

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. [redacted]V

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To be Published

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JOHN and JANE DOE/05, on behalf of \*  
their daughter, BABY DOE, \*

Petitioners, \*

v. \* DPT not shown to cause

seizure 13 days later

SECRETARY OF THE DEPARTMENT \*  
OF HEALTH AND HUMAN SERVICES, \*

Respondent. \*

\*\*\*\*\*

Paul S. Dannenberg, Huntington, VT, for petitioners.

Chrysovalantis P. Kefalas, Washington, DC, for respondent.

**MILLMAN, Special Master**

### DECISION<sup>1</sup>

On February 17, 2004, petitioners filed a petition under the National Childhood Vaccine

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<sup>1</sup> 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 clearly be an unwarranted invasion of privacy. When such a decision is filed, petitioners have 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. Since the initial Ruling on Onset issued on July 30, 2007 was redacted and reissued August 21, 2007, and reissued published on January 21, 2009, the undersigned assumes petitioners wish the instant Decision to be redacted as well. Thus, this decision is being issued redacted on July 31, 2009.

Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that their daughter Baby Doe was injured from receiving acellular DPT and HiB vaccine on March 26, 2001. The petition is silent as to the onset of Baby Doe's alleged seizures. It is also silent as to any other type of reaction to her vaccinations.

On February 17, 2004, this case was assigned to former special master Margaret M. Sweeney.

On September 21, 2005, this case was reassigned to the undersigned.

A hearing was held in Boston on May 24, 2007 solely on the issue of onset. The undersigned issued a Ruling on Onset on July 30, 2007, holding that Baby Doe's first seizure occurred no sooner than 13 days after she received acellular DPT vaccine.

A second hearing was held on May 29, 2008 with two experts for petitioners (Dr. Jacobson, a pediatric neurologist, and Dr. Johnston, a treating pediatrician) and one expert for respondent (Dr. Wiznitzer, a pediatric neurologist) to determine if petitioners' experts believed that acellular DPT can and did cause seizures 13 days after vaccination.

On September 9, 2008, petitioners filed their post-hearing brief.

On October 8, 2008, respondent filed her post-hearing brief.

On November 14, 2008, petitioners filed their reply brief to respondent's brief.

On January 21, 2009, the undersigned published her Ruling on Onset.

## **FACTS**

Baby Doe was born on September 8, 2000. Baby Doe is Jane Doe's third child.

Twelve days after she was born, Baby Doe saw Dr. Thomas C. Johnston, her pediatrician, on September 20, 2000. Med. recs. at Ex. A, p. 7. Baby Doe had been sleeping poorly at night,

waking every two to three hours. She had severe diaper dermatitis with satellite lesions in the perineum. *Id.*

Eight days later, on September 28, 2000, Jane Doe telephoned Dr. Johnston about the diaper rash. *Id.* Jane Doe had been up all night with discomfort. Jane Doe had tried everything. Dr. Jon R. Jolles referred Jane Doe to a dermatologist and she saw Dr. Saad who gave her zinc oxide and recommended Baby Doe go back to Enfamil with iron. *Id.*

Four days later, on October 2, 2000, Jane Doe telephoned Dr. Johnston. Med. recs. at Ex. A, p. 8. She began Baby Doe on Enfamil with iron on Saturday and now Baby Doe was spitting up most of her feeding, but seemed to like this formula better. Dr. Johnston suggested adding one tablespoon of rice cereal to each bottle and to call if Baby Doe had no improvement or Jane Doe had concerns. *Id.*

Two weeks later, on October 16, 2000, Jane Doe telephoned Dr. Johnston. *Id.* Baby Doe was very colicky. Jane Doe had tried multiple formulas. She had not tried Alimentum formula yet. Baby Doe was still quite fussy. Dr. Johnston recommended Jane Doe try some Zantac 1 cc. twice daily and he would see Baby Doe in a week or two. He discussed the possibility of using Nutramigen or Alimentum if this did not work. *Id.*

One day later, on October 17, 2000, Baby Doe saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 6. She had been fine until three weeks of age and, then, in the last couple of weeks, Baby Doe had been miserable. She was up at night crying. She had very colicky behavior, pulling her legs up and refluxing with spitting after almost every feeding, especially at night. Jane Doe had tried multiple formula, including soy and cow's milk. Baby Doe was currently on Carnation good start. Jane Doe did try to feed cereal to Baby Doe but Baby Doe

would not eat the formula with cereal in it. Dr. Johnston's assessment was that Baby Doe's behavior was very compatible with gastroesophageal reflux. He advised continuing Baby Doe on Zantac and to try Nutramigen for one week. He gave samples to Jane Doe. If Baby Doe did not improve, she might need a referral for a gastrointestinal clinic. It was all right to try some oatmeal in her bottle rather than cereal. *Id.*

On October 25, 2000, Tufts authorized Nutramigen for up to one year of age. *Id.*

On November 1, 2000, Jane Doe told Dr. Johnston that Baby Doe had been up the prior night with a croupy cough, but no fever. She was fussy. *Id.* Baby Doe saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 10. She had reflux, and intolerance to cow's milk and soy. She was on Nutramigen. Her sister had a cold and, the prior night, Baby Doe was up with a croupy cough but no fever. She was a little bit fussy but still eating quite well. She did not have vomiting or diarrhea. Jane Doe wanted Baby Doe checked. Baby Doe had still been miserable but no more miserable than before. Baby Doe had a mild cough in the office. Dr. Johnston's impression was Baby Doe had a cold with cough. He suggested a humidifier, bulb suction of her nose, and an upright position. *Id.*

On November 1, 2000, at 10:45 p.m., Baby Doe was brought to South Shore Hospital Emergency Department by ambulance because of difficulty breathing. Med. recs. at Ex. C, p. 212. She was on thickened Nutramigen and reflux precautions were being taken. Med. recs. at Ex. C, p. 211. The history Mr. and Jane Doe gave was that, at 2:00 a.m., Baby Doe had a cough and increased trouble breathing. Med. recs. at Ex. C, p. 213. She had decreased oral intake. She had been coughing all day and, that night, she was gasping for breath. She had vomited once and had wet diapers. She had no fever or diarrhea. Her history included reflux and thickened

Nutramigen. The diagnosis was bronchiolitis. *Id.* The medical personnel prescribed a shower, vaporizer, Vicks on Baby Doe's chest, and Tagamet. Dr. June Hanly wrote the report. Med. recs. at Ex. C, p. 214. Jane Doe said that Baby Doe had only had problems with reflux before this morning when she had a cough. The cough got much worse and her oral intake was down. She vomited once and seemed to have trouble breathing. Her parents called an ambulance but, when Baby Doe got outside in the ambulance, her breathing got much better. Baby Doe had no fever although her parents were giving her Tylenol with cold medicine. They stopped that at 4:00 p.m. She had normal bowel movements. Her wet diapers were not as wet. Her eight-year-old sibling had a cold. Baby Doe was on Tagamet. She was being treated for reflux with Tagamet, Nutramigen, and thickened feedings. Her temperature was 99.5°. Baby Doe had mild retractions. She had diffuse intermittent expiratory wheezes. Neurologically, she was within normal limits. *Id.* Dr. Hanly's differential diagnoses were upper respiratory infection versus bronchiolitis versus pneumonia. Med. recs. at Ex. C, p. 215. Baby Doe was given 0.25 Albuterol nebulizer every four hours. Her chest x-ray showed mild hyperinflation. Because Mr. and Mrs. Doe were very worried about Baby Doe's breathing at home, she was kept overnight for observation. *Id.* Baby Doe's five-year-old sibling had asthma. Med. recs. at Ex. C, p. 224. The family had a cat and a dog. *Id.* Baby Doe was admitted to South Shore Hospital at 12:05 a.m. on November 2, 2000. Med. recs. at Ex. C, p. 228. Mr. and Mrs. Doe were with her. Baby Doe was easily consoled with a bottle. She had an occasional dry, harsh-sounding cough. She was sleeping and comfortable. *Id.* At 2:00 p.m., Baby Doe was bulb-suctioned for white nasal discharge. She had no respiratory distress. She was alert and happy. *Id.* At 4:30 p.m., her breath sounds were clear. She had slight congestion and a cough. She took feeds well. She was

discharged home on a nebulizer. Med. recs. at Ex. C, p. 229.

Two days later, on November 3, 2000, Jane Doe telephoned Dr. Johnston. *Id.* She was using a nebulizer every four to six hours. Baby Doe was discharged from South Shore Hospital the prior night with a diagnosis of bronchiolitis. Baby Doe was doing well. *Id.*

Three days later, on November 6, 2000, Jane Doe telephoned Dr. Johnston. Med. recs. at Ex. A, p. 9. Jane Doe was using a nebulizer every four hours because Baby Doe was coughing a lot. He prescribed Albuterol solution 20 cc 0.5% and 0.25 ml with 2 ml of sodium chloride via nebulizer every four hours. *Id.*

Three days later, on November 9, 2000, Jane Doe telephoned Dr. Johnston. *Id.* She had taken Baby Doe to the dermatologist Dr. Saad because of her irritative rash. He gave her a sample. *Id.*

Five days later, on November 14, 2000, Jane Doe told Dr. Johnston that Baby Doe still had a cough, but no fever. Med. recs. at Ex. A, p. 10. Baby Doe saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 9. She had a history of cold symptoms. She had been admitted to the hospital overnight a couple of weeks earlier. She still had a cough but no fever. Jane Doe wanted her checked. Dr. Johnston examined Baby Doe and found her normal. His impression was she still had an upper respiratory infection. *Id.*

Four days later, on November 18, 2000, Jane Doe told Dr. Johnston that Baby Doe was up at night, cranky, and had vomited the day before. Med. recs. at Ex. A, p. 11. Baby Doe saw Dr. Johnston. This was also her two-month visit. *Id.* She had a little stuffiness lately and was still colicky and still spitting. She was on Nutramigen for this problem. *Id.*

On December 7, 2000, Baby Doe saw Dr. Johnston's nurse practitioner Catherine

Dennehy. Med. recs. at Ex. A, p. 13. Baby Doe had had congestion for about two days with some mucous from her nose for which Jane Doe used the bulb syringe. She used the nebulizer once the prior night and once that day. Baby Doe was afebrile. She was fussy, but Baby Doe was always fussy. She did not have vomiting or diarrhea. She continued to take only two ounces at a feeding, but this was her normal. Her brother had a cold at home. Baby Doe's tympanic membranes were grey and mobile. Nurse Dennehy's assessment after examination was an upper respiratory infection. She suggested elevating the head of Baby Doe's bed and using a vaporizer. *Id.*

On December 18, 2000, Baby Doe received her first acellular DPT vaccination after Jane Doe had a lengthy discussion with Dr. Jolles about whether to proceed with the vaccination. Med. recs. at Ex. A, pp. 1, 2. Baby Doe saw Dr. Jon R. Jolles, who worked with Dr. Johnston, for a vaccination update. Med. recs. at Ex. A, p. 13. Jane Doe wanted him to check Baby Doe's ears. Baby Doe was always cranky, but did not have fever. Dr. Jolles' notes record the following conversation:

**Baby Doe's brother Brandon evidently had a reaction to his DPT, this was the old formulation. He evidently was very lethargic for approximately two days. He has not received subsequent pertussis shots.** We discussed the risks and benefits of pertussis vaccine including the decreased incidents [sic] of common side effects from the new acellular vaccine, but I stated to Jane Doe that I cannot guarantee the absence of any severe reaction including neurologic damage. After discussion, she elected to go ahead and receive the DTAP and **watch her closely for any reaction.** We will wait on the Prevnar, which I also discussed until the next visit so that we can tell for sure whether there is any reaction to this present shot. [emphasis added].

Dr. Jolles examined Baby Doe and found no evidence for ear infection. Her ears and throat were clear. *Id.*

On January 2, 2001, Baby Doe saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 12. Jane Doe had Baby Doe's ears pierced about eight weeks previously. The day before, the left ear lobe got infected and swollen. Jane Doe took the earring out but the lobe was still swollen. On examination, Dr. Johnston saw the infected hole where the earring had been on the left side. Puss was easily expressed. There was some mild surrounding erythema but mostly there was just swelling and tenderness. Dr. Johnston's impression was left infected ear lobe. He prescribed Keflex 125 tid x10 and soaks. He suggested not putting the earring back in. *Id.*

Ten days later, on January 12, 2001, Jane Doe telephoned Dr. Johnston. *Id.* Baby Doe had thrush and he prescribed Nystatin oral suspension 1 ml tid x 10 days. *Id.*

Five days later, on January 17, 2001, Baby Doe saw Dr. Johnston for a sick visit. *Id.* She had had a tight congested cough and her appetite had been down. She has had thrush and had been using Nystatin with limited success. Baby Doe's brother had asthma and Jane Doe was worried about wheezing. On examination, Baby Doe was coughing. Her throat showed thrush. Her lungs had occasional wheezes but good air movement. Dr. Johnston's impression was mild bronchiolitis and thrush. He prescribed Gentian violet. Baby Doe was to go on a nebulizer at home every four to six hours. *Id.*

On January 23, 2001, Baby Doe saw Dr. Johnston for her four-month checkup. Med. recs. at Ex. A, p. 14. She was doing fine overall. She had a little bit of thrush and was still coughing. Her diet was Nutramigen and cereal and she was doing well with that. She was up a lot for a bottle. She had a history of bronchiolitis which came and went. *Id.*

On February 9, 2001, Blue Cross Blue Shield approved Baby Doe for Nutramigen for one year. *Id.*



On March 26, 2001, Baby Doe received her second acellular DPT vaccination and her third HiB vaccination. Med. recs. at Ex. A, pp. 1, 2. This was during her six-month checkup with Dr. Johnston. Med. recs. at Ex. A, p. 15. She was still on Nutramigen. She also ate oatmeal and several fruits and vegetables. Jane Doe would advance the diet very slowly as Baby Doe seemed to have problems with each new food. Baby Doe stooled with difficulty at times. Occasionally, she needed some rectal stimulation. Baby Doe had not yet rolled over, but was reaching and passing hand to hand. She sat with support. She babbled, cooed, and laughed. Her sleep was poor. Jane Doe told Dr. Johnston that Baby Doe was up at least once or twice a night for a bottle. Dr. Johnston recommended Dr. Ferber's book. *Id.*

On April 14, 2001, the day before Easter in 2001, Mr. and Mrs. Doe brought Baby Doe to South Shore Hospital Emergency Department at 8:38 a.m. because she had an episode of not breathing. Med. recs. at Ex. C, p. 116. The Emergency Department Flow Sheet notes that Mr. and Mrs. Doe stated that Baby Doe was unresponsive and not breathing for about five minutes. She arrived awake and crying. She had normal color and was alert. She made eye contact and had normal affect. Med. recs. at Ex. C, p. 117. John Doe gave the history to the doctor that Baby Doe became motionless, red, and apneic. Her seizure activity lasted about four minutes. She had no recent illness. Her temperature was 98.3°. Med. recs. at Ex. C, p. 118. Her prior medical history was colic. The doctor noted asthma. The doctor's impression was acute life threatening event (ALTE). *Id.* Dr. Michael Hughes wrote that the chief complaint was apnea. John Doe told him that Baby Doe became motionless and stopped breathing for about three to four minutes that morning. She was not eating at the time but was just being held. Her parents put her down and called 911. Then Baby Doe awoke and started breathing again. John Doe said

that Jane Doe noted that Baby Doe had an episode like this the day before (April 13, 2001), lasting only several seconds. Baby Doe did not have any recent fever, chills, vomiting, or diarrhea. She was not on any medications. Baby Doe had no significant history of other illness, other than a slight asthma noted in the past. She did not have shaking or seizure activity. Med. recs. at Ex. C, p. 119. Baby Doe's temperature was 98.3°. She was awake, alert, and moving all extremities. *Id.* Dr. Hughes' differential diagnoses were apnea, aspiration pneumonia, cardiac arrhythmia, seizure, and sepsis. Med. recs. at Ex. C, p. 120. Baby Doe was afebrile and looked well, but Dr. Hughes thought she should be admitted for observation. *Id.*

Baby Doe was admitted to South Shore Hospital at 9:56 a.m. on April 14, 2001. Med. recs. at Ex. C, p. 114. Dr. Carol Baum saw Baby Doe around noon. Mr. and Mrs. Doe were Dr. Baum's informants. The chief complaint was that Baby Doe went limp and lifeless for several minutes while lying flat for a diaper change that day at around 7:45 a.m. prior to eating breakfast. Both parents witnessed the event and Jane Doe called 911. John Doe administered two rescue breaths. Baby Doe did not seem to be breathing. Her face seemed red, but not purple. Med. recs. at Ex. C, p. 123. Baby Doe had some saliva in her oral pharynx but no emesis. She did not have tonic or tonic-clonic movements. Baby Doe was otherwise well except for an intermittent cough. She was well-appearing before the event. Her prior medical history was significant for a history of gastroesophageal reflux clinically. She was on thickened Nutramigen feeds. Usually, the head of Baby Doe's bed was elevated. Baby Doe was rarely flat. She received Zantac on an as-needed basis. She had about one to two large bouts of spitting up. On Dr. Baum's further questioning of the parents, Baby Doe had two prior episodes that occurred that week while she was lying flat for a diaper change where Baby Doe seemed to

be not responsive, lasting several seconds and resolving. (The bottom of the medical records is cut off at this point. See P. Ex. T for a duplicate which includes the bottom of the page.) (Since April 14, 2001 was a Saturday, the week would have begun on Sunday, April 8, 2001, 13 days after her vaccination. Therefore, two prior episodes occurring that week would have been between April 8<sup>th</sup> and 14<sup>th</sup>, 2001. The Does had earlier stated that one prior episode occurred on April 13, 2001.) Baby Doe also had bronchiolitis at seven weeks and used a nebulizer. She had a milk protein allergy. She also had a mild rhinorrhea and croupy occasional cough beginning that day. She had normal developmental milestones. Her immunizations were delayed secondary to hospitalization for bronchiolitis. *Id.* Baby Doe has a half-sister who had gastroesophageal reflux (GER) as an infant and was on Nutramigen, thickened feeds, and Zantac. Her half-sister outgrew GER at age one and one-half. Med. recs. at Ex. C, p. 124. Baby Doe chronically spit up large volumes of feeds. She had an occasional cough. *Id.* Her general appearance was smiling and non-toxic. Dr. Baum concluded that Baby Doe had a normal neurologic examination. Med. recs. at Ex. C, p. 125. Her chest x-ray showed a slight increase in bronchovascular markings but no infiltrate. *Id.* and Ex. C, p. 139. Dr. Baum's assessment was that the most likely diagnosis, given Baby Doe's history, seemed to be an episode of reflux with vagal stimulation.<sup>2</sup> Other possibilities included seizure, arrhythmias, and broncho/laryngospasm. Med. recs. at Ex. C, p. 126. Baby Doe would have a home apnea monitor. Baby Doe was to restart Zantac when she was discharged. The head of her bed was to be elevated. She was to

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<sup>2</sup> A vagal or vasovagal attack is "a transient vascular and neurogenic reaction marked by pallor, nausea, sweating, bradycardia, and rapid fall in arterial blood pressure which, when below a critical level, results in loss of consciousness and characteristic electroencephalographic changes." Dorland's Illustrated Medical Dictionary, 30<sup>th</sup> ed. (2003) at 178.

have thickened feeds and Nutramigen. *Id.* At 2:30 p.m., Jane Doe told the nurse that she felt as if she were going to be sick and that she had a headache. Med. recs. at Ex. C, p. 128. Baby Doe was alert and smiling and her color was pink. *Id.* Jane Doe roomed in and emotional support was provided. *Id.*

On April 15, 2001, at 8:55 a.m., Baby Doe was very irritable and Jane Doe was unable to console Baby Doe calmly in spite of encouragement to hold her and not bounce her while holding her or while Baby Doe was in the infant seat. At 2:30 a.m., Baby Doe had a rectal temperature of 100.3°. Med. recs. at Ex. C, p. 129. Baby Doe slept in her mother's arms. Jane Doe was reassured and educated numerous times regarding the apnea monitoring alarms and positioning by the nurse and Dr. Baum. Dr. Baum was with Jane Doe and Baby Doe from 4:00-5:40 a.m. Baby Doe was alert, smiled, and tracked Jane Doe at times when she was not irritable. She slept short naps only. *Id.* At 1:35 p.m., Baby Doe did not have a temperature. Med. recs. at Ex. C, p. 130. Zantac was started and Baby Doe vomited. A CPR video was shown to Mr. and Mrs. Doe. An apnea monitor was ordered and a technician was in to teach Mr. and Mrs. Doe. *Id.* Baby Doe was also on Tagamet (not give daily) and Mylicon drops for gas. Med. recs. at Ex. C, p. 140. Baby Doe was discharged from the hospital on April 15, 2001, Easter Sunday. Med. recs. at Ex. C, p. 127.

Two days later, on April 17, 2001, Baby Doe saw Dr. Johnston for a sick visit. Ex. A, p. 15. Baby Doe had an episode on April 14, 2001 and went to South Shore Hospital for further workup. The episode was a choking/stopping of breathing which occurred after she had been lying on her back while her diaper was being changed. She did not have fever at the time. She came around in several minutes just when the ambulance showed up to take her to South Shore

Hospital. Her blood work at the hospital was normal. A pneumogram was also normal. She was watched for 24 hours and sent home. She was on a monitor. Jane Doe was concerned about the possibility of a seizure. Dr. Johnston said he would arrange for a sleep-deprived EEG in the near future. Baby Doe's physical examination was normal. She was neurologically normal. Dr. Johnston's impression was possible choking episode or vasovagal response. He needed to rule out seizure with an EEG and continue with the monitor. *Id.*

On April 18, 2001, Dr. Johnston telephoned Jane Doe. Med. recs. at Ex. A, p. 16. Jane Doe had telephoned her cousin, a pediatric gastroenterologist in Utah, who recommended Reglan for Baby Doe's reflux. Dr. Johnston could not disagree although he preferred to use Cisipride, although it was off the market due to arrhythmias. He would start Baby Doe on Reglan at .1 mg/kilo per dose which worked out to .8 mg per dose 30 minutes prior to feeding. *Id.*

On April 24, 2001, Dr. Johnston telephoned Jane Doe. *Id.* Dr. Davis read the EEG as completely normal. There was no evidence that Baby Doe had seizures. Baby Doe was on Reglan, thick cereal, and Nutramigen. Dr. Johnston recommended gastrointestinal follow-up and referred Baby Doe to Dr. Pleskow for evaluation. Baby Doe was also on a monitor because of her episode which Dr. Johnston considered to be reflux and possibly aspiration a couple of weeks ago. *Id.*

On April 25, 2001, Dr. Johnston telephoned Jane Doe. *Id.* Baby Doe had had a couple of episodes that day that lasted about a minute where she appeared to be out of touch with reality, rolling her eyes up the back of her head, without motor movement. Jane Doe did not think that Baby Doe had a seizure. Jane Doe had to resuscitate Baby Doe by slapping her back several times and then she regained consciousness. There was no cyanosis, shortness of breath, or major

problems with color. Dr. Johnston recommended a local work-up and further work-up at Children's Hospital. She had a negative pneumogram, a normal EEG, and normal lab studies.

*Id.*

Also on April 25, 2001, Baby Doe was brought to Children's Hospital Emergency Department at 3:14 p.m. Med. recs. at Ex. I, p. 3. Jane Doe told them that Baby Doe had a history of reflux and one apnea spell. She had had spells for two days. Jane Doe said that Baby Doe was well until the day before (April 24<sup>th</sup>) when she had two spells, lasting 30 seconds to one minute, when she suddenly became limp with her eyes fluttering. Jane Doe rubbed her back and splashed water in her face. After the episode, Baby Doe was active and playing. She had no color change, apnea, tonic-clonic jerking, or eye rolling. She had no fever, vomiting, diarrhea, or cough. Baby Doe had two more episodes that day. Three of four episodes occurred within ½ hour of eating. She had no gagging or choking. She was eating well with a baseline amount of spitting up, slightly improved after recent Reglan. On Easter Sunday (one and one-half weeks ago), Baby Doe had a spell where she stopped breathing for two to three minutes while lying on the changing table. John Doe gave her two rescue breaths and she began breathing again. She was seen at South Shore Hospital where a pH probe and EEG were done and normal by report. She was discharged home on an apnea monitor with no further episodes. Baby Doe had a history of reflux, and was colicky/spitty in early life. She had multiple formula changes. She was on Zantac for several months. She started Reglan five days earlier (April 20, 2001) after her spell one and one-half weeks ago. She had bronchiolitis at one month of age. She was currently taking Reglan and Zantac. She was alert and nontoxic. Her reflexes were normal and she moved all extremities. She was alert and appropriate for age. She had two spells in the Emergency

Department. Observers noted Baby Doe to become limp with her eyes open, looking down. She did not respond to tactile or visual stimulation. The spells resolved in 30 seconds with Baby Doe slightly sleepy afterwards. Dr. Heather M. McLauchlan and Dr. David Greenes consulted with neurology who thought Baby Doe could have possible seizures. She was admitted to neurology for observation. A CT scan of her head was normal. She had a lumbar puncture. The assessment was new onset seizures. Dr. Greenes saw Baby Doe's episode in the Emergency Department where she was staring slightly below midline, could not engage, had no spontaneous movement, her tone was slightly increased in both upper extremities, and she had slight frothy saliva in her mouth. This resolved over 10-15 seconds with resumption of spontaneous movement and no sleepiness. *Id.*

On April 25, 2001, a Neurology consultation in the Emergency Department by a doctor whose signature is illegible states that Baby Doe had been in good health except for reflux. Med. recs. at Ex. I, p. 19. She had been a colicky baby. On April 14, 2001, her father witnessed an apneic episode. Baby Doe was active and playing and then went limp, her face turning red. John Doe thought she had stopped breathing. They called 911. They patted her on the cheeks and back without response. They gave her a couple of breaths. By the time the EMS arrived, Baby Doe was breathing normally. She had no abnormal movements and no cyanosis. She was taken to South Shore Hospital and admitted overnight. A pH probe and EEG were reportedly normal. *Id.* An EEG administered on April 26, 2001 was normal. Med. recs. at Ex. I, p. 35.

Baby Doe was admitted to Children's Hospital at 3:14 p.m. Med. recs. at Ex. I, p. 9. On April 26, 2001, at 4:15 p.m., Dr. Gary Hsich took the admission history from Mr. and Mrs. Doe. Baby Doe was well until April 14, 2001, an episode that John Doe saw. She was active and

playing and then went suddenly limp. Her face turned red and she appeared to be apneic. They called 911 and patted her on the cheeks and back without response. John Doe gave her a few breaths through the nose and mouth. When the EMS arrived, Baby Doe was breathing normally. Med. recs. at Ex. I, p. 10. She did not have abnormal movements or cyanosis. She was admitted overnight to South Shore Hospital where she had a normal EEG and pH probe. She was started on Reglan. On April 24, 2001, she had two episodes which were somewhat different. One happened shortly after she had been fed. Her eyes opened and she was staring. There was no eye rolling, abnormal movement, or back arching. She was unresponsive for 10-15 seconds. She was okay after one of the episodes and sleepy after the other. On April 25, 2001, she had another two episodes. One occurred 20 minutes after being fed. The other occurred just before eating. They were similar to the episodes on April 24<sup>th</sup>. In the Emergency Department, Baby Doe had another two similar episodes. She was sleepy after the second one. On April 26<sup>th</sup>, that day, she was still having episodes, mostly after feeding, of staring, limpness, and unresponsiveness, with desaturations to the low 80s, lasting about one minute or less. Then she became sleepy. Mr. and Mrs. Doe gave a history that she was a colicky baby with a history of reflux since her early weeks. *Id.* John Doe's brother had a neonatal brain injury with resultant seizures. Baby Doe's immunizations were up to date for age. Med. recs. at Ex. I, p. 11. On examination, Baby Doe was happy, active, playful, and nondysmorphic. When she had a seizure, she desaturated to the low 80s, went limp, unresponsive, but did not stiffen or twitch. She was sleepy afterward. *Id.* Dr. Hsich's impression was that Baby Doe had a normal examination with possible mild motor delay. She had episodes of unresponsiveness suspicious for seizure, but it could also be reflux. Med. recs. at Ex. I, p. 12.



Also on April 26, 2001, Baby Doe was seen by Dr. Jonathan T. Megerian. She had had 14 days of intermittent spells of sudden onset alteration in mental status associated with limpness. Med. recs. at Ex. I, p. 15. Her parents did not notice any color change or motor activity. The spells lasted less than one minute, usually 10-15 seconds, followed by excessive fatigue. She had a long history of gastroesophageal reflux treated early on with Zantac, which was decreased about one month earlier because she seemed to be doing better. When her new symptoms began about two weeks ago, her dose of Zantac was put back at the prior dose of 5 mg. Reglan was also begun as it was felt at that time that her spells were most consistent with gastroesophageal reflux. The spells that occurred more recently seemed more severe despite these medicine changes and were now associated with febrile illness. *Id.* Her fine motor development was appropriate for age. She rolled front to back, but not the reverse. She was not yet able to get to sit or stand, but maintained sitting when placed. She took Nutramigen secondary to intolerance to other formulas. Mr. and Mrs. Doe did not have complaints of systemic or localized illness or symptoms in the past. Dr. Megerian's assessment was vasovagal syncope. The story sounded most like a reflux-induced spell, e.g., Sandifer's syndrome.<sup>3</sup> Seizures would need to be ruled out with a bedside monitor. Jane Doe should increase Zantac to the appropriate dosage per weight. The second diagnosis was gastroesophageal reflux disease, unchanged, which was the likely cause of Baby Doe's symptoms. Zantac elixir, 75 mg/5cc 30 mg was started and Reglan 5 mg. tab. *Id.*

On April 27, 2001, Baby Doe had no further events with an increase in her Zantac. Med.

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<sup>3</sup> Sandifer's syndrome is "intermittent torticollis occurring in children as a symptom of reflux esophagitis or hiatal hernia." Dorland's Illustrated Medical Dictionary, 30<sup>th</sup> ed. (2003) at 1831.

recs. at Ex. I, p. 14. It was unclear whether she was having gastroesophageal reflux symptoms or seizures. A GI consult was ordered. *Id.*

On April 27, 2001, a gastroenterologist consulted and took a history that Baby Doe had initially been on Enfamil for three weeks but changed to Carnation for five days, then switched to Nutramigen, when her colic was much improved. Her primary medical doctor started her on Zantac for eight weeks with some improvement. Two weeks ago, she had an apneic episode lasting three minutes. Most episodes occurred after feeding but occasionally on an empty stomach. Med. recs. at Ex. I, p. 18. An EEG on April 26, 2001 was normal. Dr. Frank H. Duffy stated there were no epileptiform features to suggest an underlying diagnosis of epilepsy. Med. recs. at Ex. I, p. 35. A bedside EEG on April 27, 2001 was normal. Med. recs. at Ex. I, p. 36.

On April 29, 2001, Dr. Jolles wrote a note that may be the result of a phone call. Med. recs. at Ex. A, p. 17. Baby Doe was home from Children's Hospital Medical Center where they diagnosed seizures. She was on Zantac and Reglan. An upper gastrointestinal test result was pending. She was on antibiotics while in the hospital. She had thrush. *Id.*

On May 2, 2001, Jane Doe telephoned Dr. Johnston. *Id.* Baby Doe's upper gastrointestinal test was normal at Children's Hospital the day before. She remained on Zantac and Reglan. Baby Doe would see Dr. Pleskow the next day. There was still no diagnosis for her episodes but they dramatically improved since she increased the dose of Zantac to 2 cc twice a day. *Id.*

On May 3, 2001, Baby Doe saw Dr. Randi G. Pleskow, a gastroentologist, at Children's Hospital. Med. recs. at Ex. I, p. 200. She was begun on Zantac at two months of age which was stopped at 5.5 months of age because her spitting improved although it did not stop. About three

weeks earlier while on the changing table, Baby Doe became cyanotic, lasting about three minutes. She had a 12-hour pH probe at South Shore Hospital and was placed on an apnea monitor. She was started on Zantac at 1 cc. twice a day, and Reglan, 0.8 cc, four times a day. That episode was three hours after her last feed. She seemed to do well until the prior week, when she had several episodes of eye-rolling and became limp. She was admitted to Children's Hospital. She had her Zantac dose increased to 2 cc. twice a day and following that, the episodes stopped. The Reglan was changed to 0.5 cc., four times a day. Her mother was reluctant to feed her baby foods because Baby Doe was very irritable for two days after getting green beans and had been very gassy after certain foods such as peas. *Id.* Dr. Pleskow wondered if Baby Doe's eye-rolling episodes were associated with Reglan. Med. recs. at Ex. I, p. 201. He recommended changing the Zantac to 1.5 cc three times a day and to restart baby foods. Although he thought the eye-rolling episodes could be secondary to the Reglan, he did not feel comfortable stopping Reglan at that point considering Baby Doe's apneic episode a few weeks earlier. *Id.*

On May 7, 2001, Baby Doe saw Dr. Johnston for follow-up. Med. recs. at Ex. A, p. 18. She had approximately 10 spells of gasping for air. The apnea monitor never went off. Med. recs. at Ex. A, p. 17. Baby Doe had a long history of spells which now occurred infrequently and she had done much better over the past week. Med. recs. at Ex. A, p. 18. She had three things done prior to her spells on Sunday (the day before), including taking Mylicon, being put in a bassinet instead of a chair, and being given applesauce. She had about 10 spells the prior day (Sunday) and some were really bad. She was also on Reglan .4 and Zantac 1 ½ cc. On examination, Baby Doe was alert, bright, active, and interactive. Dr. Johnston's impression was that her spells were probably related to reflux. His plan was to discard the Mylicon, the bassinet,

and all solids except for cereal. Jane Doe was to call him in two days. *Id.*

On May 11, 2001, Baby Doe was brought to South Shore Hospital Emergency Department for seizure activity that Jane Doe stated had occurred at home. Med. recs. at Ex. C, p. 92. Baby Doe was on Prilosec and Mylanta and she had an apnea monitor. Mrs. Richards said that Baby Doe's seizure lasted one minute. She did not have cyanosis or apnea. She had gurgling. When the EMTs arrived, Baby Doe was asleep. Jane Doe stated that this was her usual post-event appearance. She had had 24 similar events since Easter (April 15, 2001). Work-up for seizures was negative. On physical examination, Baby Doe moved when touched but was asleep. Her tympanic membranes were red. She had good body tone. Dr. Dwayne E. Greene's impression was a seizure. He would consult with Dr. Johnston and transfer her to New England Medical Center. *Id.* Jane Doe stated that Baby Doe was slumped over in her chair, making funny gurgling noises. She arrived at the ER pink, lethargic, and arousable. Jane Doe said she was awake and playful prior to the incident. Med. recs. at Ex. C, p. 93.

On May 12, 2001, Baby Doe was taken to Children's Hospital Emergency Department. Med. recs. at Ex. I, p. 192. Dr. Stuart Harris and Dr. Marvin B. Harper noted she had been admitted twice for apneic episodes with reportedly negative seizure workup but with evidence of reflux. She had four minutes of staring off into space followed by bilateral arm and head/neck tonic-clonic activity. Her eyes rolled back in her head and she had grunting shallow breathing. This was followed by slight spitting up and deep sleep. This was her longest episode to date. Since her discharge from Children's Hospital on April 27, 2001, Baby Doe had 9-10 episodes on May 5<sup>th</sup> only, all lasting less than 20 seconds and not accompanied by tonic-clonic activity. All occurred following feeding. That day's episode occurred before feeding. Neurologic consult

advised discharge to home and the discontinuance of Reglan as being possibly involved. The assessment was laryngospasm. *Id.* That day, Baby Doe was given her Reglan and, two seconds later, her eyes rolled back, she was breathing rapidly, and had clonic movements of both arms and her face. Med. recs. at Ex. I, p. 195. This was different than her previous episodes because she became stiff and her legs were not moving. Afterward, she went to sleep. *Id.*

On May 18, 2001, the Hull Fire Department EMS was called to take Baby Doe to the ER. She was conscious but lethargic. Jane Doe said she was feeding Baby Doe when she had a possible seizure. Med. recs. at Ex. C, p. 95. Baby Doe was brought to South Shore Hospital Emergency Department for lethargy. Med. recs. at Ex. C, p. 91.

Dr. Dwayne E. Greene took a history from Jane Doe that Baby Doe had a one-minute seizure at home. Med. recs. at Ex. C, p. 99. She was seated in a baby chair and Jane Doe had just fed her. Jane Doe went into another room and heard Baby Doe gurgling. She came back to find Baby Doe shaking all over as if she were having a seizure. This lasted for one minute. There was no cyanosis or apnea. Baby Doe would not arouse to tactile stimulus. Jane Doe stated Baby Doe had had as many as 24 of these episodes over the past two months. She also stated she is the only person who has witnessed these episodes. A pediatrician, neurologist, and gastroenterologist evaluated Baby Doe numerous times. The current theory was reflux or sleep apnea. Mrs. Richards stated she had a recent change in her Prilosec and Mylanta which did not stop the episodes from occurring. Jane Doe was quite distraught about no one believing her when she stated Baby Doe was having seizures. *Id.* On examination, Baby Doe was well-developed and well-nourished. She was asleep in her mother's arms and moved when touched but did not awaken. Her tympanic membranes appeared red. She had good body tone.

Differential diagnoses included seizure disorder versus sleep apnea versus gastroesophageal reflux versus Munchausen by proxy.<sup>4</sup> Med. recs. at Ex. C, p. 100. Dr. Greene spoke with Dr. Johnston about his examination and Jane Doe's mental condition. Baby Doe was transferred to New England Medical Center Floating Hospital for neurologic testing. *Id.*

From May 18-25, 2001, Baby Doe was in New England Medical Center. Med. recs. at Ex. B, p. 2. John Doe signed the admitting questionnaire. Med. recs. at Ex. B, p. 66. On May 18, 2001, Dr. Uzme Vhang took a history that Baby Doe was an eight-month-old girl with multiple episodes over the past one month of episodes (putting onset in mid-April 2001). Med. recs. at Ex. B, p. 7. Dr. M. Provenca took a history on the same day that Baby Doe's apnea spells began in mid-April. Med. recs. at Ex. B, p. 6. A senior pediatric resident whose name may be Dr. Feigall wrote a history that Baby Doe had about 12 episodes of abnormal behavior over the last one month, usually occurring once in a day. Baby Doe would be awake and either go limp with eye fluttering, turn dark red, or occasionally stiffen and arch. She slept for an hour after each episode. Mrs. Doe was very frustrated since Baby Doe had multiple hospital admissions about this problem at South Shore and Children's. Jane Doe said she had been vomiting all day with nerves. Med. recs. at Ex. B, p. 39. The doctor's differential diagnoses included seizure, GERD, Sandifer's syndrome, central apnea, or potential neurologic problems. Med. recs. at Ex. B, p. 40. The only clues were that her presentation was more consistent with reflux. The hoarse cry that Jane Doe said Baby Doe had had almost since birth could be a

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<sup>4</sup> Factitious disorder by proxy is "a form of factitious disorder in which one person intentionally fabricates or induces signs and symptoms of one or more physical (*Munchausen syndrome by proxy*) ... disorders in another person under their care.... The dyad is usually that of mother and child." Dorland's Illustrated Medical Dictionary, 30<sup>th</sup> ed. (2003) at 548.

respiratory cause of distress or be consistent with reflux. *Id.*

On May 22, 2001, an ear, nose, and throat doctor whose signature is illegible took a history that Baby Doe had 12 episodes of either going limp with eyes fluttering, turning red, or occasionally becoming stiff and arching her back. She then slept for one hour after each episode. This had been occurring on six days over the last month. She had been worked up at South Shore Hospital and Children's. EEG showed no seizure activity, no spells. She had a history of spitting up and thickened feedings. The episodes occurred when she was upright and prone. Prilosec prescribed the prior Tuesday initially helped but the symptoms returned. She was also on Mylanta. Med. recs. at Ex. B, p. 9. Baby Doe's half-sister and half-brother had reflux. Her history and examination were consistent with reflux although these were only minimal findings. The doctor recommended continuing with anti-reflux medication. *Id.*

On May 23, 2001, Jane Doe conferred with nurse Susanna Hesse and said she thought Baby Doe had seizures and she wanted to put Baby Doe on anti-seizure medication. The nurse warned her of side effects of seizure medications, but said she would pass on the information to the doctors, which she did. Jane Doe was anxious. Med. recs. at Ex. B, p. 10.

Also on May 23, 2001, the social worker whose name might be Cara Weiner wrote her assessment. Med. recs. at Ex. B, p. 11. Jane Doe had her own hair salon and described Baby Doe's hospitalization to evaluate her for choking episodes as stressful for her business. Baby Doe had her first episode over Easter. Since that time, Baby Doe had been hospitalized many times in an attempt to reach a diagnosis, but without success. Jane Doe described feelings of stress and anxiety about Baby Doe's illness and lack of diagnosis. According to Jane Doe, her last choking episode was very traumatic. Jane Doe had to administer CPR while her eight-year-

old called 911. Baby Doe had not had an episode since her hospitalization but she could go five to seven days without an episode and then have one. Jane Doe also expressed concern for the effect of Baby Doe's illness on the family, including strain on her recent marriage. Jane Doe was eager to go home and anxious for answers. *Id.* That night, Jane Doe told the nurse at 10:30 p.m. that she was worried and thought in her heart that Baby Doe had seizures. Med. recs. at Ex. B, p. 54.

On May 24, 2001, a behavioral and developmental psychologist Dr. David Spitz saw Baby Doe. Med. recs. at Ex. B, p. 12. Baby Doe had a four-week history of recurrent choking/gagging spells in which she stopped breathing. On at least one occasion, the spell occurred in the presence of a pediatric neurologist and included twitching and eye fluttering. Jane Doe told Dr. Spitz that Baby Doe was a full-term baby with normal development. However, since the episodes began, her development had been thwarted. Jane Doe was afraid to put Baby Doe down to attempt crawling because Baby Doe would roll onto her back, and Jane Doe was told not to let her lie on her back. She discontinued solids because of concern about choking. Baby Doe appeared developmentally normal to Dr. Spitz. Jane Doe noted a "staring spell" during his visit with her and Baby Doe. *Id.*

Also on May 24, 2001, Dr. Rhodes, a pediatric cardiologist, saw Baby Doe to rule out a cardiac cause for her ALTE (acute life-threatening event). The history was that Baby Doe had 12 episodes of going limp with eyes fluttering over the last one month. There was a questionable association with feeds. Med. recs. at Ex. B, p. 13. She had had multiple hospital admissions (South Shore, Children's). The last episode occurred six days earlier. Dr. Rhodes' opinion was that a cardiovascular etiology was unlikely. *Id.* Again, Jane Doe expressed her frustration that



there was no medical reason identified for Baby Doe's spells. Med. recs. at Ex. B, p. 56.

On May 25, 2001, Baby Doe was discharged from New England Medical Center. Med. recs. at Ex. B, p. 32. Dr. Jeffrey Biller, a pediatric gastroenterologist, wrote the discharge summary. Baby Doe was an eight-month-old girl with about 12 episodes of abnormal behavior over the last month, usually occurring one time in a day. These happened while she was awake. She would either go limp with eye fluttering, turn dark red, or occasionally become stiff and arch. She slept about one hour after each episode. She had a normal EKG and echocardiogram, normal EEG, normal head CT scan, normal pH probe, and a normal LP and urine and blood cultures. She awoke with a hoarse cry. *Id.* Baby Doe had a pH probe showing reflux and a delayed emptying scan, both suggestive of GERD (gastroesophageal reflux disease). Med. recs. at Ex. B, p. 33. She was continued on Alimentum thickened with oatmeal and Prilosec. She was started on Erythromycin 10 mg twice a day. Her appetite remained good throughout hospitalization. She received one Glycerin suppository for constipation with good result. She developed a fever on the second day of hospitalization, treated with Tylenol and Motrin. With the fever, Baby Doe had congestion with a barking cough. She was treated with cool mist and considered to have a viral upper respiratory tract infection. Her spells seemed associated with her being laid supine. An H type fistula was ruled out due to a normal upper GI study. A neck film showed mild tonsillar enlargement with some enlargement of the pre-vertebral soft tissues. *Id.*

Two days later, on May 27, 2001, an ambulance was called at 8:10 a.m. to pick up Baby Doe. Med. recs. at Ex. C, p. 86. She was alert and crying. She had a seizure lasting approximately three minutes. She had been to the hospital five times over the prior weeks and

was discharged two days previously from Children's. Baby Doe's parents said that Children's stated that Baby Doe's seizures were due to severe reflux. They described the seizures as having some tonic movement. She had a temperature of 101°. Baby Doe was alert and crying throughout transport. *Id.* Baby Doe was brought to South Shore Hospital Emergency Department for a possible seizure. Med. recs. at Ex. C, p. 102. Baby Doe arrived with her father. She had been discharged from Children's Floating Hospital two days previously where a seizure disorder was ruled out, according to John Doe. Now Baby Doe was crying with her gaze to the left. She was inconsolable and did not make eye contact. Her temperature at 8:30 a.m. was 102.5°. Dr. John Leonard was with Baby Doe and she was given Tylenol. Med. recs. at Ex. C, p. 103. Baby Doe would not take a bottle. She was resting in her father's arms and appeared quieter. Jane Doe came in and refused to have Baby Doe catheterized. She was transferred to Children's Hospital. *Id.* The final impression was a febrile illness. Med. recs. at Ex. C, p. 104. Dr. Leonard wrote that John Doe stated Baby Doe apparently had an apneic period approximately six weeks ago (putting onset on April 15, 2001) and, since then, had overnight admission at South Shore Hospital, three-day admission at Children's Hospital, and a recent seven-day admission at Children's Floating Hospital. Med. recs. at Ex. C, p. 105. John Doe stated Baby Doe had a GI evaluation which showed a significant reflux, and had a neurological evaluation consisting of EEGs, neuroimaging studies, and lumbar puncture, all of which were unremarkable. He stated that, over the last six weeks, Baby Doe had approximately 20 episodes where she became limp and nonresponsive lasting approximately 30 seconds. John Doe stated that, over the prior week, Baby Doe had had three episodes where she had had tonic rhythmic activity of the upper extremities. When she was at Floating Hospital about a week ago for a

week, she had no seizure-like activity. She did have fevers there. John Doe said Baby Doe had been doing well. That day, she woke up and had a seizure. *Id.* Her temperature was 102.5°. She was crying and responsive to local stimuli. She did not have focality or tonic-clonic activity. Med. recs. at Ex. C, p. 106. Dr. Leonard's differential diagnoses were seizure, cardiac arrhythmia, syncope, apnea, transient hypoglycemia, occult infection, and febrile seizure. His clinical impression was transient altered level of consciousness consistent with seizure. *Id.* His second diagnosis was febrile illness. Med. recs. at Ex. C, p. 107. She was transferred to Children's Hospital. *Id.*

On May 27, 2001, at 12:30 p.m., Baby Doe entered Children's Hospital Emergency Department with both parents. They gave Dr. Karen Dull a history of episodes which began April 19, 2001. The initial episode occurred while Baby Doe was lying on the changing table where she turned deep red for two to three minutes. Med. recs. at Ex. C, p. 112. She was admitted to South Shore and diagnosed with reflux. One week later, she had a negative EEG. On April 25, 2001, she had three episodes lasting 30 seconds when she was admitted to Children's Hospital for three days and had a negative CT, LP, and EEG. On May 4, 2001, she had seven episodes. Her parents called the EMTs but she was not brought to the ED. On May 12, 2001, she had gasping sounds associated with feeding. On May 18, 2001, Baby Doe was in her jumper and had upper extremity tonic-clonic shaking for four minutes. She was admitted to New England Medical Center and started on Prilosec and Mylanta. Her formula was changed. She had an EEG, gastric emptying, and an upper GI showing mild reflux. She had a negative EKG and echocardiogram. She was home May 25, 2001. On May 26, 2001, she had one episode in the morning treated with oxygen. On May 27, 2001, she vomited once in her sleep

and later had four to five minutes of tonic-clonic shaking with her head down. She appeared sleepy, with her eyes straight ahead. She was sleepy after the event. She was taken to South Shore with 102° temperature. Her appetite was somewhat decreased. She had normal urine output. She had two episodes of diarrhea that day. On examination, she was alert and nontoxic appearing. *Id.* In the ED, a nurse saw a 30-second event when Baby Doe went limp and then vomited. Med. recs. at Ex. C, pp. 112-13. The neurology service was consulted and felt this was not seizure activity. She vomited twice that day and had two small episodes of diarrhea. She took some formula without vomiting. She appeared alert and smiling before discharge. Baby Doe was to have an outpatient continuous EEG that week. Dr. Dull's assessment was reflux, gastroenteritis, and fever. Med. recs. at Ex. C, p. 113.

Two days later, on May 29, 2001, Baby Doe saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 19. She had a long story of possible seizures versus reflux episodes. She went to Children's Hospital Medical Center two days earlier after having a three-five minute spell which included tonic-clonic movements of her arms. She was quite sleepy after the episode, indicating possible post-ictal episode. Children's evaluated her and sent her home pending a home EEG. Children's called yesterday and wanted her to be re-admitted but Jane Doe refused. Baby Doe had had 14 stools since yesterday. Jane Doe was worried about dehydration. Baby Doe also had a slight fever. She got episodes more frequently on the weekend which included staring, fluttering of the eyes, and then immediate sleeping. Dr. Johnston's impression was most likely a stomach bug on top of everything else. He advised clear liquids. He would discuss the case with Dr. Gary Hsich, a neurologist at Children's. *Id.*

On May 30, 2001, Dr. Johnston telephoned Jane Doe. Baby Doe was having fever with a

gastrointestinal bug. *Id.* The day before, she had diarrhea leading to vomiting. She might have had blood in her stool the prior night after a bowel movement. Jane Doe said Baby Doe was doing much better that day. Her stools were less frequent and she was feeling better. Dr. Johnston offered Jane Doe an appointment, but she declined. *Id.*

On June 12, 2001, Baby Doe saw Dr. Johnston for a sick visit. Med. recs. at Ex. A, p. 20. Jane Doe was concerned about an ear infection. Baby Doe had had a 48-hour history of nasal congestion without fever, vomiting, or diarrhea. Her appetite was all right. She had a slight cough. No other family members were sick. According to Jane Doe, Baby Doe's prolonged EEG was completely normal. She had been concerned about possible seizures. On physical examination, Baby Doe's ears were gray, mobile, and shiny. Her nose showed minimal congestion. Her throat was clear. Dr. Johnston diagnosed a minor cold and provided reassurance. *Id.*

One day later, on June 13, 2001, an ambulance was called at 5:31 p.m. to pick up Baby Doe. Med. recs. at Ex. C, p. 80. Jane Doe stated that petitioner had seizure-type activity for less than two minutes. She noticed Baby Doe was not breathing and gave her two rescue breaths. Baby Doe had been fighting a cold for three days and was taking Tylenol. She was on an apnea monitor. On the way to the hospital, Baby Doe was responsive to pain and cried several times. She had good skin color and her skin felt warm. Her last meal was about 4:30 p.m. and she did not seem to be in any distress. She slept en route to the ER. *Id.* She was brought to South Shore Hospital Emergency Department for seizures. Med. recs. at Ex. C, p. 85. Jane Doe said Baby Doe had been in her walker and stiffened and could not catch her breath for a couple of minutes. She was awake, crying, and consolable with feeding. Med. recs. at Ex. C, p. 73. Over the prior

two months (putting onset in April), she had had 20-25 episodes. Dr. June Hanley wrote the diagnosis was possible seizure versus reflux episode. *Id.* Both parents gave the history to Dr. Hanley. Med. recs. at Ex. C, p. 76. For the last two months, she had been having 20-25 episodes. Medical conclusions were that they were not seizures. She had a four-day EEG. The GI people after a pH probe and an upper GI were done felt that her reflux was not that bad. Neurology evaluation included a spinal tap and CT scan. Her echocardiogram was normal. Today's episode occurred an hour after feeding. Baby Doe was upright in her walker when Jane Doe saw her eyes roll back and her face turn red. Baby Doe began to have generalized tremulousness, lasting seconds. She was stiff and red. She passed out and Jane Doe said this lasted 10-15 minutes. *Id.* On physical examination, Baby Doe was very well-appearing. Med. recs. at Ex. C, p. 77. Neurologically, she had no focality and was normal. Dr. Hanly's differential diagnoses included seizure versus reflux versus benign episode versus breath-holding spell. Dr. Hsich, a neurologist at Children's Hospital, was at a loss and felt that this was probably some kind of reflux and they could do another EEG. Throughout her stay in the ER, Baby Doe appeared very well and fed normally. *Id.*

Five days later, on June 18, 2001, an ambulance was called to pick up Baby Doe who was lying on her mother's lap. Jane Doe told the paramedics that Baby Doe had had convulsions and stopped breathing for about 45 seconds. She gave her rescue breaths. She had just finished eating when the event occurred. Med. recs. at Ex. C, p. 68. En route, Baby Doe became apneic but recovered when the EMT squeezed her hand. *Id.* Baby Doe went to South Shore Hospital Emergency Department. Med. recs. at Ex. C, p. 58. Jane Doe stated Baby Doe had a grand mal seizure with apnea. She was awake and alert at the ER. She was transferred to Children's

Hospital. *Id.* Jane Doe said Baby Doe had seized after having a one-ounce bottle. She gave Baby Doe one rescue breath. Baby Doe was awake, alert, looking around, and playing. Med. recs. at Ex. C, p. 59. On June 18, 2001, Dr. John Leonard at South Shore wrote that Baby Doe had a transient altered level of consciousness and seizure. Med. recs. at Ex. C, p. 64. She had a history of gastroesophageal reflux, apnea, and a questionable seizure disorder. Jane Doe said she was feeding Baby Doe when she became apneic and had a generalized seizure lasting seconds. The etiology of her transient spells was unclear. She had multiple negative EEGs, LPs, and endoscopy. She had no recent fever, chills, or sweats. Jane Doe denied there was any pattern of the spells. She had had six episodes in the last two days. She requested transfer to Children's Hospital. *Id.* Neurologically, Baby Doe was nontoxic and moving all extremities. She drank without difficulty. Jane Doe was very anxious. Dr. Leonard's differential diagnoses included seizure, bradyarrhythmia, hypoxemia, Munchausen,<sup>5</sup> meningitis, central nervous system mass or lesion. Med. recs. at Ex. C, p. 65. Dr. Leonard discussed the case with Dr. Johnston, Baby Doe's pediatrician. *Id.*

Jane Doe said Baby Doe had a "true seizure" and apneic episode that morning. Med. recs. at Ex. I, p. 68. Jane Doe said Baby Doe had been doing well until Easter 2001 when she had her first spell. Jane Doe said Baby Doe had had 25 episodes since Easter, occurring with increasing frequency over the past month. She had three spells on Saturday and three spells on Sunday. This morning, she took one ounce of formula, burped, then began gasping and appeared

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<sup>5</sup> Munchausen's syndrome is "a condition characterized by habitual presentation for hospital treatment of an apparent acute physical illness, the patient giving a plausible and dramatic history, all of which is false...." Dorland's Illustrated Medical Dictionary, 30<sup>th</sup> ed. (2003) at 1826.

as if trying to swallow. Her hands were shaking and she curled in a cat-like position. She looked as if she were choking to death. Her apnea monitor beeped and Jane Doe gave her two rescue breaths and called 911. Jane Doe said Baby Doe was breathing when she gave her rescue breaths but looked like she was going to stop any minute. The episode lasted three to four minutes, per Jane Doe. Jane Doe said she was not going home without an answer for these spells. Jane Doe's cousin in Utah, who is a pediatric specialist, believed reflux caused laryngospasm which caused apnea and a hypoxic seizure. All of Baby Doe's workups had been essentially negative, most suggestive of GI reflux. Jane Doe said that the gastroenterologist thought they were seizures and the neurologist thought they were reflux-related. *Id.* Baby Doe had not been having any fevers. Between spells, she was eating and eliminating normally. She had a history of slow GI motility. She was on Alimentum with oatmeal. Jane Doe had started Baby Doe on some solid foods that week. She had no URI symptoms, no rashes, and no swollen glands. She was developmentally normal per Jane Doe. Baby Doe was colicky with reflux as a newborn, per Jane Doe, and treated with Zantac between the ages of two to five and one-half months. *Id.* Dr. Kara Gasink and Dr. David Greenes reviewed the case with Baby Doe's pediatrician Dr. Johnston and his assessment was that Baby Doe had chronic reflux leading to laryngospasm leading to apnea and hypoxic seizure, with Munchausen by proxy potentially contributory. Examination showed Baby Doe to be alert, active, and in no distress. Differential diagnoses included GE-reflux-related laryngospasm and apnea, primary seizure disorder, and Munchausen syndrome by proxy. Med. recs. at Ex. I, p. 69. Jane Doe told Dr. Sara Toomey on admission June 18, 2001 that Baby Doe had multiple episodes since Easter. Zantac might have helped. Reglan made Baby Doe fussy. She still had spells with Prilosec and Mylanta. Med.



recs. at Ex. I, p. 78.

On June 19, 2001, at noon, Dr. Gary Hsich, neurologist, wrote a note. Med. recs. at Ex. I, p. 82. Baby Doe had been hospitalized in April for similar spells. The spells resolved when her Zantac dose was doubled. He arranged for a bedside video EEG to capture any spells. *Id.*

On June 20, 2001, Dr. Chiang at Children's Hospital Medical Center telephoned Dr. Johnston and they agreed Baby Doe should stay until she had an episode. She would be monitored with video as well as EEG. Jane Doe was concerned they were not doing anything for Baby Doe. The episodes sounded like events but Dr. Johnston could not tell if they were seizures or hypoxic gagging events. There was no need for medication at that point. *Id.*

On June 23, 2001, Baby Doe was discharged from Children's Hospital. Med. recs. at Ex. I, p. 74. Dr. Vincent Chiang wrote the discharge summary. After consultation with neurology, they placed Baby Doe on phenobarbital. Baby Doe had been on a continuous EEG monitor for signs of seizures. On hospital day 5, she had an episode of staring and unresponsiveness lasting about two to three minutes followed by a period of crying and being alert. Jane Doe was clearly anxious throughout the admission. Social work and psychiatry were consulted to aid in the case. Jane Doe was referred to the Coping Clinic. Baby Doe was discharged on phenobarbital and Pepcid. *Id.*

On July 2, 2001, Baby Doe saw Dr. Johnston to check her phenobarbital level. Med. recs. at Ex. A, p. 21. She had staring spells noted at Children's Hospital during her last admission and was started on 45 mg per day of phenobarbital. She had had a few staring spells but no motor activity noted. She also developed a recent rash on areas touching clothing. She did not have fever, diarrhea, or cough. She had occasional vomiting as before. Dr. Johnston

diagnosed a seizure disorder and mild dermatitis. *Id.*

On January 2, 2002, Baby Doe saw Dr. James J. Riviello, a neurologist at Children's Hospital. Med. recs. at Ex. I, p. 172. In reviewing Baby Doe's history, Dr. Riviello identified Baby Doe's episodes as of two types. One type of episode was significant for choking, arching, and apnea. The other type of episode was relatively minor and involved staring and unresponsiveness for about one minute. *Id.*

On April 8, 2002, Baby Doe saw Dr. Johnston. Med. recs. at Ex. A, p. 28. Jane Doe's biggest concern was Baby Doe's seizure disorder although she had not seized recently. Jane Doe wanted to put a hold on immunizations for the time being. No immunizations were administered that day. *Id.*

On September 16, 2002, Baby Doe saw Dr. Johnston. Med. recs. at Ex. A, p. 30. She was still on phenobarbital for her seizure disorder, and Pepcid for reflux. Jane Doe refused all immunizations at this time due to Baby Doe's seizure disorder. *Id.*

On September 9, 2003, Baby Doe saw Dr. Johnston. Med. recs. at Ex. A, p. 42. Decisions were to be made about possible discontinuation of phenobarbital and possible completion of the immunization series which Jane Doe was "dead set against." *Id.* "We talked about the national vaccine compensation act and how Baby Doe might qualify as a person who has been damaged by vaccines." *Id.*

On September 19, 2005, Baby Doe saw Dr. Johnston. P. Ex. R, p. 1. Baby Doe had a seizure disorder. "Thought to be post vaccinations seizures". *Id.* She was not administered acellular DPT or IPV "because of previous seizures presumably from vaccinations." *Id.*

On February 6, 2006, Baby Doe saw Dr. Cynthia Rooney, a neurologist at Children's

Hospital. Med. recs. at Ex. 21, p. 5. She last saw Baby Doe on October 17, 2005 and was on phenobarbital (32.4 mg tablet), half-tablet in the morning and one tablet in the evening. At the last appointment, Dr. Rooney asked Jane Doe to decrease this dose, but Jane Doe did not do this until mid-December. Baby Doe did very well with the reduction in phenobarbital. Jane Doe felt that Baby Doe's language abilities increased greatly. *Id.*

On June 19, 2006, Baby Doe saw Dr. Rooney again. Med. recs. at Ex. 21, p. 2. Jane Doe had not decreased Baby Doe's phenobarbital dose because she was under a lot of emotional stress at that time. Dr. Rooney told Jane Doe that she would very much like to get Baby Doe off phenobarbital because it can interfere with a child's learning abilities. Baby Doe toe-walked, but her father also toe walked. *Id.*

#### **Other submitted material**

On July 27, 2004, petitioners filed the affidavit of Jane Doe, dated February 11, 2004. P. Ex. G. Jane Doe states Baby Doe suffered a vaccine injury. *Id.*

On August 10, 2004, petitioners filed the second affidavit of Jane Doe, dated July 26, 2004. P. Ex. H. Jane Doe states that within a few days of her vaccination on March 26, 2001, Baby Doe began to exhibit unusual behavior, beginning with periods of deep staring and erratic head movements from side to side. Jane Doe states that, at times, Baby Doe's eyes started to roll back, although this occurred only very slightly at first. Baby Doe also began to scream uncontrollably for extended periods of time which she had never done before. P. Ex. H, ¶ 4. Jane Doe states that on Saturday, April 14, 2001, a much more dramatic event occurred at 7:30 a.m. while Baby Doe was being changed on a changing table. Both Mr. and Mrs. Doe saw Baby Doe turn limp, roll her eyes back in her head, and have her face turn red. They realized she was

not breathing and called 911. P. Ex. H, ¶ 5.

On December 22, 2005, petitioners filed the third affidavit of Jane Doe, dated December 2, 2005. P. Ex. N. Jane Doe states that Baby Doe's onset of unusual behavior was within a few days of her vaccinations of March 26, 2001. The reason Jane Doe did not mention these early symptoms when she brought Baby Doe to the hospital on April 14, 2001 was that her symptoms at that time were so much worse and she was focused only on the current emergency. Baby Doe had suddenly become limp, stopped breathing, her face had turned red, and John Doe had to resuscitate her. This was a life-threatening event which scared both her and John Doe and they rushed Baby Doe to the hospital by ambulance. Jane Doe had a bad headache and felt as if she were going to be sick at the hospital. Neither she nor John Doe thought of the events that occurred in March. P. Ex. N, p. 1. They just wanted Baby Doe to be alive and well. P. Ex. N, p. 2.

On February 27, 2006, petitioners filed the fourth affidavit of Jane Doe, dated February 14, 2006. P. Ex. P. Jane Doe says that Baby Doe's behavior changed approximately two to three days after her vaccination on March 26, 2001. Her unusual behavior was staring and moving her head, lasting a few seconds. When asked why she did not take Baby Doe to her pediatrician before April 14, 2001 despite having told Dr. Jolles on December 18, 2000 (at the time of Baby Doe's first acellular DPT vaccination) that she intended to watch Baby Doe closely for any reaction, Jane Doe responded that either she did telephone the pediatrician's office and mention the reaction to the nurse or doctor or the unusual behavior was so brief and infrequent that, at the time, "I possibly thought it was just a one time thing." P. Ex. P, p. 1. Only after the major episodes did she look back and try to determine what was normal and what was unusual.

P. Ex. P, pp. 1-2.

On February 27, 2006, petitioners filed the affidavit of John Doe, dated February 14, 2006. P. Ex. O. He states that, after Baby Doe's vaccinations on March 26, 2001 and prior to April 14, 2001, he did not notice anything abnormal about Baby Doe other than her crying a little more. He was working full-time. His wife noticed some strange behavior and told him about it on three occasions. She first mentioned that Baby Doe had seemed briefly unresponsive to her, lasting a few seconds, and that Baby Doe acted almost as if she were not with her, as if she were somewhere else. This occurred on March 30<sup>th</sup> or 31<sup>st</sup>. Jane Doe again mentioned it to John Doe on April 4<sup>th</sup> or 5<sup>th</sup>. These events lasted a few seconds and Jane Doe might not have seen each of them. Afterwards, Baby Doe appeared fine. P. Ex. O, p. 1. Mr. and Mrs. Doe talked about calling the doctor the second time Jane Doe reported the occurrence to John Doe, but since it seemed so minute, lasted so briefly, and Baby Doe was normal afterwards, they decided to wait to see if it happened again. P. Ex. O, pp. 1-2. Jane Doe wanted to give it some time to see if the occurrences would pass. Just a few minutes prior to the seizures of April 14, 2001, John Doe was changing Baby Doe's diaper and he and Jane Doe were discussing Baby Doe's unusual behavior when the more serious event happened. John Doe asked Jane Doe if what was occurring was what Baby Doe had experienced before. They rushed Baby Doe to the emergency room. P. Ex. O, p. 2.

On December 4, 2006, petitioners filed the affidavit of Nancy Fleck, dated October 31, 2006. P. Ex. Q. Ms Fleck is a friend of Jane Doe whom she has known for many years. P. Ex. Q, ¶ 2. She visited Jane Doe and Baby Doe at the Doe home one or two days after Baby Doe's vaccinations of March 26, 2001. Baby Doe was screaming in pain and constantly crying. She

was inconsolable and nothing would calm her. Baby Doe got stiff and screamed. P. Ex. Q, ¶ 4. Some time in April, Ms. Fleck saw Baby Doe have staring spells where she would stare off into space, and be zoned out and blanked out. Jane Doe and Ms. Fleck would clap their hands and call Baby Doe's name to get her to snap out of it. Jane Doe told Ms. Fleck that, prior to this, Baby Doe had been acting strangely with brief staring spells. P. Ex. Q, ¶ 5.

After the hearing on May 24, 2007 in Boston, Massachusetts, the undersigned issued an Order dated May 25, 2007 that petitioners file an affidavit from Jane Doe's mother, Ida Fagone-McNamara. On July 2, 2007, petitioners filed Ms. Fagone-McNamara's affidavit, dated June 19, 2007. P. Ex. 25. Ms. Fagone-McNamara states that she is very close to her daughter, Jane Doe, and speaks to her often, sometimes three to four times a day. P. Ex. 25, ¶ 2. Within a week or two of Baby Doe's March 25, 2001 vaccinations, Ms. Fagone-McNamara states she remembers speaking with Jane Doe on the telephone and Jane Doe told her that Baby Doe did a strange thing that day when she suddenly fell asleep all of a sudden. During another call at around this same time, Jane Doe told Ms. Fagone-McNamara that something really weird happened where Baby Doe was in her crib playing and, suddenly, she fell asleep and Jane Doe could not wake her right away. She also suddenly fell asleep in her jumper. P. Ex. 25, ¶ 4. Ms. Fagone-McNamara states that Jane Doe called her another day around the same time period and said Baby Doe was doing it again. Ms. Fagone-McNamara rushed over to the Doe house and picked Baby Doe up. Baby Doe looked at her with a smile and, the next moment, was asleep in her arms and would not wake up for a while. P. Ex. 25, ¶ 5. At Jane Doe's beauty shop, Ms. Fagone-McNamara was having her hair done and Jane Doe told her that Baby Doe did something funny that day when she suddenly dozed off and slept. P. Ex. 25, ¶ 6. Afterwards, Jane Doe called Ms. Fagone-

McNamara and she was screaming, saying that Baby Doe had stopped breathing. The fire department came and took her to the emergency room. P. Ex. 25, ¶ 7.

### TESTIMONY

Nancy Fleck testified first for petitioners. Tr. at 6. She went to high school 21 years ago with Jane Doe. Jane Doe interjected that they have been friends for longer than 21 years. Tr. at 7-8. They would visit, hang out, eat lunch together, and take walks. Tr. at 8. Ms. Fleck's daughter is one year older than Jane Doe's daughter Brittany, and Ms. Fleck's son is one year older than Jane Doe's son Brandon. Tr. at 9. Ms. Fleck was aware that Baby Doe had gastroesophageal reflux disease at the age of five weeks. *Id.* She spat up when she had formula. *Id.* A day or two after the vaccinations on March 26, 2001, Ms. Fleck visited Jane Doe and Baby Doe was screaming, crying, stiff as if she were in pain. Tr. at 10-11. They could not get her to stop. Tr. at 11. She was crying uncontrollably. *Id.* Jane Doe told Ms. Fleck she was worried and she thought it was because of the vaccinations because Baby Doe had been fine before and then, all of a sudden, a couple of days after the vaccinations, she was acting different. *Id.* Ms. Fleck believed that Jane Doe had talked to her doctor about this. Tr. at 12. Ms. Fleck called and a couple of days after, Baby Doe was the same, still not herself. *Id.*

Ms. Fleck lived close to the Does. Tr. at 13. In trying to explain what she meant by Baby Doe's being stiff, Ms. Fleck said her hands were out and her legs were straight. Tr. at 14. Petitioners' counsel asked if Baby Doe's body was like a board and Ms. Fleck agreed. Tr. at 15.

In April, Baby Doe had a staring spell and Ms. Fleck and Jane Doe would clap their hands to get her out of it. *Id.* Once they made a loud noise, Baby Doe would come out of it. Tr. at 16. She saw Baby Doe about once a month, if that often. Tr. at 18. Ms. Fleck knew that

Baby Doe had recently received a vaccination because Jane Doe told her. Tr. at 19. Ms. Fleck told Jane Doe to call the doctor in March after the vaccinations. Tr. at 21.

Mrs. Jane Doe testified next for petitioners. Tr. at 24. Before Baby Doe's March 26, 2001 vaccinations, Baby Doe was regular, that is, Jane Doe did not find anything different about her. She was her third child. *Id.* Jane Doe said that gastroesophageal reflux disease was not a big issue for Baby Doe. *Id.* She said there was no medicine given to Baby Doe for her reflux. Tr. at 24-25. Jane Doe denied that Baby Doe was ever diagnosed with gastroesophageal reflux disease. Tr. at 25. Baby Doe did throw up, but it did not change any normal daily behavior. *Id.* The records show that New England Medical Center gave her a pH probe which showed reflux and Baby Doe had a delayed emptying scan. Therefore, the Center diagnosed Baby Doe with gastroesophageal reflux disease, but Jane Doe testified that the doctors could not figure out what was Baby Doe's problem. *Id.* Then Jane Doe admitted that Baby Doe had reflux, but so did her older daughter Brittany. Tr. at 26. All three children threw up. *Id.*

The undersigned questioned Jane Doe about Baby Doe's visit to the pediatrician Dr. Jolles on December 18, 2000 when she was to receive her first acellular DPT vaccination. Tr. at 34. According to the medical records, Jane Doe was concerned because her son Brandon had had a reaction to his DPT vaccination. *Id.* Jane Doe testified that Brandon did not have a reaction to the vaccine. She stated that his only reaction was redness at the vaccine site and a fever, but he never reacted to the vaccines. *Id.* Jane Doe stated she would never have had another child vaccinated if Brandon had had a reaction. Tr. at 34-35. The undersigned then read from the records, Exhibit A, p. 13, in which Jane Doe tells Dr. Jolles that Brandon had a reaction to the whole cell vaccine and became very lethargic for about two days. Brandon had not



received any other pertussis vaccinations. Jane Doe elected to have Baby Doe vaccinated with acellular DPT and would watch Baby Doe closely for any reaction. Tr. at 35. Jane Doe, while denying Brandon had a reaction, testified he was not acting like himself but that was not like what the Does were experiencing with Baby Doe. *Id.* Jane Doe also testified that Brandon finished all his vaccinations and she did not think he went without further pertussis as part of those vaccines. Tr. at 35-36. Brandon was up to date with everything. Tr. at 36.

Jane Doe denied she brought Baby Doe in to see the pediatrician just for an infected ear lobe due to an earring. She thought it probably was for something else. *Id.* She stated that she had a good pediatric practice and she called them for just about anything. Tr. at 37. She does not let her children go even a 12-hour span without taking them to get checked if there is a problem. *Id.* Jane Doe lives 20 minutes from the pediatrician's office. Tr. at 38.

Baby Doe was fine on the trip home from the pediatrician's office on March 26, 2001 when she received her second acellular DPT vaccination. Tr. at 38-39. There was nothing unusual that day. Tr. at 39. Jane Doe remembered saying to Ms. Fleck probably a couple of days after the vaccinations that Baby Doe was just not herself. She can remember clearly saying that Baby Doe was different and she wondered if it were something to do with her vaccinations. Tr. at 40. It was no more than four or five days after the vaccinations. *Id.* Baby Doe was fussy. *Id.* When the undersigned asked Jane Doe to comment on Ms. Fleck's testimony that Baby Doe was screaming bloody murder because she was in pain, Jane Doe responded that she was sure that she called the doctor about that. She knows she would have because she has such a good relationship with her pediatrician. Usually, the office would say, if there is a problem like that, just to watch her. *Id.* Jane Doe said she did not like to bring Baby Doe to the doctor because she

was “germaphobic.” Tr. at 41. When one is at the pediatrician’s office, the children catch something while they are waiting. *Id.*

Jane Doe does not believe Baby Doe had a fever or she would have brought her in to the doctor, at least if it were a high fever. *Id.* Out of all the children Jane Doe has, Baby Doe was the easiest. Baby Doe was very laid back and that was why it dawned on Jane Doe that something was different because of the vaccines Baby Doe received. There was a change. She was just different. Tr. at 42. Jane Doe recalled saying to Ms. Fleck that Baby Doe acted so different since she had the vaccinations. *Id.* Baby Doe’s vaccination site looked normal, not red or swollen. *Id.* Ms. Fleck was just with Jane Doe for an hour in the morning. Tr. at 43. Baby Doe continued to be fussy from then on. She was different. She was not content and not sleeping as long or eating as well. She was crying a lot more. *Id.*

Jane Doe testified that Baby Doe gradually started to get sicker and she remembered saying to her mother that Baby Doe was different. *Id.* Baby Doe was not comfortable. Tr. at 44. She took the same amount of formula in her bottle. Baby Doe would look at her but, when she started to daze out for a few seconds, it was different than reflux. *Id.* Jane Doe knows reflux because Brittany had it. *Id.* Brittany is eight years older than Baby Doe, and Brandon is five years older than Baby Doe. Tr. at 45. Baby Doe used the same number of diapers after March 25, 2001. *Id.* Her behavior was different because she was not comfortable, fussy, not content. Jane Doe had to hold Baby Doe constantly. *Id.* After the vaccination, Jane Doe had to buy a baby carrier because she could not just leave Baby Doe and vacuum. Tr. at 46. She had to hold her. It was a completely different situation. Baby Doe just did not feel well. *Id.*

Jane Doe recalls telephoning her pediatrician’s office and saying, “It sounds ridiculous,

but I can't help but say she's doing something strange or she's acting weird." *Id.* Jane Doe did not remember Baby Doe being on Reglan. Tr. at 47. Jane Doe did not know why in each of her affidavits she did not mention the screaming that Ms. Fleck put in her affidavit describing Baby Doe's behavior two days after vaccination. *Id.* Then she explained that this was such a bad situation and so long ago, but then it was not long ago at all but an every day worry, that maybe she did not describe the screaming, but she remembered it very clearly. Tr. at 48.

In Jane Doe's affidavit of February 14, 2005, she described the change in Baby Doe's behavior as staring and moving her head, lasting a few seconds, occurring two or three days after vaccination. In her testimony, Jane Doe agreed her prior description and said it was just a weird jerk. *Id.* She telephoned her mother and told her that Baby Doe did something so strange; she just fell asleep so quickly in her crib. *Id.*

When the undersigned read to Jane Doe her answer in her affidavit dated December 2, 2005 to the question why she did not tell anyone about Baby Doe's early symptoms when she and her husband brought Baby Doe to the hospital on April 14, 2001 because her symptoms on April 14<sup>th</sup> were so much worse, Jane Doe denied that she did not mention the early symptoms. It was just that she could not explain them. She said you cannot explain a five-second stare unless you saw it. Tr. at 48-49. Petitioner's counsel mentioned that in paragraph 4 of Jane Doe's affidavit of July 26, 2004 (Ex. H), she mentioned that Baby Doe began to scream uncontrollably for extended periods of time within a few days of her March 26, 2001 vaccinations. Tr. at 51. Aside from Baby Doe's screaming, her other symptoms were very subtle, including 10 seconds of staring. Tr. at 51.

On cross-examination, respondent's counsel asked Jane Doe about her testimony that

Baby Doe was her easiest child out of the three, by which she meant having a good temperament and not crying much. Tr. at 60. Counsel read from Ex. A, p. 8., a telephone call to Dr. Johnston that Jane Doe made on October 16, 2000 when Baby Doe was five weeks old that Baby Doe was very colicky and still quite fussy. Tr. at. 61. Jane Doe testified that if Baby Doe were fussy, she is sure she would have called. *Id.* Jane Doe does not remember Baby Doe being that bad with reflux unlike Brittany. Tr. at 62. When respondent's counsel read Jane Doe the note for a sick visit to Dr. Johnston on October 17, 2000 (Ex. A, p. 6) that Baby Doe had been fine until she was three weeks of age and the last couple of weeks had been miserable with Baby Doe up every night crying, very colicky, pulling her legs up and refluxing with spitting almost every feeding, especially at night, Jane Doe testified that Baby Doe was never diagnosed with reflux. *Id.* She thought that doctors always diagnose colic when a baby cries. *Id.* When respondent's counsel continued with Dr. Johnston's impression that Baby Doe's symptoms were very compatible with gastroesophageal reflux, Jane Doe replied that Baby Doe was not diagnosed with reflux. Tr. at 62-63.

Respondent's counsel read from a sick visit on November 1, 2000 when Baby Doe was seven weeks old (Ex. A, p. 10), which describes Baby Doe as still miserable, but no more than before, and she had a cold and cough. Tr. at 63. Jane Doe responded that Baby Doe may have had intermittent crying with a bellyache, but this was different than what happened after the vaccinations. Tr. at 64. Jane Doe testified that she believed she called Dr. Johnston a couple of days after the vaccinations. She asserted that she knew she did. *Id.*

Respondent's counsel asked Jane Doe if she recalled bringing Baby Doe to South Shore Hospital Emergency Room on November 1, 2000, and she said she did. It was for the croup. *Id.*

She said the circumstances were nothing compatible [perhaps she meant comparable] to Baby Doe's post-vaccination condition. Tr. at 65. Baby Doe did not stop breathing on November 1, 2000. Jane Doe said she probably overreacted and needed to make sure Baby Doe was fine because she was so small. *Id.* [The medical records show that Mr. and Mrs. Doe brought Baby Doe in to the ER because Baby Doe had difficulty breathing. Ex. C, pp. 212, 213.]

Jane Doe testified that she did not recall anything being wrong with Baby Doe until March 2001. Tr. at 66. Both of her other children had colic which can go on for a long time with crying and screaming, but that is nothing and does not bother her. What bothered her is when she could not run to the supermarket because there was no one to watch Baby Doe because they were afraid to watch her. Tr. at 66-67.

When respondent's counsel moved to the December 18, 2000 visit to the pediatrician's office (Ex. A, p. 13) which that day was with Dr. Jolles, Jane Doe denied that she had seen Dr. Jolles because she always saw Dr. Johnston. Tr. at 67. There was nothing to remember about Baby Doe's first acellular DPT vaccination. *Id.* When the undersigned questioned Jane Doe about her denial of seeing Dr. Jolles on December 18, 2000, she reiterated that she was almost positive that Baby Doe's appointments were with Dr. Johnston. *Id.* When the undersigned asked why Dr. Jolles signed the December 18, 2000 medical record, Jane Doe said she did not know, unless Dr. Johnston was away. Tr. at 67-68. Then she retracted and said she did not think Baby Doe saw Dr. Jolles more than twice. Tr. at 68. The undersigned asked about Jane Doe's visit with nurse practitioner Katherine Dennehy on December 7, 2000 during which Jane Doe described Baby Doe as having congestion for two days. *Id.* N.P. Dennehy writes that Baby Doe was fussy but she was always fussy, conveying to the undersigned that Baby Doe was a fussy

child. Tr. at 69. Jane Doe tried to explain that she had had such a bad experience with Brittany who cried for months and then stopped that Baby Doe seemed to her very easy. *Id.* To Jane Doe, “fussy” does not mean screaming and crying all day long. *Id.*

Respondent’s counsel turned to March 26, 2001, the second acellular DPT vaccination and Jane Doe’s testimony that everything was fine that day and the next day. *Id.* Within a few days, Baby Doe was crying and not herself. Tr. at 70. She had side to side movements of her head for a few seconds which was weird. If this had happened before March, she would have known. *Id.* Jane Doe was absolutely sure that Baby Doe had erratic head movements within a few days of her March 26, 2001 vaccinations. Tr. at 71. She remembered quick staring spells and possibly her eyes moving back, but it was April when they were really rolling back because if that had happened earlier, she would have called the ambulance. It was just very gradual and very different from day to day. *Id.* What happened was a quick 10-second stare or her head moving side to side or falling asleep quickly. Jane Doe would shake Baby Doe a bit. *Id.* The doctors were not sure what it was because they could not see it. Tr. at 72.

When the undersigned asked Jane Doe about erratic head movements, Jane Doe said they were not quick but slow. Tr. at 73-74. Her head would just move from side to side. Tr. at 74. It was almost as if her head was doing something her body was not doing. Her head would just jerk from side to side. *Id.* In the infant carrier, Baby Doe would move her head from one side to the other side very slowly. Tr. at 75. Jane Doe said that “being a mother, honestly, you know when there’s something the matter.” Tr. at 78. John Doe accompanied Jane Doe to the hospitals. *Id.*

When the undersigned asked Jane Doe about her history to Dr. Baum on April 14, 2001

that Baby Doe had two prior episodes that week of not being responsive, Jane Doe said she could remember it as if it were yesterday. *Id.* It could have been a couple of weeks prior to that that things were different. It was gradual. Tr. at 79.

Jane Doe remembered telling someone at her hair salon that Baby Doe did something different. *Id.* Jane Doe did believe she called the pediatrician after the vaccinations and may have had a brief conversation. Tr. at 80. She probably spoke to a nurse. Tr. at 81. She recalled talking to her mother about it that morning, too. *Id.* She talks to her mother every morning, but it was a couple or a few days after the vaccinations when she spoke to her. *Id.*

Jane Doe said that, on April 14, 2001, she thinks she was so freaked out that she probably did not think about anything else that morning. Tr. at 82. She explained that she did not take Baby Doe to the doctor after the vaccinations until April 14, 2001 because she probably overlooked Baby Doe's unresponsiveness for a couple of seconds as just something weird. Tr. at 83. She is sure that she mentioned to the doctors that Baby Doe's health took a turn for the worse after her vaccinations, specifically Dr. Johnston. *Id.* Jane Doe explained her giving a history that Baby Doe was well until April 14<sup>th</sup>, that it did not mean things were not different after March 26<sup>th</sup>. Tr. at 87. She reiterated that Baby Doe changed slowly but surely after her vaccinations in March. Tr. at 92. It was the normal practice for both Mr. and Mrs. Doe to go to the hospital with Baby Doe. Tr. at 94. She said the reason she did not bring Baby Doe in after the March 26<sup>th</sup> vaccinations was that she did not have a fever. Tr. at 95. Jane Doe testified that she knows the vaccine did this to Baby Doe. Tr. at 96.

Jane Doe made another attempt to explain why every single history she and her husband gave on and after April 14, 2001 omits any mention of screaming and unresponsiveness and

head-turning after the March 26, 2001 vaccinations:

You could call the doctor and say she's screaming and what are they going to say? They're not going to make you bring her there. I mean, if her eyes—if she was staring or her head were subtly turning, I could call or bring her there and they're not going to see it anyway. So I tried to carry on with my everyday living, hoping that it was something out of the ordinary that was going to change. I am a very—I take my kids to the doctor even when they don't need to go if they really, really, really don't look right or don't feel right. She would've been there. I thought maybe it was just the different—something just weird. Just a fluky thing.

Tr. at 100. [Jane Doe, however, did not answer why she and/or her husband did not give this history to any doctor on or after April 14, 2001.] Jane Doe then denied that she thought at the time Baby Doe was turning her head or crying that she thought the vaccinations were the cause.

Tr. at 101. However, she remembered saying that Baby Doe had not acted right since her vaccinations. *Id.* Baby Doe was not screaming and rolling her head at the same time. She would cry and then stare. Tr. at 106.

John Doe, Baby Doe's father, testified next for petitioners. Tr. at 108. On April 14, 2001, John Doe was doing a change of Baby Doe's diaper on the changing table at 7:30 or 7:45 a.m. and talking to Jane Doe who mentioned that Baby Doe had done a funny thing the day before or maybe a couple of days before during a walk. *Id.* Baby Doe looked like she was staring. At that moment, Baby Doe had started to do something weird and John Doe picked her up and asked Jane Doe if what she had described was anything like that. Tr. at 109. Baby Doe was lifeless, eyes rolled back, and head flopped to the right. Jane Doe took Baby Doe and tried to pat her on the back, but she did not respond. He immediately called 911. He took Baby Doe from Jane Doe. Baby Doe's face was dark reddish. Her gave her a couple of rescue breath on the carpet, and the paramedics were at the door. Baby Doe was breathing and yawning. Tr. at



110.

John Doe remembers Baby Doe not sleeping well, being fussy and colicky and spitting up before March 26, 2001, but he said she was a fairly easy baby. Tr. at 110-11. He said that Jane Doe would always feel the pain of her child. Tr. at 113. [This was John Doe's way of answering whether Jane Doe had ever told him that Brandon had a reaction to his DPT and was never given pertussis again.] She would always do what Dr. Johnston said. *Id.*

John Doe thinks he noticed Baby Doe being a little fussy two to three days after her March 26, 2001 vaccinations. Tr. at 114. Jane Doe told him she thought Baby Doe was crying a lot more since the vaccinations. They agreed that if Baby Doe did not improve by the beginning of the following week, Jane Doe would call the doctor. *Id.* [John Doe thought that March 26, 2001 was a Thursday, but it was actually a Monday. The beginning of the next week would then have been April 2, 2001.] John Doe did not see anything else prior to April 14, 2001. Tr. at 115. Jane Doe had mentioned to him a couple of times that Baby Doe was staring. *Id.* He did not think he could say that Baby Doe was a different baby between March 26 and April 14, 2001. Tr. at 116-17. He thinks that Jane Doe mentioned an episode the following week after the March 26, 2001 vaccinations where Baby Doe was kind of staring and then, three or four days later, another episode. Tr. at 117-18.

John Doe insisted that he and Jane Doe gave histories to the doctors and nurses that Baby Doe had been experiencing something strange or different since the end of March. Tr. at 119. "And we absolutely would've mentioned and did mention previous staring episodes." *Id.* He mentioned giving a history which is in the records of his mentally retarded brother that had a seizure. *Id.* But until Baby Doe was diagnosed with a seizure in June 2001, John Doe said that

they were never in a confident, comfortable frame of mind to give accurate details. Tr. at 120. Baby Doe's initial staring spells were subtle and minute. Tr. at 127. He thought it was a fair history that two prior episodes the week of the April 14<sup>th</sup> episode had occurred. Tr. at 128. He thinks it was Jane Doe who gave that history and that she was trying to piece together the most recent events. Tr. at 129. John Doe said he has learned from the Internet that vaccinations cause different behavior in children. Tr. at 131.

John Doe testified that Jane Doe told him the weekend after the March 26, 2001 vaccination that the vaccine was the cause. *Id.* That was before any doctor brought up the vaccinations in June or July. *Id.* Baby Doe never had a fever. Tr. at 133-34.

## **DISCUSSION**

The issue of onset was the focus of the hearing because of the discrepancy between the multiple histories both parents gave to the doctors, and because petitioner's expert neurologist, Dr. Ronald I. Jacobson, posited his opinion on an onset occurring within one week, whereas the earliest onset of Baby Doe's purported seizures was the week of April 8, 2001, or 13 days after vaccination..

The law is clear that when there is a discrepancy between the contemporaneous history given in the medical records and the testimony and affidavits given after litigation has begun, the history given contemporaneously is more credible because it is given closer in time to the actual events when there is strong motivation to be truthful in order to obtain an accurate diagnosis and effective treatment compared to a history given years later, when memories have faded and the impetus to succeed in litigation may cloud memories or conflate events.

Well-established case law holds that information in contemporary medical records is

more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Mr. and Mrs. Doe have been through an ordeal with Baby Doe's episodic events, occasioning numerous, frustrating visits to the emergency rooms of and admissions to various hospitals until Baby Doe received phenobarbital in June 2001 which ended the episodes. This experience has no doubt influenced them in increasing the stress throughout the entire family.

Certainly, there could be no more vigilant a mother than Jane Doe, to her credit. She puts the health of her children above all else. She is not shy about demanding and receiving medical attention for her children's slightest problem. But she has a selective memory and her testimony not only was at odds with the histories she and her husband gave multiple times to many doctors, but she also denies the histories she gave concerning Baby Doe before the vaccinations at issue.

Jane Doe denied that Baby Doe's pre-March 26, 2001 behavior was difficult. Yet,

between Baby Doe's date of birth on September 8, 2000 and her March 26, 2001 vaccinations, Jane Doe brought Baby Doe in to see the doctor or to the hospital 10 separate times<sup>6</sup> and telephoned the pediatrician's office six times.<sup>7</sup> That is the space of six and one-half months. Including two well-baby visits<sup>8</sup> when Baby Doe actually was well, Jane Doe brought Baby Doe in for medical attention 12 times in six and one-half months, in addition to six phone calls. This is a huge amount of visits and contacts.

Jane Doe denied that Baby Doe had ever had breathing problems before her post-March 26, 2001 vaccinations, but the medical records establish that Baby Doe had trouble breathing when she was brought in for croup/bronchiolitis at seven weeks.

Jane Doe denied telling Dr. Jolles (whom she at first denied even seeing) on December 18, 2000, when it was time for Baby Doe's first acellular DPT vaccination, that her son Brandon had had a reaction to his DPT vaccination and she was concerned about Baby Doe's responding similarly. Jane Doe not only denied telling Dr. Jolles about this reaction, she denied that Brandon had ever had a reaction beyond a red and swollen vaccination site. (The history she gave to Dr. Jolles was Brandon had two days of lethargy after his DPT vaccination.) She also denied that Brandon had not received any future pertussis vaccinations. Of interest is that Dr. Jolles wrote at the end of the medical record that Jane Doe said she would watch Baby Doe closely after the vaccination to see if she reacted. (She did not react.)

For the undersigned to accept that Jane Doe never gave this history to Dr. Jolles is

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<sup>6</sup> The visits were 9/20/00, 9/28/00, 10/17/00, 11/1/00, 11/2/00, 11/14/00, 11/18/00, 12/7/00, 1/2/01, and 1/17/01.

<sup>7</sup> The calls were 10/2/00, 10/16/00, 11/3/00, 11/6/00, 11/9/00, and 1/12/01.

<sup>8</sup> The well-baby visits when Baby Doe was well were on 1/23/00 and 3/26/01.

inconceivable. There is no earthly reason for the undersigned to believe that Dr. Jolles imagined this conversation with Jane Doe, that Brandon did not have two days of lethargy after his whole-cell DPT vaccination, that Brandon continued to receive more pertussis vaccinations, that Dr. Jolles did not give Jane Doe information about the difference between whole-cell and acellular DPT, that Dr. Jolles did not tell Jane Doe he could not promise that Baby Doe would not have a neurologic reaction to the DPT, and that Jane Doe did not say she would be watching Baby Doe carefully after vaccination to see if she had a reaction. This conversation occurred and the consequence of this conversation is the natural expectation that Jane Doe, a truly vigilant and attentive mother, would be extra observant about Baby Doe's behavior after vaccination because of her prior experience with Brandon's reaction to his DPT vaccination.

Jane Doe denied in her testimony that Baby Doe had ever been diagnosed with reflux, but Dr. Johnston diagnosed Baby Doe with reflux when she was five weeks old and various treaters continued that diagnosis repeatedly in the medical records. Baby Doe was constantly changing formulas. She was constantly spitting up. She was also colicky. She took Zantac as medication for her reflux, although Jane Doe denied in her testimony that Baby Doe had ever received medication for reflux.

Jane Doe testified that Baby Doe was laid back and was her easiest child among the three she has. But the history she gave to N.P. Dennehy was that Baby Doe was miserable and she was always miserable. Baby Doe cried, had trouble sleeping, and constantly spit up. Jane Doe was afraid to feed her solid food because of Baby Doe's difficulty ingesting. Jane Doe made sure never to lay Baby Doe flat. This is not an easy or laid back child. And that does not include her bronchiolitis at the age of seven weeks when she had trouble breathing.

Nancy Fleck, Jane Doe's close friend from before high school (whom she sees on a regular basis), testified that two days after the March 26, 2001 vaccinations, Baby Doe was screaming, stiff as a board, and in pain. In only one of Jane Doe's five affidavits did Jane Doe describe Baby Doe as screaming after the vaccinations. But there is no visit or telephone call to Dr. Johnston from March 26, 2001 until April 17, 2001, even though Jane Doe at first testified that she brought Baby Doe in or at least telephoned Dr. Johnston's office as soon as Baby Doe began screaming and/or staring. Ms. Fleck testified that Jane Doe told her Baby Doe was reacting to her vaccinations, although Jane Doe, during her testimony, denied saying that to Ms. Fleck.

It is extremely unlikely that Jane Doe, who brought Baby Doe in to see Dr. Johnston for an infected ear lobe in January 2001, would not telephone or bring Baby Doe in when she was having a reaction to her vaccinations, especially in light of her fear, expressed to Dr. Jolles on December 18, 2001, that Baby Doe would react to DPT because her half-brother Brandon had reacted to DPT, and her promise to watch Baby Doe closely after vaccination with DPT..

Of importance, Jane Doe testified that she is very close to her mother Ms. Ida Fagone-McNamara. In the affidavit from Ms. Fagone-McNamara, Jane Doe's mother states that she speaks to her daughter three or four times a day. She says the first time Jane Doe told her that Baby Doe was behaving strangely was one to two weeks after the vaccinations. Ms. Fagone-McNamara does not mention screaming, crying, and stiffness two or three days after the vaccinations. She does not mention strange staring spells lasting seconds, or turning of the head slowly, or head jerking, all occurring within two or three days after the vaccinations. Ms. Fagone-McNamara's affidavit is consistent with an onset of these staring episodes at the earliest

on April 8<sup>th</sup> (the Sunday before the Saturday, April 14<sup>th</sup> admission), which was 13 days after the March 26, 2001 vaccinations. Her affidavit is also consistent with Baby Doe's not having a screaming and stiffening reaction to her vaccinations.

Jane Doe never explained satisfactorily why she did not bring Baby Doe in to see Dr. Johnston or at least telephone him within two or three days of the vaccinations. At first, she said she did telephone him or one of the nurses. But there is no record of a telephone call and Dr. Johnston's office reliably records telephone calls such as the six phone calls Jane Doe made to his office between Baby Doe's birth and her March 26, 2001 vaccinations. Then Jane Doe said that Baby Doe's movements were so subtle and everything was so gradual, that she just waited for these weird (her word) movements to go away. It seems extremely unlikely that Jane Doe would let any of her children have a medical problem and then just wait for it to go away. In addition, the screaming and stiffening that preceded the staring spells and the purported additional crying were hardly subtle.

When asked why, in the numerous histories Mr. and Mrs. Doe gave to the doctors on and after April 14, 2001, neither one gave a history that Baby Doe had this screaming, stiffening behavior followed by excessive crying, staring spells, and either slow or jerky (Jane Doe testified to both) head turning within days of her March 26, 2001 vaccinations, Jane Doe said she just could not recall it in the stress of the moment while John Doe said they did tell the doctors. What the records show is that the doctors asked if Baby Doe's immunizations were up to date, and the Does answered no because her bronchiolitis at age seven weeks delayed her vaccinations. This would have been a perfect time for Jane Doe to mention that Baby Doe's episodes actually began two or three days after her March 26, 2001 vaccinations, consisting of

non-stop screaming, stiffening, staring, and head turning, not that the onset was two episodes occurring the week of April 14, 2001, including one the day before the April 14<sup>th</sup> episode.

When asked how Baby Doe's health had been before the mid-April 2001 onset of episodes, both parents told the hospital personnel that Baby Doe was fine except for reflux and bronchiolitis. This also would have been a perfect time for them to give a history that Baby Doe had "weird" spells where she zoned out for a few seconds or turned her head either slowly or jerkily, starting in late March 2001. But they gave no such history, although John Doe testified that they did give that history. His testimony on that point is not credible. It is inconceivable that the doctors would write voluminous notes on Baby Doe's pre-April 14<sup>th</sup> history but omit that she had been having staring spells since two or three days after her March 26, 2001 vaccinations and that she had experienced an increase of crying following her screaming and stiffening two or three days after her March 26, 2001 vaccinations.

Between April 14, 2001 and the end of June, Mr. and Mrs. Doe saw an astounding number of medical personnel and never told one of them about screaming, stiffening, increased crying, staring spells, and waving or jerking of Baby Doe's head two or three days after the March 26, 2001 vaccinations. Between April 14, 2001 and the end of June 2001, Mr. and Mrs. Doe saw: Dr. Michael Hughes, Dr. Carol Baum, Dr. Heather McLaughlan, Dr. David Greenes, Dr. Gary Hsich, Dr. Jonathan Megerian, Dr. Randi Pleskow, Dr. Dwayne Greene, Dr. Stuart Harris, Dr. Marvin Harper, Dr. Rhodes, Dr. Uzme Vhang, Dr. John Leonard, Dr. Feigall, Dr. M. Provenca, Dr. Jeffrey Biller, Dr. Karen Dull, Dr. June Hanly, Dr. Kara Gasink, Dr. Sara Toomey, Dr. Vincent Chiang, and Dr. James Riviello, besides the psychologist Dr. David Spitz and the case worker Cara Weiner (and these are the names the undersigned could decipher from the



medical records). To none of these 24 people did Mr. and Mrs. Doe divulge that the onset of Baby Doe's spells began at the end of March or two to three days after her March 26, 2001 vaccinations because that information is not in one single record.

One would also expect that Dr. Johnston, whom Jane Doe and Baby Doe saw on April 17, 2001, would have written in his records that Baby Doe had experienced screaming, stiffening, increased crying, and staring spells with head waving or jerking within two or three days of her March 26, 2001 vaccinations when Jane Doe and Baby Doe saw him. But there is no such record. Dr. Johnston has been a faithful recorder (as has Dr. Jolles) of Jane Doe's complaints about Baby Doe's health problems since Baby Doe's birth. It is inconceivable that if Jane Doe had given him this history on April 17, 2001, or telephoned him two to three days after the March 26, 2001 vaccinations, he or a nurse would not have written this information down. The only reasonable conclusion is that Jane Doe did not give him this history for another two and one-half years when she decided Baby Doe had reacted to her vaccinations.

On April 8, 2002, 13 months after the onset of Baby Doe's seizures, Jane Doe told Dr. Johnston that she did not want to have Baby Doe vaccinated that day. This is the first record showing Jane Doe's aversion to further vaccination for Baby Doe.

On September 16, 2002, one and one-half years after the onset of seizures, Jane Doe told Dr. Johnston that she did not want Baby Doe vaccinated because of Baby Doe's seizure disorder. This record still does not contain a history that Baby Doe reacted to her last vaccinations. It would not be unreasonable to keep someone with a seizure disorder from being vaccinated. According to the record of December 18, 2000, Jane Doe had never let her son Brandon receive further pertussis vaccinations after his reaction to whole-cell DPT vaccine. She denied this ever

happened in her testimony, however. Her testimony is not credible.

Not until September 9, 2003, two and one-half years after Baby Doe's onset of seizures, is there a notation in Dr. Johnston's records of Jane Doe having a discussion with him about Baby Doe's possibly having a vaccine injury claim.

John Doe testified that Jane Doe's relationship to Dr. Johnston was guru-like. It would only be reasonable that, if Baby Doe had reacted to her March 26, 2001 vaccinations with screaming, stiffening, excessive crying, followed by staring spells and head waving or jerking, that Jane Doe would seek help from the doctor to whom she was so close and tell him immediately after the onset of Baby Doe's seizures, if they had occurred two or three days post-vaccination, that his office had given Baby Doe the second DPT and look what happened: screaming, stiffening, crying, a changed baby, an unwell child, staring episodes, jerking or slow turning of her head. She had warned Dr. Jolles of her concern on December 18, 2000 and had said she would watch Baby Doe closely after her DPT vaccination.

The only explanation for Jane Doe's failure to tell Dr. Johnston immediately about what Baby Doe was experiencing purportedly within two or three days of her second acellular DPT is that she did not have screaming, stiffening, and excessive crying, and that the onset of Baby Doe's staring spells occurred weeks later, no earlier than 13 days later. Jane Doe did not associate the staring spells with the March 26, 2001 vaccinations until years had passed and she had conflated the timing of the spells with the date of the vaccinations. The history that the Does gave to more than 24 hospital personnel and doctors from April through June 2001 was accurate. Baby Doe began having two staring episodes the week of April 8, 2001 (one of which was on April 13, 2001) culminating in the third spell of a stoppage of breathing on April 14, 2001 and

there was nothing untoward in her prior medical history other than gastroesophageal reflux, colic, and bronchiolitis.

The undersigned held that the onset of Baby Doe's spells after her March 26, 2001 vaccinations was no earlier than April 8, 2001, which is 13 days post-vaccination in a Ruling on Onset initially issued on July 30, 2007. 2007 WL 5187610, at \*33 (Fed. Cl. Spec. Mstr. 2007).

The undersigned also held that Baby Doe did not have any unusual behavior, such as screaming, stiffening, crying out in pain, or becoming a different child, within days of Baby Doe's March 26, 2001 vaccinations. Jane Doe would have taken Baby Doe to the doctor or at least called his office, particularly in light of her concern over Brandon's reaction to DPT. Moreover, Jane Doe would have told her mother with whom she was in frequent and daily telephone contact if this had actually occurred and she did not. Her testimony and that of her close friend Nancy Fleck was not credible. 2007 WL 5187610, at \*33.

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)). Lampe also concerned petitioners' failure to prove DPT caused their daughter's seizure disorder and the inapplicability of the National Childhood Encephalopathy Study or NCES.<sup>9</sup> The vaccinee in Lampe had seizures within seven days of her third DPT vaccination, unlike Baby Doe in this case. 219 F.3d at 1368. The Federal Circuit affirmed the dismissal of the case. *Id.*

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<sup>9</sup> The NCES is an exhibit in the instant action as Court Exhibit # 1. The title of the NCES is "The National Childhood Encephalopathy Study, in Whooping Cough: Reports from the Committee on Safety of Medicines and the Joint Committee on Vaccination and Immunisation 79 (Department of Health & Social Security ed., 1981) by R. Alderslade et al.

The special master has “broad discretion in determining credibility because he saw the witnesses and heard the testimony.” Bradley v. Sec’y of HHS, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Since Jane Doe denied in her testimony that Baby Doe ever had gastroesophageal reflux and petitioners’ counsel waffled over whether petitioners were now alleging that Baby Doe had seizures starting at five weeks (when Dr. Johnston first diagnosed gastroesophageal reflux), which precedes the March 26, 2001 vaccinations, the undersigned issued an Order at the end of the Ruling on Onset for the counsel to do the following:

1. Send a copy of the Ruling on Onset to their respective experts (Dr. Jacobson and Dr. Johnston for petitioners; Dr. Max Wiznitzer for respondent).

2. (a) File supplemental reports from the medical experts Drs. Jacobson, Johnston, and Wiznitzer answering whether they think that Baby Doe never had gastroesophageal reflux but always had seizures, starting at five weeks, and if so, the basis for their opinion. If they believe that Baby Doe’s seizures began before her March 26, 2001 vaccinations, then petitioners must be alleging that the March 26, 2001 vaccinations significantly aggravated her pre-existing seizure disorder. The medical experts Drs. Jacobson, Johnston, and Wiznitzer shall include in their supplemental reports their opinion whether the March 26, 2001 vaccinations significantly aggravated her pre-existing seizure disorder and, if so, the basis for their opinion.

- (b) If the medical experts Drs. Jacobson, Johnston, and Wiznitzer did not believe that Baby Doe had a seizure disorder before March 26, 2001, in light of the undersigned’s holding that the onset of her spells was no earlier than April 8, 2001 (13 days post-vaccination), the medical experts Drs. Jacobson, Johnston, and Wiznitzer shall include in their supplemental

reports whether or not they believe that the March 26, 2001 vaccinations caused Baby Doe's spells 13 or more days later and, if so, the basis for their opinions. Petitioners' counsel filed reports from Dr. Jacobson and Dr. Johnston that were not responsive to the undersigned's Ruling on Onset, but instead argued that the undersigned was wrong and that Baby Doe's seizures began within seven days of her vaccination. Upon striking those nonresponsive portions of petitioners' doctors' reports, the undersigned ordered that the doctors file responsive reports. Their supplemental reports still argued for a closer onset than the undersigned held or, in the alternative, an insidious onset. P. Exs. 28 and 29.

To explore the reasoning of Drs. Jacobson and Johnston, the undersigned held a hearing on May 29, 2008 with Dr. Jacobson and Dr. Johnston testifying for petitioners, and Dr. Wiznitzer testifying for respondent.

### **TESTIMONY**

Dr. Ronald Jacobson testified first for petitioners. Tr. at 141. (The pagination is a continuation of the pagination from the first transcript on the issue of onset.) He is a pediatric neurologist. Tr. at 142. In defining partial complex seizures, Dr. Jacobson said they can be very subtle from brief moments of facial twitching or head turning. Tr. at 148-49. The undersigned asked Dr. Jacobson the following question and received the following response:

THE COURT: Doctor, how would you distinguish between a child who was having such subtle symptoms of seizures that no one noticed and a child who wasn't having seizures at all?

THE WITNESS: It is a challenging clinical problem. The formal way to determine that once it [sic] somebody comes to attention would be to do a video EEG analysis or a continuous EEG and record the suspicious events and see what's happening electrically on the EEG. In some cases it would be 95 plus percent reliable. There are cases of very subtle EEG findings. Depending where

the EEG abnormality is it doesn't show up on a recording. If you record an event and the EEG is normal, then one usually concludes the event is not a seizure. It shouldn't be taken as an 100 percent certainty, though, but it's close.

In this case, this child had multiple EEGs which were normal and then went on actually to have continuous EEG monitoring and had events recorded which did not show EEG abnormalities, and so there was the conclusion made the child in fact was not having seizures based on that proof.

This is a case that eventually was determined to be having seizures based on a therapeutic trial of antiseizure medication, which some authors state that's the ultimate diagnostic test: you get better with the treatment of the problem.

Tr. at 149-50.

The last seizure Baby Doe had was in June 2001. Tr. at 157. Dr. Jacobson thought Baby Doe should have been given a trial off Phenobarbital. Tr. at 158. In partial complex seizures, an individual might have an aura consisting of an unusual smell, taste, or sensation, which might result in funny movements of the face. Tr. at 158. An aura could be confused with gastrointestinal reflux. Tr. at 158-59. The undersigned asked Dr. Jacobson if he agreed with Jane Doe that her daughter Baby Doe had never had reflux but had always had seizures. Tr. at 159. He stated that many, virtually all, infants have some component of reflux. *Id.* However, until the child has events that are much more substantial in appearance than mild reflux, he would not have any way to conclude that every event from the first was a seizure. Tr. at 160.

In June 2001, Baby Doe's episodes responded to Phenobarbital. Tr. at 161. When the parents took Baby Doe to the emergency room on April 14, 2001, this was a sentinel event. Tr. at 162. Dr. Jacobson's opinion is that Baby Doe's DTaP vaccination on March 26, 2001 caused her seizures. *Id.* Commonly, the onset of seizures after an immunization is two to three days. Tr. at 163. There is information that it can occur as late as seven days after vaccination. *Id.* Dr.

Jacobson testified that “If it is determined in some way or another that the absolute first seizure occurred on day 13 after the vaccine, then, as I indicated in my last response to your question, I do not have the opinion that that all by itself represents an etiology related to the vaccine, so I have to put that if in there.” Tr. at 163-64. However, if the reaction occurred in episodes occurring within a few days or a week of vaccination, then DPaT caused the seizures. Tr. at 164.

The following colloquy ensued:

THE COURT: Okay. So basically, if onset was beyond a week, your opinion is that DPaT is not the cause of these seizures, but if onset is within a week, your opinion is that it is. Am I characterizing your testimony correctly?

THE WITNESS: That’s correct. I mean, it comes to me to look like a threshold question here.

Tr. at 164.

Dr. Jacobson agreed there was no medical record containing a history contemporaneous with an onset of Baby Doe’s seizures within a week of vaccination. Tr. at 170. He believes Baby Doe had a complex partial seizure on April 14, 2001. *Id.* He stated it was a “likely possibility” that one would have earlier episodes of seizure. Tr. at 171. When the undersigned asked if he said a likely probability or likely possibility, Dr. Jacobson would, “I would say it’s a possibility.” *Id.* He stated as far as the question of prior subtle seizures occurring before the noted seizure, that “I would have to comfortably put that still in the realm of possibility not probability. ... I, in my medical opinion can’t cross a threshold to say that it’s probable. I would have to say it was possible on that one.” Tr. at 172.

Petitioners’ counsel attempted numerous times to have Dr. Jacobson change his testimony to Baby Doe’s having seizures during the first week after her second acellular DPT

vaccination, but Dr. Jacobson held to his opinion that it was only possible not probable:

BY MR. DANNENBERG:

Q. Dr. Jacobson, could a reason why there were no histories of prior episodes to the April 8 [seizure] because these were the partial complex seizures with such subtle –

THE COURT: We've already been here, Mr. Dannenberg. Dr. Jacobson admitted that. There was no difference between a child who was having seizures that are so subtle nobody notices it and a child who isn't having seizures at all. Am I paraphrasing your answer correctly, Dr. Jacobson?

THE WITNESS: Yes.

Tr. at 178-79.

Dr. Jacobson stated that his opinion of causation in fact had a cut off of seven days after vaccination based upon the NCES report “and some other literature as well.” Tr. at 181. Dr. Jacobson said he was familiar with the NCES “in general.” Tr. at 183. He agreed that the NCES focused on two types of children: (1) those who had an acute encephalopathy after receiving whole-cell DPT, and (2) those children who had seizures lasting more than 30 minutes. Tr. at 184. One exception to the second group were those children who had seizures within a week of vaccination that were not longer than 30 minutes but, within a month, had seizures lasting more than 30 minutes. If the authors of the NCES could connect pathologically the earlier seizures to the later ones, they would include them in the study. *Id.* Dr. Jacobson agreed that Baby Doe did not at any time have a seizure lasting more than 30 minutes. Tr. at 185. He also agreed that she did not have an acute encephalopathy after the vaccination either. *Id.* He furthermore agreed that Baby Doe would never have been included in the NCES. *Id.*

Dr. Jacobson then changed his testimony to opining that the onset of Baby Doe's symptoms was within the first week after her second acellular DPT vaccination. Tr. at 189. He



based his belief on the one-week onset in the parents' affidavits and not on the medical histories they gave in the contemporaneous records. Tr. at 190, 191. The reason for his change in opinion is that the NCES mentions in the context of infantile spasms (which Baby Doe did not have) that onsets can be insidious. Tr. at 189. Dr. Jacobson now felt that Baby Doe's onset of seizures was insidious. Tr. at 190.

In explaining his idea of a biologically plausible medical theory for Baby Doe having an onset of seizures within a week, Dr. Jacobson stated most reactions, but not all, include a fever. (Baby Doe did not have a fever.) Tr. at 192. The basis for his explanation is his clinical practice. Tr. at 193. He found temporality to be an important element. Tr. at 194. Since the type of seizure, i.e., subtle, also influenced Dr. Jacobson's opinion that Baby Doe had an insidious onset, the undersigned asked Dr. Jacobson the following:

THE COURT: So she could have been seizing since her first DPT in December of the prior year and it was so subtle nobody noticed it, is that right, Dr. Jacobson?

THE WITNESS: That's correct.

Tr. at 196.

Dr. Jacobson then quoted from Jane Doe's affidavit that she saw Baby Doe's behavior change about two or three days after the March 26, 2001 vaccination in that she was staring and moving her head for a few seconds. Tr. at 197. The court asked Dr. Jacobson if he was aware from the records that Jane Doe

wasn't reluctant to bring her daughter to see Dr. Johnston or his partner, Dr. Jolles, ... or to even the hospital when she had bronchiolitis, or to call if she didn't bring her in. So if anything had been a change in [Baby Doe's] behavior, particularly because she was so worried at the time of the discussion of December 2000 about [Baby Doe] even receiving the

DPT, even though it was acellular, because her son had had a reaction to his DPT, and she said that she would be very careful to watch [Baby Doe], you know she would have brought [Baby Doe] in if she had seen any change in behavior after her second DPT, the one that was March 26, 2001, don't you agree, doctor?

THE WITNESS: Yes. I think that's well-stated.

Tr. at 197-98.

Apparently, from that answer, Dr. Jacobson was back to his original stance at the hearing that there was no unusual behavior before 13 days after the second DPT vaccination. At this point, petitioners' counsel asked Dr. Jacobson if he held his opinions to a reasonable degree of medical certainty, and he said he did. Tr. at 198.

However, respondent's counsel steered Dr. Jacobson back to his other opinion that onset of seizures began in late March 2001 and the seizures continued through April 8, 2001. Tr. at 198-99. Dr. Jacobson said he had no opinion whether Baby Doe's HiB vaccination caused her seizure disorder. Tr. at 199. But he agreed that if the seizures began 13 days after vaccination, acellular DPT vaccine did not cause them. *Id.* He also agreed that Baby Doe had afebrile seizures. *Id.* He furthermore agreed that no contemporaneous medical record refers to any reaction within a few days of the March 26, 2001 vaccination. Tr. at 199-200. He completely relied on the affidavits and the parents' testimony for his opinion on onset. Tr. at 200.

Dr. Thomas Johnston testified next for petitioners. Tr. at 215. He has been Baby Doe's pediatrician since her birth and still is her pediatrician. Tr. at 217. Baby Doe was a colicky baby. She probably had reflux and had one episode of bronchiolitis. *Id.* On April 14, 2001, Baby Doe had a limp episode or an ALTE (acute life threatening event), which was unclear as to etiology, but over time was thought to be a seizure. Tr. at 218. He stated he is not a neurologist

and does not claim being an expert in the field. *Id.* Dr. Johnston thinks the onset of Baby Doe's seizures is unclear, but he thinks "it was within the first week after, and that's in retrospect listening to mom and dad talk about how the child was behaving slightly differently." *Id.* He agreed that the onset of within one week was not based on the medical records. Tr. at 219.

Dr. Johnston does not remember if he or his nurse had any telephone conversations with the parents during the first week after vaccination. *Id.* He described Jane Doe as "a good mom but a needy mom, and I talked to her frequently about multiple problems that the child was having." *Id.* The undersigned asked Dr. Johnston if Munchausen syndrome by proxy was at play here, since it was mentioned in the medical records:

THE COURT: You know, there's been a mention in the records about Munchausen syndrome by proxy. Is this a case in which Munchausen syndrome by proxy is applicable?

THE WITNESS: Again, a very difficult diagnosis to make. It has crossed my mind on occasion. On the other hand, she follows through appropriately with all medical recommendations and she, you know, I think is a good mom overall. I can't say yes or no on the Munchausen by proxy.

Tr. at 219-20.

Petitioner's counsel asked if Dr. Johnston wrote a note for every time a patient phoned his office and he said "We try our darndest." Tr. at 223. The chart is usually called for appropriately. He could not say every call gets documented, but he and his staff try. *Id.*

In answer to petitioners' counsel's question whether Baby Doe's March 26, 2001 vaccinations triggered her seizure "syndrome," Dr. Johnston replied:

A. I've debated this for a long time and I think it's difficult to know for sure in this situation. I wish it were more clear cut, I wish that they had an EEG that was definitive, I wish that the child, if it were going to have it, had it within a week, but I think

this is one of those subtle cases where, you know, in retrospect things, you know, were a little different than the way they presented in retrospect. Upon thinking about it, I think it's a possibility. I do. I can't say for sure, and I don't think anybody can.

THE COURT: So it's possible but not probable?

THE WITNESS: You know, how can anyone assign a number of 50.1 percent to something that's so nebulous? That's my attitude. You know, people mentioned GERD as a possibility of all these symptoms. Why can't you have both? Why can't you have GERD and a seizure disorder. I mean, nobody's alluded to that. They all try to make it seem as though it's one or the other. I think it's more complicated than that. I think it's not so simple and can't be reduced to simple numbers. That's the problem I see with the whole issue.

Tr. at 224-25.

Dr. Johnston said he was not a "big fan" of Reglan to treat reflux. Tr. at 225. Baby Doe had a short trial of it. *Id.* GERD was a problem somewhat from the beginning and he and Jane Doe tried different formulas. *Id.* Formula changes are some of the first things to do for colic and GERD, adding cereal, and this was done. Tr. at 226. Dr. Johnston had Baby Doe on Nutramigen and added cereal to help with the reflux. *Id.* The risk of putting a baby with GERD on its back, for instance, for a diaper change, is that in 80 percent of the cases, the sphincter can be really loose, the stomach is in line with the esophagus, and the stomach contents come shooting up. Tr. at 228. The undersigned then asked the following:

THE COURT: If a child has GERD and he or she has one of those attacks, can you see the child lose consciousness, or go limp, or stop breathing because of that attack?

THE WITNESS: With respect to GERD?

THE COURT: Yes.

THE WITNESS: Yes. GERD can do a lot of different things. There can be fluid coming out of the mouth. It can sometimes be projectile but usually it's more likely to be just a little drool of formula to the side of the mouth. Occasionally they can choke on it. There are kids that, think of yourself swallowing the wrong way, you know, getting formula or juice down your windpipe instead of your esophagus. That can set off a reaction where the eyes close and they grimace. These can all mimic seizures and vice versa.

Tr. at 228-29.

Dr. Johnston's opinion is that the March 26, 2001 vaccinations caused Baby Doe's seizures based on her having symptoms within a few days based on the history that the parents gave in their affidavits. Tr. at 231-32. His opinion is not based on the history that they gave in the medical records or even the history they gave to Dr. Johnston. Tr. at 232. Dr. Johnston admitted he is a very patient person. *Id.* He thinks that Jane Doe could have possibly picked up the phone or come in, but he could not say that because human beings do not always behave in a rational pattern. Tr. at 232-33. He stated, "You know, if [Jane Doe] was really worried, she'd come in. If she wasn't so worried, she'd give us a call. So I can't say yes or no to that question [the question being if Baby Doe were behaving abnormally, would not Jane Doe have been in Dr. Johnston's office]." Tr. at 233.

Dr. Johnston stated that Baby Doe had subtle changes based on the parents' affidavits, but the seizure activity of April 13, 2001 was the more important, significant event. *Id.* About a month later, he met Jane Doe and Baby Doe at South Shore Hospital and had to do blood work and start an IV, and it "was really difficult to deal with from the mother's emotions as well as the diagnostic dilemma." *Id.* Baby Doe had partial complex seizures. Tr. at 234. These were breath holding spells with subtle movements and grimacing of the face. *Id.*

Dr. Johnston has Dr. Jolles in his practice and three nurse practitioners. Tr. at 235. It is absolutely his practice to keep accurate notes and inform other members of the practice about a patient's clinical history. *Id.* When Dr. Jolles warned Jane Doe that he could not promise that Baby Doe would not have a reaction to her December 2000 acellular DPT, that warning was absolutely consistent with his office practice. Tr. at 238.

When Jane Doe saw Dr. Johnston on April 17, 2001 and told him that Baby Doe had an episode on April 14, 2001 of choking, breathing cessation while lying on her back, and no fever, Dr. Johnston found Baby Doe to be normal neurologically although he wanted to rule out a seizure with an EEG. He did not put in his records that Baby Doe had a reaction to her March 26, 2001 vaccination. Tr. at 240-41. On April 24, 2001, he made a telephone call to Jane Doe that Baby Doe's EEG was normal. Tr. at 242-43. On May 7, 2001, Dr. Johnston noted that the spells were probably related to reflux. Tr. at 244.

On April 8, 2002 (over one year after the second acellular DPT vaccination), Dr. Johnston noted in his records that Jane Doe did not want to give Baby Doe any more vaccinations for the time being. Tr. at 247-48. He agreed that doctors are conservative in not taking chances with children who have seizures receiving vaccinations. Tr. at 248. Dr. Johnston stated:

If you've got a mother who is high anxiety, nervous about her child who is a little delayed and you've got myself in my office not wanting to induce another seizure, the logical thing to do is to hold off. You know, would I do it if she was completely comfortable with getting the shots? You know, I don't know. That's not the way it evolved. It evolved that she was nervous, she thought it might have caused it and she didn't want to give them. I was nervous, I didn't know whether it caused it, but I wasn't going to give it at that point. That's a logical medical decision based on the history of the child and what the parents are dealing with with this

child. That's what a logical person, pediatrician, would do. I'm not a specialist. I called in people to help me, the neurologists and so forth, and I think they even said hold off on shots for the time being. So it's a logical thing to do. Whether or not it caused it is another story. I don't know. I've told you that. I don't know. I think it did, but I don't know.

Tr. at 250-51.

Dr. Johnston's first linkage of Baby Doe's seizures to her vaccinations is in a medical record dated September 19, 2005, in which he states the seizure is presumably from the vaccine. The record is dated after the petition was filed in 2004. Tr. at 256, 257, 258. His view is that if the Does wanted to pursue a vaccine claim, they should go ahead and pursue it. Tr. at 258.

Part of Dr. Johnston's opinion on causation is based on his assumption that onset was within a few days or a week of vaccination. Tr. at 260. He was not opining that onset 13 days post-vaccination was still causally related to the vaccine, but he mentioned that the NCES excluded people and said "Who is to say absolutely whether that seven day time period is the right time period? It was arrived with scientific effort and so forth, but I don't think they could say 100 percent one way or the other." Tr. at 260. Dr. Johnston agreed with the statement that we do not know what is the medically appropriate time frame between vaccination and onset to show causality. Tr. at 260-61. The Institute of Medicine Report on DPT vaccine and chronic nervous system dysfunction does not support a temporal association lasting more than seven days. Tr. at 261-62. Dr. Johnston stated that the seven-day period is the time period that people have established. It is not necessarily perfect but it is established. Tr. at 262. When asked if a seizure occurring 13 days after vaccination is likely caused by it, Dr. Johnston answered:

THE WITNESS: That's where you get into difficulty, you know? That's what's hard to say. I think seven days can be considered arbitrary. If you look at how studies are done, they exclude the

patients somewhat arbitrarily not to establish findings but to set up these studies and they don't necessarily reflect what's actually going on in every case. Each case is an individual case and we're trying to compare it to studies which don't necessarily take that into account. So the answer is I don't know, and I don't think that the experts even know 100 percent.

Tr. at 263.

He agreed that some children develop afebrile seizures where there is no identifiable cause. Tr. at 265. He refers his seizure patients to a neurologist. *Id.* He cannot rule out the possibility of coincidence in Baby Doe's case. *Id.*

Dr. Max Wiznitzer, a pediatric neurologist, testified for respondent. Tr. at 267, 268. He is board-certified in pediatrics, neurology, and neurodevelopmental disabilities. Tr. at 268. His opinion is that Baby Doe's afebrile seizures are not related to her March 26, 2001 vaccinations. Tr. at 274. He noted that Baby Doe has never had a brain MRI, which would be part of a routine evaluation for children with recurrent seizures in order to look at small areas that may not have developed correctly and can be the source for seizures. Tr. at 275.

The basis for Dr. Wiznitzer's opinion that the March 26, 2001 vaccinations and Baby Doe's seizures are unrelated is that there is no documentation in the medical records that any event occurred prior to April 8, 2001. Tr. at 276. April 8<sup>th</sup>, which is 13 days post-vaccination, is "much too late for any postulated or putative mechanism of action that anyone could hypothesize that could be associated with immunization. It's just too far out from that point in time. To me, that's not even a temporal association. It's gone too far." Tr. at 277.

The following colloquy ensued with respondent's counsel asking:

Q. What is your basis for your conclusion that it's too far out?

A. My conclusion is based on if you're going to get a reaction,



whether it's a seizure of any type, to a DTaP immunization, which is the immunization that's being provided here, the data that we have available to us is that an event like that would occur within the first days after the immunization. It's not going to occur 13 days later.

*Id.*

When asked about the NCES, Dr. Wiznitzer replied:

What they [the NCES authors] did was statistical analyses and they said in what time periods is there an increased risk for either an encephalopathy or for seizures lasting more than half an hour, either condition resulting in an admission to a hospital, at what time period is there an increased risk after immunization with DTP? When they looked at it and basically at time periods of epochs they found the first seven days had an increased risk while the second seven days, which means days eight through 14, did not, which means that people looked at this, and asked that question and determined that your chances of being admitted to the hospital because either you had prolonged seizures or you had an encephalopathy were no different seven to 14 days after a fixed time period if that time was associated with an immunization or not because they had a control group that was present.

Tr. at 281.

Dr. Wiznitzer stated that Baby Doe's seizures never lasted 30 minutes or even close to 30 minutes. Therefore, you cannot take the results of the NCES analysis and apply them to her. Tr. at 282. When John and Jane Doe took Baby Doe to the hospital on April 14, 2001, they gave a history and said there had been two other prior events occurring in the week before. Tr. at 283. The prudent pediatric neurologist would then ask the parents if the child had any unusual behavior, a staring spell, fading out, unresponsiveness, and Dr. Wiznitzer assumes that the parents were asked these questions during the numerous visits to pediatric neurologists that they made. Tr. at 284. Baby Doe's parents had lots of opportunities to identify these events as occurring within two or three days after vaccination, instead of within a week of April 14<sup>th</sup>, and

they did not do so. *Id.*

Dr. Wiznitzer agreed with Dr. Johnston that Baby Doe did not have just a seizure disorder. Tr. at 285. Baby Doe had gastroesophageal reflux or GERD as well as seizures. Tr. at 285-86. The date on which Dr. Wiznitzer could clearly identify that Baby Doe was having a seizure is April 24, 2001, not April 14, 2001. Tr. at 287. This is based on the parents' history. *Id.* April 24th is the first time that they described Baby Doe as keeping her eyes open during an episode, indicating a seizure. During the first described event on April 14<sup>th</sup>, Dr. Wiznitzer assumes Baby Doe's eyes were closed because her parents said she looked limp and lifeless. Therefore, he would not assume that was descriptive of a seizure, but was descriptive of GERD. *Id.* If the eyes are open, it is a seizure. If the eyes are closed, it is GERD. *Id.*

In Dr. Wiznitzer's clinical experience, he does not know the cause of seizures in about half of the infants who are patients. Tr. at 288. Baby Doe had several types of events. She had events where she basically stopped, stared, and had some eye fluttering. Tr. at 299. She also had events where she shook all over. *Id.* When Jane Doe came to Dr. Johnston's office three days after the April 14<sup>th</sup> event, Jane Doe had three days to sit and basically think about whether there had been prior events she could report. Tr. at 302. There were plenty of doctors within that first month to six weeks after onset of these paroxysmal events to whom the parents could have reported episodes two to three days after vaccination, but they did not. *Id.* Jane Doe is hypervigilant and very concerned for Baby Doe's welfare. She would have reported unusual events. Tr. at 304. Dr. Johnston pointed out that Jane Doe is a very conscientious mother and reported events to him on a regular basis. Tr. at 305. On April 14, 2001, John and Jane Doe reported that Baby Doe choked, turned red, and became lifeless. Tr. at 308. To Dr. Wiznitzer,

that sounds like gastroesophageal reflux caused a brief apneic episode. Tr. at 308-09. Dr. Johnston said it happened, and we know that happens with other children. Tr. at 309.

Petitioners' counsel asked Dr. Wiznitzer whether the seven-day limit of the NCES study applied to Baby Doe since the NCES would not have included her in the study (she did not have acute encephalopathy or a seizure lasting more than 30 minutes):

MR. DANNENBERG: You start at day one and you can go farther than seven days because the NCES can't apply.

Tr. at 314.

Dr. Wiznitzer responded as follows:

THE WITNESS: No. In fact, I think that is an illogical thinking pattern. There [are] data about adverse events following immunization for DTaP. People have gathered data. I mean, they had to gather it when the immunizations were being developed. So we have a timeframe in which these kind[s] of events occur, which is in the first days afterwards. That data itself tells us that it doesn't occur three weeks later or four weeks later.

THE COURT: Or two weeks later?

THE WITNESS: Or two weeks later, or any time period of that type, even 13 days later. It doesn't occur like that.

Tr. at 315.

Dr. Wiznitzer stated that some of the epilepsy team at Boston Children's Hospital saw Baby Doe and they are very good and competent physicians. Tr. at 316. Usually people who have been trained in child neurology know how to take a history and are able to elicit the details. Tr. at 319. Dr. Wiznitzer, on questioning from petitioners' counsel, referred him to page 124, Table E.17 of the NCES, which shows the authors broke the data to within 72 hours of vaccination, 72 hours to seven days, and seven days to 14 days. They even looked at 14 to 21

days, noted in Table V.12. Tr. at 320. The purpose of the NCES study was to look at events occurring after vaccinations and decide what is the risk time period. Tr. at 321-22. In a later publication, the authors of the NCES said you cannot apply the conclusions of the NCES to any individual case. Tr. at 322. Pediatric neurologists have a series of set questions that they ask of parents with children who have seizure disorders. Tr. at 323. One of the key questions is timing of the seizure because that is an important piece of information. Tr. at 323-24.

### **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[.]"

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.

Petitioners must show not only that but for the acellular DPT vaccine, Baby Doe would not have had seizures, but also that the vaccine was a substantial factor in bringing about her seizures. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The focus of the second hearing in this case was solely on whether petitioners' experts viewed acellular DPT as the cause of Baby Doe's seizures whose onset was no earlier than 13 days after vaccination. This second hearing followed the first hearing whose sole focus was onset. Although the parents, in the context of litigation, filed affidavits and gave sworn testimony that Baby Doe's seizures began two or three days after vaccination, all the contemporaneous medical histories they gave to over 20 physicians was that onset was within a week of April 14, 2001, or April 8<sup>th</sup> at the earliest, which is 13 days after vaccination.

If Dr. Wiznitzer, respondent's expert at the second hearing, is correct, apparently Baby Doe's episode on April 14, 2001 was actually apnea due to her gastroesophageal reflux, and not a seizure, because her parents described her as limp and did not describe her as having fluttering of her eyes, as they did on April 24, 2001. If indeed April 24, 2001 was the day of Baby Doe's first seizure, the onset interval after acellular DPT was 29 days, not 13 days. For the purposes of this discussion, 13 or 29 days is irrelevant since both timeframes are too long after the vaccination to be show a medically appropriate timeframe for vaccine causation.

When asked if he would support causation in fact from the vaccine if the timeframe were 13 days, Dr. Jacobson said he could not. The undersigned has already held that 13 days is the onset interval and nothing that petitioners' experts stated dissuaded the undersigned from that holding. The petitioners' experts repeatedly stated they relied on the parents' affidavits and testimony in forming their opinions, and not the contemporaneous medical records or the likelihood that Jane Doe, as the hypervigilant, conscientious, anxious mother that she is, would call Dr. Johnston or bring in Baby Doe to see him if she were seeing any unusual behavior two or three days after vaccination. The fact that she never even mentioned to Dr. Johnston, whom

her husband called his wife's guru, on April 17, 2001, three days after the April 14, 2001 seminal event that Baby Doe had had unusual behavior just after the vaccination makes any occurrence so close to vaccination extremely unlikely.

Since Dr. Jacobson, petitioners' expert neurologist, could not offer an opinion on causation favorable to petitioners in light of an onset of 13 days, petitioners' case rested solely on Dr. Johnston, the treating pediatrician.

Dr. Johnston, admitting that he is not an expert in neurology and that he refers all his seizure patients to neurologists, opined that he did not see why there should be a seven-day timeframe for causation, although he admitted that the seven-day cutoff had been established in the medical community. As far as he was concerned, there should not be any end point, because he did not know of any. Dr. Johnston's opinion on an open-ended timeframe is not persuasive. A time interval that has no end is no time interval at all.

Petitioners have not satisfied the third Althen prong of proving a medically appropriate timeframe between vaccination and seizure onset 13 days later with testimony that: (1) there is no proof of causation after seven days (Dr. Jacobson) or (2) there is no end to the time interval no matter how much time passes (Dr. Johnston).

At this point, the undersigned should comment that both Dr. Jacobson and Dr. Johnston impressed the undersigned favorably. Dr. Jacobson, a pediatric neurologist, was frank in admitting that he could not help petitioners in their case if onset were after seven days. Dr. Johnston, Baby Doe's treating pediatrician, has tried his level best to give the most assistance medically to Baby Doe and her mother. His ruminations about whether or not there can ever be an end to the time interval that shows vaccine causation are just the thoughts of an intelligent,

questioning professional. They do not, however, come close to the specialized knowledge that Dr. Jacobson and Dr. Wiznitzer, both pediatric neurologists, have about seizures in infancy, and Dr. Johnston would be the first person to admit that. Jane Doe and Baby Doe are fortunate in Dr. Johnston's dedication to them.

Dr. Wiznitzer, respondent's expert pediatric neurologist, confirmed what petitioners' expert Dr. Jacobson, also a pediatric neurologist, stated. There is no proof of causation from a vaccine administered more than seven days before seizure onset. Moreover, Dr. Wiznitzer would not accept vaccine causation beyond a few days after vaccination, but that is not the issue here. Interestingly, Dr. Wiznitzer gave sound reasons for diagnosing Baby Doe with her first seizure on April 24, 2001, not April 14, 2001 (much less April 8, 2001) because only on April 24, 2001 was there a history that Baby Doe's eyes were fluttering. Dr. Johnston also opined that much of what Baby Doe was experiencing during this time period was a result of apneic episodes caused by GERD and that she had both GERD and seizures. Dr. Wiznitzer agreed with Dr. Johnston on the continuance of Baby Doe's GERD and apneic episodes (identifying the April 14, 2001 event as due to GERD), which is what made diagnosing Baby Doe with seizures so challenging for so many professionals, a number of whom Dr. Wiznitzer knew to be quite competent. It seems in this case that Baby Doe has received the best medical care from all concerned. The difficulty in her care stems not from the quality of the professionals treating her, but the confusion of similar symptoms of GERD/apnea and seizures.

Petitioners have failed to prove causation in fact because they have not proved there was a medically appropriate timeframe between vaccination and onset of seizures. In light of petitioners' failure to satisfy the third prong of Althen, the undersigned need not discuss whether

or not they satisfied the first two prongs of Althen. The undersigned notes, however, that petitioners' counsel's attempt to satisfy those two prongs was based solely on an onset within a week, and Dr. Jacobson's answers to petitioners' counsel's questions about a biologically plausible medical theory were also based on an onset within a week. There was no discussion, obviously, of a biologically plausible theory connecting the vaccination with the seizure 13 days later or a logical sequence of cause and effect with an onset of 13 days between vaccination and seizure since Dr. Jacobson said he could not offer an opinion in support of causation with that 13-day timeframe.

The undersigned understands the ordeal that petitioners went through, remembering their vivid testimony in the first hearing in Boston about how many times they called for an ambulance which frequently arrived after Baby Doe's brief episode was over. It was particularly frustrating to them not to have a diagnosis for weeks. The undersigned can understand how petitioners could conflate the timing of Baby Doe's seizures to an earlier period after the second acellular DPT because of the trauma of their experience. However, sympathy alone does not mean that the facts and the medical expert testimony in this case warrant a ruling in petitioners' favor.

## **CONCLUSION**

This petition is dismissed. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.<sup>10</sup>

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<sup>10</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.



**IT IS SO ORDERED.**

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DATED

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Laura D. Millman  
Special Master