. at 224. He thinks a significantly decreased level of consciousness is indicated by one of three things, including decreased eye contact, inconsistent response to external stimuli, or decreased response to the environment. Tr. at 225. From Mrs. Doe's history, Baby Doe lost development and was not fully responsive in that she stared straight ahead and did not make eye contact. Tr. at 225-26. Based on Baby Doe's decreased or absent eye contact, he thinks she had an encephalopathy. Tr. at 227. He did not see anything in the medical records that would support that Baby Doe had absent eye contact and did not look at her family members or others. Tr. at 228.

Dr. Miller said that if Baby Doe was not lethargic, did have eye contact, was not in a daydream state, and was not staring straight ahead, then she would not meet the criteria for a diagnosis of encephalopathy. Tr. at 231-32. Dr. Miller said that electronic medical records do not provide the same information as the old written information. Tr. at 236. The information

pointed out to him was in longhand and is probably more valid than the electronic medical records. He thinks it is good documentation. *Id.*

Sheela McKenney, Baby Doe's maternal grandmother, testified next for petitioners. Tr. at 238. Before petitioners moved to Oklahoma, both Ms. McKenney and they were in Colorado. Tr. at 239. She moved to Oklahoma in June 2005. *Id.* Mrs. Doe called Ms. McKenney from the emergency room close to hysteria, saying Baby Doe had not been able to move her legs and had a high fever. Tr. at 240. Mrs. Doe was in a panic. *Id.* The hospital staff initially questioned the parents to find out if any abuse had occurred. Tr. at 242. Ms. McKenney kept in touch. Eventually, Baby Doe's fever decreased and she started moving one of her legs and then the other one. *Id.*

During the next five or six months, Mrs. Doe said that Baby Doe did not get back the energy she had and was not progressing. She was not the same bouncy, happy child she had been before. Tr. at 243. She could move both her legs and did not have fevers, seizures, or medical concerns requiring medical attention. It was just a slow recovery. *Id.*

Ms. McKenney moved back to Oklahoma in June 2005 and saw Baby Doe. Tr. at 239. She was surprised to see how tiny she was. She was not very active, but was quiet and reserved. Tr. at 243. Baby Doe did not engage with her over time and seemed to have a different personality than when Ms. McKenney remembered from before. *Id.* Baby Doe was not growing as she should have. Her mother took her back to the doctor with Ms. McKenney's encouragement. Tr. at 244. Baby Doe had a diagnosis of failure to thrive. *Id.* Mrs. Doe had a fear of Army hospitals and of medical doctors. *Id.* They thought that Baby Doe had almost died.

Tr. at 245. Mrs. Doe had not established a good relationship with the physicians at Fort Sill and did not know if she could trust them. *Id.*

During those months, Baby Doe was never sick enough to warrant a visit to the doctor again because of anything significant such as diarrhea or vomiting so, combined with Mrs. Doe's fear, she chose not to return. Tr. at 245.

They did not realize what the diagnosis of failure to thrive meant until a few months later. Tr. at 246. When Ms. McKenney worked at a hospital in Lawton, she realized that child protective services usually got involved most times when children were diagnosed with failure to thrive. *Id.* In addition, "we weren't sure that people were believing us that we were feeding Baby Doe, you know, we were taking care of her and she still wasn't growing caused a lot of alarm." *Id.*

Ms. McKenney went with her daughter and Baby Doe to Dr. Hultquist's office. Tr. at 247. She was concerned that because of the failure to thrive diagnosis, Baby Doe might be temporarily removed from her home as she had seen in her work as a social worker. *Id.* Ms. McKenney wanted to know if Dr. Hultquist thought that Mrs. Doe was neglecting Baby Doe in not giving her the proper food. Tr. at 248. Dr. Hultquist reassured them. *Id.*

Dr. Richard Hastings, an internist, testified next for petitioners. Tr. at 251. His original specialty was anatomy. Tr. at 251-52. He then became an osteopath. Tr. at 252. His practice as an internist does not involve the routine care and treatment of pediatric patients. Tr. at 254. He does not routinely see children. Tr. at 256. Dr. Hastings did an examination on Baby Doe before Dr. Miller did. Tr. at 261. He described "encephalopathy" as any diffuse injury, disease, or damage to a brain structure or brain function. Tr. at 263-64. The National Institutes of Health

have listed some factors to consider for a diagnosis of encephalopathy, including an alteration in mental status. Someone might have memory loss or cognitive loss, subtle personality changes, inability to concentrate, lethargy, a progressive loss of consciousness, myoclonus, involuntary twitching of muscle groups, nystagmus (rapid, involuntary eye movements), tremors, muscle atrophy, muscle weakness, dementia, seizures, or loss of the ability to swallow or the ability to speak. Tr. at 264.

Dr. Hastings considers Baby Doe to have had an encephalopathy because she had an alteration of mental status or lethargy. Tr. at 265. Mrs. Doe noticed brief horizontal rapid eye movement which is nystagmus. Tr. at 266. The kind of neurological deficits that Baby Doe has can result from an encephalopathic event. Tr. at 269. Someone can have an encephalopathic event without having a localized reaction at the injection sites. *Id.* Someone could have soreness in the legs if someone had injections in the legs. Tr. at 271.

Dr. Hastings said that encephalopathy can affect very focal areas of the brain. Tr. at 278. He did not think someone had "to have 24 hours a day, seven days a week of it." *Id.* His opinion is that the vaccinations of January 12, 2005 caused encephalopathy in Baby Doe. Tr. at 280. He does not find any alternate cause. Tr. at 281.

Dr. Hastings has never taken any formal classwork in developmental abnormalities in children other than medical school and independent reading. Tr. at 283. He testifies "quite a bit in the area of injury." *Id.* He has "a pretty sizeable practice with the U.S. military people." *Id.* He would say that litigation matters have evolved over the last eight or nine years to include probably 75 or 80 percent of what he does. Tr. at 284. He has testified 10 to 15 times in court over the last eight years. *Id.*

Dr. Hastings considers any temperature over 100.5° to be a high fever. Tr. at 289. In the hospital, Baby Doe's fever was documented on several occasions as 101° which he considers to be a high fever. Tr. at 289-90. Dr. Hastings based his conclusion that Baby Doe had upper and lower extremity neuromuscular motor flaccidity with temporary near paralysis on the way Mrs. Doe explained Baby Doe to him. Tr. at 290. The records indicate that Baby Doe had some less than normal functional activities in her lower extremities. Tr. at 290-91. Dr. Hastings said that he could understand why a lay person would think this was paralysis, but he did not believe that it was permanency of a loss of function in the lower extremities. Tr. at 291.

Dr. Hastings based his conclusion that Baby Doe had a decrease in her level of consciousness with cognitive decline from the notation in the record that she was lethargic and the mother's history that Baby Doe did not seem to be as conscious in terms of interacting with her as she had been. *Id.* He connects cognitive change to the lethargy and concedes "[m]aybe that's not the correct term," but Baby Doe was not interacting normally with her mother. *Id.*

Dr. Hastings based his conclusion that Baby Doe had a seizure on the mother's history to him that Baby Doe had rapid eye motion, although no one diagnosed Baby Doe as having a seizure while she was hospitalized. Tr. at 291-92. Baby Doe did not have upper extremity flaccidity. Tr. at 292. If he had been Baby Doe's treating doctor, he would have thought it was a case of Guillain-Barré Syndrome. *Id.* He believes there is an autoimmune attack of some manner or immunological attack upon the myelin of Baby Doe's lower extremity nerve groups that was causing her problems. Tr. at 293. It did not turn out to be GBS, but it looked like a neurological attack or injury. Tr. at 294. Dr. Hastings' opinion is that Baby Doe had an

encephalopathic event. *Id.* Her CT scan was normal. *Id.* Baby Doe was not diagnosed with GBS or acute disseminated encephalomyelitis because she did not have it. Tr. at 295.

Dr. Hastings had no opinion about what Mrs. Doe was talking about when she said that Baby Doe would arch her back. Tr. at 296-97. Baby Doe was not in a coma. Tr. at 297. He thinks that Baby Doe's problems later with speech are due to the initiating event. Tr. at 298.

Shawn Andrew Brewer, Baby Doe's father, testified next for petitioner. Tr. at 306. He basically said that all his wife had said was what he would describe. Tr. at 307.

Dr. Michael E. Cohen, a pediatric neurologist, testified for respondent. Tr. at 308. He was board-certified in 1969 with recertification in 2004. Tr. at 310. He has served as a senior examiner of the American Board of Psychiatry and Neurology for over 20 years. *Id.* The Board is the certifying agency for all neurologists and child neurologists in the United States who seek recognition. *Id.* Dr. Cohen has developed questions for those boards and also examined doctors wishing to be certified. Tr. at 311. He is also board-certified in clinical neurophysiology. *Id.*

Dr. Cohen thinks it a difficult question whether or not Baby Doe had an encephalopathy. Tr. at 312. She did have a reaction to her vaccination which was both local and systemic. The systemic reaction was characterized by fever and lethargy. The local reaction was characterized by her refusing to use her legs. Tr. at 312. The whole reaction was very short-lived and resolved over a period of 48 or less hours. *Id.*

When the undersigned asked to what he attributed Baby Doe's deficits, such as speech and fine motor, Dr. Cohen responded that was a difficult question to answer with any conviction or firmness because many children have language problems. *Id.* Baby Doe has normal intelligence and seems to have normal understanding. *Id.* She seems to have normal

development and has no really defined motoric abnormalities, although her fine motor control is arguably abnormal. Tr. at 313. What Baby Doe cannot do is form her words correctly. This is called phonologic abnormality. It happens to every child as they learn to speak. *Id.* It is not clear to Dr. Cohen if Baby Doe was delayed in babbling. *Id.* He does not know what the fine motor movement problems mean. Tr. at 314. He does not think that Baby Doe's holding a pencil awkwardly is indicative of an abnormal nervous system. *Id.* Dr. Cohen does not know what a sensory problem means. *Id.* A child's tendency not to want to be touched or to avoid sensation is more behavioral than indicative of an abnormal nervous system. Tr. at 315. That is not the way our nervous system develops. *Id.*

Dr. Cohen does not know what the developmental pediatrician Dr. Kukas's notation of hypotonia of Baby Doe's oral motor muscles means. *Id.* Baby Doe is not hypotonic by any measure of the imagination and she was never flaccid. *Id.* She did have trouble moving her legs, but she was never flaccid as that term implies, i.e., an abnormality, a paralysis. *Id.*

Dr. Cohen stated that when someone examines a child neurologically, he tries to determine what part of the nervous system is involved. Tr. at 316. In Baby Doe's situation, that is very difficult to know. Her arms were okay, she was awake, and she was feeding normally. *Id.* Certainly, there was nothing wrong with her brain. Maybe there was something wrong in her spinal cord. *Id.* GBS was unlikely. *Id.*

Dr. Cohen testified that no one did a good neurological examination of Baby Doe when she was admitted to the hospital. Tr. at 317. No one tested her deep tendon reflexes. *Id.* GBS would not occur where the arms are spared and only the legs are involved. *Id.* Baby Doe might have had a transverse myelitis. *Id.* Dr. Cohen could not localize Baby Doe's abnormality to a

specific part of her nervous system based on the record and the various doctors who examined her. *Id.* He does not think that Baby Doe's failure to move her legs reflected damage to her nervous system. *Id.* On the other hand, her lethargy, fever, maybe the irritability, and her not being as responsive as she was previously probably was a neurologic reaction. *Id.*

Dr. Cohen stated that he had no doubt that the parents were correct in saying something happened to Baby Doe. Tr. at 317-18. Dr. Cohen testified that the systemic reaction was neurologic. Baby Doe had fever, lethargy, and less responsiveness to her mother. That is a neurologic reaction. Tr. at 318. But that does not mean it left a permanent sequelae. *Id.* Dr. Cohen pinpointed the reticular activating system, the part of the nervous system that keeps us awake, as the place where Baby Doe's nervous system problem resided. Tr. at 319. It is located in the middle of the brain. Tr. at 320. Dr. Cohen thought her problem could be there or Baby Doe had a diffuse problem that involved the entire substance of the whole brain. Tr. at 321. He agreed that encephalopathy means some kind of disease process in the brain. *Id.* Someone with either a reticular activating system in the middle of the brain or a whole brain problem can have an encephalopathy. *Id.* Dr. Cohen agrees that Baby Doe had an encephalopathy, but he would say it was probably a transient encephalopathy. Tr. at 322. If someone had a high fever with an alteration in the level of awareness, or someone got drunk and did not know what he was doing, those could be an encephalopathy. *Id.*

Dr. Cohen testified that an encephalopathy that led to sequelae would have a continuous line. *Id.* You would see a continuous line and not a patient looking bad one minute and perfectly normal the next minute, but six months later, looking bad again. *Id.* If there were permanent sequelae, the child would not awaken, would not be alert, would not walk

appropriately, would not use her hands appropriately, would not be aware, and would have decreased cognition. Tr. at 323.

Dr. Cohen stated that Baby Doe had her series of vaccinations and had pain in her legs where she had two vaccinations in each leg. Tr. at 327. The vaccinations are commonly associated with a systemic reaction of fever. Sometimes the white count rises and the child became lethargic and irritable. *Id.* The child does not have to get inflammation to have a lot of pain and soreness in her legs. Tr. at 328. There is no evidence that Baby Doe's nervous system was compromised based on her examination. A child with a 101° fever does not usually get a lot of attention. When the temperature goes up to 103,° 104,° or 105,° that is when you pay attention. *Id.* Baby Doe's fever in the hospital was very low grade. It would not have concerned anyone that she was infected. *Id.* Mrs. Doe was able to breast feed her. A child does not breast feed unless she is hungry and can bond with the mother. *Id.* The hospital put in the nasogastric tube to keep Baby Doe hydrated, but it does not have enough calories in the Pedialyte. Tr. at 329. Dr. Cohen could not answer why breast feeding Baby Doe would not have kept Baby Doe hydrated. *Id.*

The next day after Baby Doe went to the hospital, she was doing better and, two days later, she was home. Tr. at 329-30. The doctors did not tell Mrs. Doe that Baby Doe had a problem or may be developmentally delayed. Tr. at 332.

When Baby Doe walked at 15 or 16 months, that was a normal milestone. Tr. at 333. When Baby Doe went to the clinic on July 20, 2005 and they identified her milestones, she was functioning at a normal level. Tr. at 334. At 11 months of age, she could feed herself with her fingers, respond to her name, sit independently, crawl, creep, pull to a standing position, and

play patty cake. *Id.* She was starting to prehend, i.e., pick up small objects. Tr. at 334-35. She started to prehend between nine and 15 months. Tr. at 335.

Dr. Cohen stated that speech problems are very common and, for most children, we do not have a focus in the nervous system allowing us to say where that speech problem is or how it developed. *Id.* He does not know of any disease that causes those problems. Tr. at 335-36. His opinion is that Baby Doe's encephalopathy was minimal. Tr. at 336. She came into the hospital with fever, lethargy, and some staring. By the time she left the hospital, she was normal. She was alert, active, playful, smiling, and feeding. That is not encephalopathy. *Id.* He does not know what caused her speech problem or if she will have it in the future. Tr. at 337. He does not know of any encephalopathic problem that will end this way. *Id.*

Dr. Cohen testified that "the problem of a language delay in a child who was cognitively normal does not make any sense to me in terms of a sequelae of an adverse reaction...." Tr. at 348. Baby Doe's main problems are her socialization and her language. Tr. at 349. She may have some motor skills impairment but they are minor and will resolve at some point. *Id.* Dr. Cohen said, in reference to the comparison of Mrs. Doe's testimony and the records, "I can't look at this record with all the people that have seen [Baby Doe] subsequently and say in fact that [her mother is] right and everybody else is wrong. I mean, I just don't know how I can do that." Tr. at 352.

Dr. Cohen knows that Baby Doe has an expressive language disorder (the phonologic aspect), but does not know that she has an expressive disorder as Dr. Kukas states in her report. Tr. at 357. It is not clear to him that Baby Doe has an oral dysphagia. Tr. at 358. He does not know how Dr. Kukas thinks Baby Doe has possible hyperacusis (abnormal central auditory

processing). *Id.* He does not believe for one moment that Baby Doe has hypotonia or poor body awareness in space. *Id.* Baby Doe does have behavioral problems such as separation anxiety, temper tantrums, and social abnormalities, which are all behavioral in nature and relate to the family situation. *Id.* This is a military family with four children and lots of stress. *Id.* Dr. Kukas prescribes things that are out of the mainstream of medical thinking in terms of eating and foods. *Id.* Dr. Kukas recommended giving Baby Doe vitamins. Tr. at 368. Dr. Cohen is unaware of how vitamins will help attention deficit disorder. *Id.* Dr. Kukas seems to think that a high carbohydrate load would alter Baby Doe's behavior and recommended she increase protein and reduce carbohydrates. *Id.*

Pediatricians have a very difficult time defining what "hypotonia" means. Tr. at 359. The word "hypotonia" means abnormal resistance to movement. *Id.* A child who is walking, has normal reflexes, can climb on a chair, can get out of chair, and can climb stairs is not hypotonic. Tr. at 359-60. Dr. Kukas also talks about hypotonia in oral motor ability and Dr. Cohen has no idea what she is talking about. Tr. at 360. If Baby Doe had paralysis of her facial musculature, then yes, she has hypotonia. *Id.* Hypotonia does not just mean muscle weakness. It means decreased tone, not weakness. Tr. at 361. Dr. Kukas has no factual evidence to support her diagnosis of Baby Doe with residual developmental delays and encephalopathy related to her adverse reaction to her four-month vaccinations. *Id.*

Dr. Cohen admits that Baby Doe had a neurological injury to her central nervous system. Tr. at 364. Baby Doe had a neurologic event from which she had a complete recovery. The event lasted a short period of time. She went home from the hospital and was perfectly normal. Tr. at 365. Some time later, Baby Doe went to the doctor and had some difficulty with language.

Id. Baby Doe does not have any specific insult to her brain that would suggest in fact that her nervous system is damaged. Tr. at 366. Baby Doe may have some developmental defects that cause her to have poor language, but he also thinks that her language will improve. He thinks she has developmental language delay independent of the vaccination. *Id.*

On July 20, 2005, Baby Doe's overall intelligence seemed to be normal. Her cognition was normal. Dr. Cohen thought that if she had major neurological problems, her cognition would be decreased. Tr. at 370.

DISCUSSION

To satisfy their burden of proving causation in fact, petitioners must prove by preponderant evidence "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

The first and third prongs of Althen are not in dispute here. Respondent accepts that pertussis vaccine can cause serious encephalopathy with permanent sequelae and that an adverse reaction to pertussis vaccine can occur the same day as vaccination. The issue in this case is the second prong of Althen, i.e., is there a logical sequence of cause and effect **between** (1) (a) pain from two vaccinations in each thigh causing a five-month-old baby not to move her legs for a

couple of days and (b) fever causing a transient encephalopathy consisting of brief lethargy, anorexia, and fussiness, **and** (2) failure to thrive, speech delay, fine motor delay, and social integration issues in a child not provided sufficient nutrition from the ages of five to 11 months who also has a family history of speech delay and of immaturity in adaptive and emotional skills?

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. *Id.* at 1148. Doctors such as Dr. Hultquist in the instant action stating that Baby Doe's failure to thrive, speech delay, fine motor delay, and social integration issues had to be caused by her transient encephalopathy because there is no other cause do not assist petitioners in proving their case since the Federal Circuit requires petitioners to fulfill an affirmative duty to show actual or legal causation.

Petitioners must show not only that but for the vaccine, Baby Doe would not have had failure to thrive, speech delay, fine motor delay, and social integration problems, but also that the vaccine was a substantial factor in bringing about her failure to thrive, speech delay, fine motor delay, and social integration problems. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Petitioners do not allege a Table injury of encephalopathy in this case because Baby Doe cannot meet the requirements for a Table injury of encephalopathy as listed in 42 C.F.R. § 100.3(b)(2)(i)(A), which include "a significantly decreased level of consciousness lasting for at least 24 hours." "A significantly decreased level of consciousness" is defined as requiring one of the following three clinical signs for at least 24 hours or greater under subsection (D)(1), (2), and

(3): decreased or absent response to environment, decreased or absent eye contact, or inconsistent or absent responses to external stimuli. Subsection (E) states that the following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness: irritability (fussiness), and sleepiness.

A causation in fact encephalopathy is less serious than a Table encephalopathy because any petitioner who could assert a Table encephalopathy would do so in order to benefit from the presumption of causation attached to a Table injury.

Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at p. 610 defines "encephalopathy" as "any degenerative disease of the brain." Stedman's Medical Dictionary, 27th ed. (2000) at p. 588 defines "encephalopathy" as "Any disorder of the brain." Based on the evidence before the undersigned, unless fever causing lethargy and fussiness is considered a degenerative disease or disorder of the brain, the undersigned would hold that Baby Doe did not have an encephalopathy. No treating doctor at the time Baby Doe was in Reynolds Army Community Hospital for her adverse reaction to pertussis vaccine (and possible viral illness) diagnosed her with encephalopathy. She was never referred to a neurologist and she never saw a neurologist until her parents filed a petition under this Program and their attorney directed them and Baby Doe to Dr. Miller who wrote an expert report and testified for petitioners.

Respondent's expert Dr. Cohen provided testimony that conflicted with his expert report in which he opined that Baby Doe did not have an encephalopathy. Dr. Cohen inched his way into the diagnosis of encephalopathy by first testifying that he thought Baby Doe's reaction was neurologic. The following colloquy occurred:

THE COURT: Did you say there was a neurologic reaction?
THE WITNESS: I think the systemic reaction was neurologic, yes.
THE COURT: Could you explain what that means?
THE WITNESS. Well, yes. I mean, I think that the child had fever. I think the child was lethargic and the child probably was not as responsive to the mother as she had been even – I don't know – the previous day or several hours before.
Well, that's a neurologic reaction, but that doesn't mean it was going to leave itself any permanent sequelae, and that's the thing that I think you're looking at.
I mean, the easiest thing, for instance, is if a football player knocks himself out on the football field and has a concussion and doesn't respond you take him out of the field of play. You leave him there, depending how bad it is, for a week or a month, and he goes back and he plays again.
He had technically an encephalopathy. That's what knocked him out. That's what the concussion was, but he's normal.

Tr. at 318-19.

Then Dr. Cohen proceeded to diagnose "encephalopathy:"

THE COURT: So encephalopathy means you have some kind of disease process in the brain. Encephalopathy.
THE WITNESS: That's absolutely correct. The word encephalo refers to brain. The word pathology or pathos refers to disease. There's an abnormality of the nervous system, and that's all it means. ...
THE COURT: So you agree that Baby Doe had an encephalopathy?
THE WITNESS: Yes, I would say she had a transient encephalopathy. I would say that's probably correct.
But a fever, a high fever to anybody if they have an alteration in level of awareness, if they become confused is an encephalopathy. If I get drunk and not know what I'm doing, that's an encephalopathy. If I get confused and see things, which you commonly do when you get drunk, that's an encephalopathy.
THE COURT: But there are encephalopathies which do lead to sequela. Is that correct?
THE WITNESS: Yes, they do. There are encephalopathies that do lead to sequela, but those encephalopathies I think that you're referring to are continuous line. You don't see something where in fact the patient looks bad one minute, looks perfectly normal the next minute and six months later looks bad again.

Tr. at 321-22.

Because of Dr. Cohen's testimony, the undersigned holds that Baby Doe had an encephalopathy as part of her adverse reaction to her vaccinations. The issue remaining is whether that encephalopathy was merely transient because Baby Doe's fever was gone in the hospital, her fussiness and lethargy ended, she became awake, alert, responsive to her mother, smiling, cooing, wetting and soiling her diapers, and breast feeding so that when she left the hospital on January 15, 2005, she weighed more and was in the 90th percentile for weight than when she was admitted to the hospital on January 13, 2005 and was in the 55th percentile for weight. Three days later, she saw Dr. Hultquist for a follow-up and she was neurologically normal, moving her extremities, awake, alert, and weighed even more than she had when she was discharged three days earlier.

Petitioners allege that Baby Doe's encephalopathy was damaging. Mrs. Doe denies the truth of all the medical notations that Baby Doe was awake, alert, breast feeding, cooing, smiling, reaching for toys, and gaining weight. As far as she is concerned, Baby Doe became comatose for weeks, regardless of the notes of Dr. Davis in the hospital and Dr. Hultquist three days after discharge that she was awake and alert. Mrs. Doe never took Baby Doe to see a doctor for six months after her discharge from the hospital. Mrs. Doe's mother came back from her school studies in Colorado to Oklahoma in June 2005 and, when she saw how tiny Baby Doe had become, she encouraged Mrs. Doe to take her to the doctor. Mrs. Doe took Baby Doe to the pediatric clinic at Reynolds on July 20, 2005, and saw Dr. Janice Gibbons to whom she told that Baby Doe was a good eater. Baby Doe went from the 90th percentile in weight at five months when she was discharged from the hospital to below the fifth percentile in weight on July 20,

2005. Dr. Gibbons diagnosed Baby Doe with failure to thrive and directed Mrs. Doe to return in one week.

Mrs. Doe did not return for seven weeks. The next time Mrs. Doe brought Baby Doe in to see the doctor at the pediatric clinic, she brought her mother with her. Mrs. Doe directly asked Dr. Hultquist if he was accusing her of neglect and he denied it. He said he was trying to cover all bases. And he did try. He attempted to find out if the reason that Baby Doe was malnourished for those six months from January to July 2005 was due to a bowel obstruction. He did not find a bowel problem. Dr. Jones, the pediatric gastroenterologist, tried to find out if Baby Doe had a hyperthyroid condition to explain why Baby Doe was malnourished from January to July 2005, but there is nothing in the records to show that anyone reached that conclusion although Baby Doe did have two abnormal TSH readings.

If Baby Doe had been malnourished because she refused to eat, petitioners might succeed in trying to show causal connection to a serious brain injury. But Mrs. Doe told Dr. Gibbons at the July 20, 2005 visit that Baby Doe was a good eater. Mrs. Doe and her mother reiterated that Baby Doe was a good eater when they saw Dr. Hultquist seven weeks later with Baby Doe. When Mrs. Doe finally gave Baby Doe enough food to eat, Baby Doe began to gain weight and resumed normalcy in weight and height. Petitioners' assertion that Baby Doe's failure to thrive was due to her vaccine reaction is not credible. Mrs. Doe's credibility is non-existent in this case because of her constant dramatization, embellishment, and invention of symptoms Baby Doe did not have. Whereas the medical records show that Baby Doe was awake, alert, smiling at her mother, cooing, reaching for toys, responding to noise by turning her head right and left, breast feeding, urinating and defecating, Mrs. Doe says all these records are wrong. In later visits to

doctors, Mrs. Doe paints a picture of a child that is not Baby Doe. She said Baby Doe never breast fed in the hospital and that the nasogastric tube had breast milk in it which is what fed Baby Doe. That is untrue. The nasogastric tube had Pedialyte in it, not breast milk. The nursing staff timed Mrs. Doe's breast feeding sessions with Baby Doe..

Mrs. Doe stated that Baby Doe lay there staring into space. But Baby Doe's lethargy was solely transient. Mrs. Doe told providers that Baby Doe almost died. This is untrue. She told providers that Baby Doe had flaccid paralysis and her experts Dr. Hastings and Dr. Miller relied on this in forming their opinions that Baby Doe had permanent sequelae from her encephalopathy. But Dr. Hultquist, her treating pediatrician, testified that Baby Doe did not have flaccid paralysis. He was there. Apparently, Dr. Hultquist's statement at trial and the contents of the contemporaneous medical records made no impression on Dr. Hastings or Dr. Miller, who testified in accordance with their expert reports. They must think that Mrs. Doe is more credible than the doctor who took care of Baby Doe when her parents brought her into Reynolds. There is no treating doctor, Hultquist or Davis, who diagnosed Baby Doe with flaccid paralysis and the medical records note Baby Doe had no flaccidity. Dr. Hultquist was not disturbed by Mrs. Doe's "diagnosis" because she is a lay person and basically, you do not expect a lay person to be accurate. But Mrs. Doe's "diagnosis" forms the basis of Dr. Miller's and Dr. Hastings's expert opinions.

Dr. Cohen also testified Baby Doe did not have flaccid paralysis. With the lack of truth-telling that Mrs. Doe has manifested throughout these records as well as in her testimony, the undersigned does not accept her contrary versions of Baby Doe's behavior during the six months Mrs. Doe kept her at home between her hospital discharge and her trip back to the pediatrician

Dr. Gibbons. These two versions are either Baby Doe was subdued and not herself (to Dr. Hastings) or that she was screaming and crying like a colicky baby (to Dr. Miller). If she were subdued, it would be from lack of adequate nutrition, not from the effects of encephalopathy.

The special master's "assessments of the credibility of the witnesses" are "virtually unchallengeable on appeal." Lampe v. Sec'y of HHS, 219 F.3d 1357, 1362 (Fed. Cir. 2000) (quoting Hines v. Sec'y of HHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

Mrs. Doe informed speech pathologist Sarah Kay on March 14, 2008 that speech delay runs in her family. Mrs. Doe informed developmental pediatrician Dr. Laurie Kukas on July 28, 2008 that her youngest son Aidan had early intervention for immaturity in adaptive and emotional skills. There are sound reasons to link a logical sequence of cause and effect between the family history of speech delay and of immaturity in adaptive and emotional skills with Baby Doe's speech delay and social integration problems. There are sound reasons as well to query whether a baby not fed appropriately from the age of five to 11 months will have resultant failure to thrive not only physically, but neurologically, if indeed Baby Doe has fine motor skill delay. Dr. Cohen questioned whether Baby Doe has fine motor delay.

Petitioners have made two statements throughout this hearing that are untrue. The first is that the mother knows best. Mrs. Doe has dramatized and embellished Baby Doe's symptoms to every treater subsequent to her January 18, 2005 visit to Dr. Hultquist. She has told diametrically opposite stories about Baby Doe's behavior during the six months Baby Doe was at home and not receiving adequate nutrition. Either Baby Doe was lying subdued for six months without any normal activity or she was screaming and crying like a colicky baby. She told Dr. Hastings, her expert internist, as well as the court the first version, and she told Dr.

Miller, her expert pediatric neurologist, the second version. She told every doctor that Baby Doe had flaccid paralysis in the hospital, but her treating pediatrician Dr. Hultquist testified that Baby Doe did not have flaccid paralysis. So, for that matter did Dr. Cohen. The medical records themselves state "no flaccidity." She denied that Baby Doe could eat in the hospital and said that the staff had to put breast milk in the nasogastric tube that Baby Doe had. This is untrue. The NG tube had Pedialyte to prevent dehydration. The nurses timed Baby Doe's breast feeding which lasted 86 minutes. She soiled her diapers. She had wet diapers. She put on weight. Mrs. Doe denied all the hospital records stating that Baby Doe was awake, alert, smiling at her mother, cooing, turning to right and left in response to sounds, moving her legs, and reaching for toys. Dr. Hultquist attempted to come to Mrs. Doe's aid by saying that they were not pediatric nurses. One could argue that a nurse does not have to be trained in pediatrics to recognize if someone was awake, alert, etc. But the fact is that Dr. Davis, who is Dr. Hultquist's partner, also noted that Baby Doe was awake and alert. Dr. Hultquist did not mention Dr. Davis's notes that are consonant with the notes of those non-pediatric nurses. Dr. Davis diagnosed Baby Doe with a normal immunization reaction and questioned whether she also had a virus because of her rash.

Interestingly, all the symptoms that Baby Doe had during her transient encephalopathy are listed as adverse reactions in the GlaxoSmithKline informational material that petitioners filed as Exhibit 21. These are, however, not neurologic symptoms. The drug manufacturer's list of symptoms and Baby Doe's symptoms were transient vomiting, diarrhea, fever, irritability, drowsiness, pain, restlessness, and anorexia. GlaxoSmithKline would not have listed Baby Doe as having an encephalopathy based on their definition of "encephalopathy" as including coma, decreased level of consciousness, and prolonged seizures. The Vaccine Act requires the

manufacturer to report adverse reactions to the respondent with a VAERS report. Ex. 21, p. 395. GlaxoSmithKline would not have reported Baby Doe to VAERS as having an encephalopathy. In fact, Dr. Hultquist did file a VAERS report on January 21, 2005 and he did not report that Baby Doe had an encephalopathy. He did say she had recovered from her reaction.

Mrs. Doe told providers that Baby Doe almost died in the hospital. This is untrue. She told subsequent providers that Baby Doe had had a seizure in the hospital. Then she changed that story to one where Baby Doe had had a seizure before she and her husband took Baby Doe to the emergency room and then Baby Doe had other seizures (in the plural) in the hospital. Petitioners' petition states that Baby Doe had a seizure before coming to the ER and multiple seizures in the hospital. There is no contemporaneous record of Baby Doe's ever having had a seizure. Even Dr. Miller, petitioners' expert pediatric neurologist, was skeptical because Mrs. Doe did not describe what this supposed seizure looked like. In the courtroom, Mrs. Doe described eyelids fluttering and eyes moving back and forth. The nurses were in Baby Doe's room constantly, making sure that Mrs. Doe knew where the call button was. When Mrs. Doe was particularly aggravated, the nurse called Dr. Hultquist who talked to Mrs. Doe for 40 minutes. Everyone knew to watch and keep close tabs on Baby Doe which they did and to make sure Mrs. Doe was all right because of Mrs. Doe's panic. If Mrs. Doe had seen anything unusual in Baby Doe, she would have called in the nurse and the nurse would have noted it in the records and told Dr. Davis or Dr. Hultquist. This never occurred (although Mrs. Doe testified that she did speak with a nurse who saw the supposed seizure). Because Mrs. Doe has embellished Baby Doe's symptoms continually, insisting that she was paralyzed, near death, not feeding even for weeks (when the records reflect Baby Doe was awake, alert, and gaining weight), the

undersigned does not believe Mrs. Doe's stories about Baby Doe having had one or many seizures. Mrs. Doe also thought Baby Doe might be autistic (she was not), that she might have lead or mercury poisoning (nothing in the record reflects that), or that she was at risk of toxic shock and dying as supposedly another infant did (Dr. Apost questioned whether this were true) when Baby Doe had white lesions on her tongue.

The Vaccine Act does not allow the undersigned to give credence to Mrs. Doe's various and conflicting accounts of Baby Doe's symptoms when they are unsupported by medical records or medical opinion: "The special master or court may not make such a finding [that petitioner is entitled to compensation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). Any doctor who subsequently relied upon Mrs. Doe's history of flaccid paralysis, seizures, 105° fever, refusal to suck, and continuing unresponsiveness would reach a conclusion that is erroneous, and the doctors who testified for petitioners did reach erroneous conclusions in this case. An expert opinion is no better than the soundness of the reasons supporting it. Gurr v. Sec'y of HHS, 37 Fed. Cl. 314, 320 (Fed. Cl. 1997) (petitioners' claims conflicted with the contents of the medical records; petitioners' medical expert opinion "plagued by gaps in his logic and was unsupported by the totality of evidence on record;" petition dismissed; dismissal affirmed); Raley v. Sec'y of HHS, No. 91-0732V, 1998 WL 681467, at *7 (Fed. Cl. Spec. Mstr.1998). When Mrs. Doe told Dr. Hastings and Dr. Miller that Baby Doe had a significantly decreased level of consciousness, 105° fever, seizures, and flaccid paralysis, their conclusions were as faulty as the information she gave them. The mother does not know best when she denies the accuracy of the reports of numerous nurses and her treating pediatricians, Dr. Davis and Dr. Hultquist, that Baby Doe was

awake, active, alert, breast feeding, gaining weight, responding to sound by turning her head left and right, cooing, smiling at her mother, reaching for toys, wetting and soiling her diapers, and being normal neurologically on discharge. Dr. Davis, her treating pediatrician, was correct when he diagnosed Baby Doe as having a normal immunization reaction. Dr. Hultquist was correct three days later in the follow-up examination when he wrote that Baby Doe was normal neurologically, and, three days after that, when he filed the VAERS report, that Baby Doe had recovered from her vaccine reaction.

An examination of Song v. Sec'y of HHS, 31 Fed. Cl. 61 (1994), aff'd without opinion, 41 F.3d 1520 (Fed. Cir. 1994) is instructive. In Song, the Honorable Robert J. Yock affirmed the dismissal of a mother's petition which alleged that her child Nicholas's learning and speech disabilities were due to his reaction to DPT vaccine. The ground of Judge Yock's affirmance of the dismissal was that the mother failed to establish a causal connection between Nicholas's disabilities and the then-Table injury of residual seizure disorder. Nicholas developed a slight fever of 101 degrees on the day of his second DPT vaccination. Two days later, he appeared to have two seizures and was taken to the ER. In the hospital, he had two more seizures. Afterward, he was found to be alert and all his hospital tests proved normal. He was discharged on anti-convulsants. 31 Fed. Cl. at *63. Five months later, he had reached appropriate milestones. Subsequently, he was noted to have delay in his expressive and receptive language functions. *Id.* Petitioner alleged that Nicholas's Table reaction to DPT resulted in learning disability, expressive language delay, and hypotonia. *Id.*

Respondent defended, stating that Nicholas did not have an injury lasting more than six months after onset and that his current problems were unrelated to his seizure episodes. *Id.* The

chief special master dismissed from the bench, stating that although Nicholas had the Table injuries of encephalopathy and residual seizure disorder, petitioner failed to establish a causal link between those injuries and his subsequent language deficits. 31 Fed. Cl. at *63-64, 65. As Judge Yock noted, Nicholas did not have to manifest the speech delay within six months of his injury, but petitioner had to prove that there was a causal connection between Nicholas's Table injuries and his speech delay. 31 Fed. Cl. at *66. Petitioner's expert offered only conclusory statements that Nicholas's current speech delays were a result of his Table injuries. 31 Fed. Cl. at *67. Petitioner's expert stated merely, "This child had a DTP shot, followed by a series of seizures. The seizures indicated to me that he suffered encephalopathy, and as a result of that, he now has the speech and language problem." *Id.* The expert admitted there were many other factors that can cause speech delay. 31 Fed. Cl. at *68.

Respondent's expert denied that Nicholas's encephalopathy and residual seizure disorder caused his speech problems based on the fact that Nicholas suffered no loss of clinically significant milestones between the date of his seizures and six months later. *Id.* In addition, respondent's expert gave as a basis for no causation between the Table injuries and Nicholas's speech problems the fact that there were no laboratory data or clinical presentation showing that Nicholas's brain was injured. *Id.*

In the instant action, Baby Doe made her nine-month milestones, and there were no laboratory data or clinical presentation when she was hospitalized from January 13-15, 2005 that indicated her brain was injured, regardless of the many histories Mrs. Doe subsequently gave which indicated otherwise, and the conclusory statements of her medical witnesses that the

encephalopathy had to be the cause of her failure to thrive, speech delay, fine motor delay, and social integration problems because what else could be the cause.

These witnesses's testimony that the encephalopathy had to have been the cause because what else could be is the second untrue statement in this hearing. As respondent's expert Dr. Cohen stated during the hearing, encephalopathy does not disappear and come back. If a child has an encephalopathy serious enough to cause developmental delay, you will see a different child, not a child who is awake, alert, with normal muscle tone and strength, feeding normally, urinating and defecating normally, reaching for toys, responding to sound, smiling at her mother, and cooing. The undersigned accepts Dr. Cohen's testimony as more persuasive than that of Dr. Miller and Dr. Hastings. The undersigned focuses more on Dr. Miller's testimony because Dr. Miller is a pediatric neurologist, rather than Dr. Hastings's testimony, because he is just an internist.

Dr. Cohen is the Chairman of the Department of Neurology at the State University of New York at Buffalo. He has authored 79 articles, co-authored three books, and written 17 book chapters. Dr. Miller has written two published articles, one on epilepsy and the other on pediatric migraine. Dr. Miller's conclusions about Baby Doe's condition (encephalopathy leading to developmental delay) were based exclusively on Mrs. Doe's history which was filled with embellishments and untruths. One might ask, since Dr. Miller also did a record review, how he ignored the discrepancy between the contents of the contemporaneous medical records and Mrs. Doe's subsequent embellishments in order to reach his conclusion. The undersigned finds persuasive Dr. Cohen's opinion that a transient encephalopathy does not lead to permanent sequelae, and holds that Baby Doe's speech delay, fine motor skill delay (if it exists), and social

integration issues were not caused by her vaccine reaction. Petitioners in this case have the same legal problem as in Song: they have failed to prove more than six months sequelae of Baby Doe's vaccine injury, as the Vaccine Act requires. 42 U.S.C. §300aa-11(c)(1)(D)(i).

As the Federal Circuit stated in Hines v. Sec'y of HHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991), "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error [is] extremely difficult to demonstrate." The Federal Circuit in Hodges v. Sec'y of HHS, 9 F3d 958, 961 (Fed. Cir. 1993), also stated that the court is "not to second guess the Special Master[']s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." The Federal Circuit stated, "That level of deference is especially apt in a case in which the medical evidence of causation is in dispute." 9 F.3d at 961. Hodges dealt with the parents' failure to prove sequelae of an alleged Table injury or, in the alternative, causation in fact.

Petitioners' statement that Baby Doe's encephalopathy had to have caused her failure to thrive could only be true if Baby Doe had refused to eat. But, as Mrs. Doe told Dr. Janice Gibbons on July 20, 2005, when she finally brought Baby Doe to see a doctor, Baby Doe was a good eater. There was nothing wrong with her brain to keep her from eating. She did not have a bowel obstruction (Dr. Hultquist investigated) or a hyperthyroid condition (Dr. Jones investigated). When finally Mrs. Doe saw the nutritionist Walmsley and could be persuaded to increase Baby Doe's nutrition beyond breast milk and cereal and fruit (if she was giving Baby Doe the latter), Baby Doe grew and developed. She was ultimately diagnosed as no longer having failure to thrive. Then nutritionist Walmsley tried to steer Mrs. Doe into giving Baby Doe more quality food than cheeseburgers, ice cream, and candy. Nutritionist Walmsley

inserted in her notes the only reasonable conclusion, i.e., when given enough to eat, Baby Doe gained weight.

On clinical evaluation, Baby Doe was always normal neurologically. Dr. Cohen made it clear that he did not know if Baby Doe's speech delay had any neurologic reason since speech delay is a common childhood problem. Since Baby Doe's family has a history of speech delay, Dr. Cohen's opinion is a reasonable one. Moreover, considering the family history of immaturity in adaptive and emotional skills (Baby Doe's brother Aidan was receiving early intervention for these problems), Dr. Cohen's opinion that Baby Doe's social integration problems have a behavioral, not a neurological, basis also is a reasonable one. He is unsure that Baby Doe even has fine motor skill delay since she can hold a pencil and other objects.

Dr. Cohen took issue with the developmental pediatrician Dr. Kukas's examination of and recommendations (including vitamins) for Baby Doe. Mrs. Doe gave Dr. Kukas a copy of her neurological expert Dr. Miller's report which was based on the misinformation that Mrs. Doe gave Dr. Miller before Dr. Kukas ever reached her conclusions. Dr. Cohen could not understand how Dr. Kukas could find that Baby Doe has hypotonia and low tone orally (whatever that means). No one who examined Baby Doe, even Dr. Miller, her expert pediatric neurologist, found anything abnormal about Baby Doe's muscle tone.

It may even be that Baby Doe has no neurologic problems. Baby Doe weighed less than the fifth percentile when she saw Dr. Gibbons on July 20, 2005 at 11 months of age and yet she made her nine-month milestones, according to Mrs. Doe: feeding herself with her fingers, responding to her name, sitting independently, crawling and creeping, pulling to a standing position, and playing patty cake. One might note that this description hardly comports with a

child who is just lying in her crib, subdued in affect, just having a blood pressure and breathing, as Mrs. Doe testified. It also does not comport with Mrs. Doe's occasional history that Baby Doe spent those cloistered six months screaming and crying like a colicky baby.

Petitioners have failed to prove the second Althen prong because there is no logical sequence of cause and effect between a transient encephalopathy and permanent sequelae. Baby Doe had two days of fever, lethargy, and fussiness, followed by normal behavior, including being awake, alert, responding to noise, cooing, smiling, reaching for toys, breast feeding, soiling and wetting her diapers, and gaining weight. Petitioners have failed to make a prima facie case of causation.

The Federal Circuit in Grant stated that petitioners have the affirmative burden of proving causation in fact. That means petitioners cannot prevail with the statement that Baby Doe's failure to thrive, speech delay, fine motor delay, and social integration problems must be due to her adverse reaction because what else could have caused them.

In order for petitioners to prevail, the Vaccine Act, §13(a)(1), requires petitioners to prove (a) by a preponderance of the evidence that the vaccine in question caused Baby Doe's current condition, and, in addition, (b) there must not be preponderant evidence that a known factor unrelated to the vaccine caused Baby Doe's current condition. Over the years, the question has arisen over which party has the burden of proving there is no factor unrelated to the vaccine that is the cause of the vaccinee's injury and/or sequelae. The Federal Circuit answered that question in Pafford v. Sec'y of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006) ("Under this court's precedent, [petitioner] must prove by preponderant evidence both that her vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm

would not have occurred in the absence of the vaccination"). The Pafford Court quoted the language of its decision in Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999): "We adopt the Restatement rule for purposes of determining vaccine injury, that an action is the 'legal cause' of harm if that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action." 451 F.3d at 1255.

Petitioners herein did not prove by preponderant evidence that Mrs. Doe's failure to provide adequate nutrition to Baby Doe for six months (when Baby Doe was five to 11 months of age), plus Baby Doe's family history of speech delay and of immaturity in adaptive and emotional skills were not factors unrelated to the vaccination which caused in fact her speech delay, fine motor delay, and social integration problems. In other words, petitioners did not prove that "but for" the vaccination, Baby Doe would not have had failure to thrive, speech delay, fine motor delay, and social integration problems. Shyface, 165 F.3d at 1352.

In Pafford, petitioners sued alleging that DTaP, MMR, and polio vaccinations caused their child's systemic juvenile rheumatoid arthritis or Still's disease. Petitioners failed to prove a medically appropriate time interval between the vaccinations and the onset of the Still's disease or the third Althen prong. 451 F.3d at 1357. Petitioners also never established that the vaccinations were a but-for cause of the child's Still's disease. *Id.*

In Walther v. Sec'y of HHS, 485 F.3d 1146 (Fed. Cir. 2007), the Federal Circuit repeated its holding in Pafford that when petitioners do not make a prima facie case, the requirement of showing no other factor unrelated to the vaccine caused the injury or sequelae is petitioners' burden, stating that in Pafford, it held "that a petitioner as a practical matter may be required to eliminate potential alternative causes where the petitioner's other evidence on causation is

insufficient...." 485 F.3d at 1150-51. The Federal Circuit repeated the "but-for" standard adopted in Shyface, stating "if the petitioner did not successfully eliminate other causes, then the petition would fail and the second prong would not be reached." 485 F.3d at 1151. The Federal Circuit continued by stating that "the petitioner may find it necessary to [use evidence eliminating other potential causes of the harm] when the other evidence on causation [from the vaccine] is insufficient to make out a prima facie case, as was true in Pafford. In such instances, clearly the special master must evaluate what evidence a claimant presents as part of determining whether the claimant makes a prima facie case." *Id.* In footnote 4, the Federal Circuit states, "Where multiple causes act in concert to cause the injury, proof that the particular vaccine was a substantial cause may require the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine." *Id.*

In deBazan v. Sec'y of HHS, 539 F.3d 1347, 1352 n.3 (Fed. Cir. 2008), the Federal Circuit stated that petitioners's failure in Pafford to eliminate other potential causes was fatal to the petition when they had not provided evidence of a proximate temporal relationship between the vaccine and the injury.

In the instant action, petitioners have failed to satisfy the second Althen prong. The undersigned finds respondent's expert neurologist Dr. Cohen's testimony persuasive that a transient encephalopathy caused by a fever, resulting in a day or so of lethargy and fussiness (to which pain from the four injections also contributed), does not have permanent sequelae, and there is no logical sequence of cause and effect between the transient encephalopathy and Baby Doe's failure to thrive, speech delay, fine motor delay, and social integration problems.

The factors unrelated to vaccination here include insufficient nutrition during the ages of five to 11 months, and a family history of speech delay and of immaturity in adaptive and emotional skills. Petitioners never proved these other factors (insufficient nutrition and family history) were not the cause of Baby Doe's failure to thrive, speech delay, fine motor delay, and sensory integration problems. In the absence of petitioners's making a prima facie case because they failed to satisfy the second prong of Althen, they had the burden to prove these other factors were not the cause of Baby Doe's problems. They never satisfied this burden.

Petitioners's experts Dr. Hastings and Dr. Miller based their opinions on histories that were untrue (flaccid paralysis, 105° fever, inability to respond, failure to suck in the hospital, seizures) and Dr. Hultquist, a treating pediatrician, based his opinion on causation on his view that what else could have caused Baby Doe's failure to thrive, speech delay, fine motor delay, and social integration but her vaccine reaction. Dr. Hultquist is not a neurologist and may never have familiarized himself with Baby Doe's subsequent records to realize that speech delay and immaturity in adaptive and emotional skills run in Baby Doe's family. But even if there were no alternative causes for Baby Doe's current problems, "the absence of alternative causes does not alone suffice to ascribe causation to the vaccine." Lampe, 219 F.3d at 1361, citing Grant, 956 F.2d at 1149. The undersigned finds Dr. Hastings's, Dr. Miller's, and Dr. Hultquist's opinions on sequelae unpersuasive. The probative value of the evidence and credibility of the witnesses are matters within the purview of the fact finder. Lampe, 219 F.3d at 1360.

Petitioners have failed to make a prima facie case that a logical sequence of cause and effect exists between a transient encephalopathy and failure to thrive, speech delay, fine motor delay, and social integration problems. Since they have not made a prima facie case of

causation, they have failed to satisfy their burden of proving that factors unrelated to the vaccinations (insufficient nutrition and family history) are not the cause in fact of Baby Doe's current problems.

CONCLUSION

This petition is dismissed. The Clerk of the Court shall enter judgment in accordance with this decision.

IT IS SO ORDERED.

October 23, 2009
DATE

s/Laura D. Millman
Laura D. Millman
Special Master