

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 05-163V

Filed: September 26, 2007

Unpublished

JOHN and DEBORA DURDEN, as the
Legal Representatives of their minor son,
JONATHAN DURDEN,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

Respondent.

DTP or DT Vaccine,
Proof of Vaccination,
Causation,
Juvenile
Sclerodermatomyositis
Overlap Syndrome

Curtis R. Webb, Esq., Webb, Webb, & Guerry, Twin Falls, ID, for petitioner.
Robin L. Broderick, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

Vowell, Special Master:

On January 21, 2005, John and Debora Durden filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et*

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

seq.² [the “Vaccine Act” or “Program”], on behalf of their minor son, Jonathan Durden [“Jonathan”], alleging that Jonathan received either a DT or DTP³ vaccination on February 12, 2002, that caused him to develop “scleroderma, juvenile dermatomyositis overlap syndrome.” Petition, ¶ 3. Various medical records accompanied the petition; more were subsequently filed.⁴ On April 21, 2005, respondent filed a Vaccine Rule 4 report recommending that compensation be denied.

This case was reassigned to me on February 8, 2006. On March 15, 2006, I ordered petitioners to file the report of a medical expert by April 10, 2006. Based on petitioners’ requests for additional time, I extended the deadline, and on May 8, 2006, petitioners filed the report of Dr. Alan Levin, Dr. Levin’s curriculum vitae, and medical literature in support of his opinion. On June 16, 2006, respondent filed the report of Dr. Carlos Rosé and his curriculum vitae. Medical literature in support of Dr. Rosé’s opinion was filed on August 31, 2006. I conducted a causation hearing on October 19, 2006. Petitioners John and Debora Durden, Dr. Levin, and Dr. Rosé testified in person.

During the course of the hearing, an issue arose concerning the record of Jonathan’s immunizations, which required substantial post-hearing submissions of evidence. However, the documentary submissions failed to resolve questions regarding the vaccination alleged to be causal. To settle the outstanding issue as to Jonathan’s immunization, I heard the telephonic testimony of Jonathan’s primary care physician, Dr. Terry Cone, on March 23, 2007. The resolution of this issue is set forth in Part II A, below.

To be eligible for compensation under the Vaccine Act, a petitioner must either demonstrate a Vaccine Table⁵ injury, to which a statutory presumption of causation attaches, or prove by a preponderance of the evidence that a vaccine listed on the Vaccine Table caused or significantly aggravated an injury. *Althen v. Sec’y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Grant v. Sec’y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir.

² Hereinafter, for ease of citation, all “§” references to the Vaccine Injury Compensation Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2000 ed.).

³ “DT” refers to a pediatric strength diphtheria and tetanus vaccination. Neil M. Davis, MEDICAL ABBREVIATIONS [“MED. ABBREV.”] at 122 (2005). “DPT” refers to a diphtheria, tetanus, and pertussis vaccination. *Id.* at 120. For reasons set forth, *infra*, I conclude that Jonathan received a DT vaccination, one without the pertussis component.

⁴ I required respondent to subpoena the medical records of Jonathan’s primary care provider, Dr. Terry Cone. The subpoena generated some recent medical records not previously supplied to the court, as well as some of Dr. Cone’s records obtained from other sources. The records filed in response to the subpoena were filed as Respondent’s Exhibit [“Res. Ex.”] F; more complete records were subsequently obtained and filed as Res. Ex. G. The concerns that generated the subpoena are discussed, *infra*.

⁵ A “Table” injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified.

1992). The petitioners in this case do not contend that Jonathan suffered a “Table” injury. Therefore, in order to prevail, they must demonstrate 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*, 418 F.3d at 1278. See also, *Hines v. Sec’y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

After considering the record as a whole,⁶ including the testimony of petitioners, Dr. Levin, Dr. Rosé, and Dr. Cone, I find that Jonathan received a DT vaccination on February 12, 2002, and that he developed symptoms that led to his diagnosis with juvenile sclerodermatomyositis overlap syndrome. However, I hold that petitioners failed to establish by preponderant evidence that the DT vaccination caused this illness. Therefore, I deny the petition for compensation.

I. Jonathan’s Medical History

Jonathan was born at home on December 23, 1993, the sixth of seven children. Petitioners’ Exhibit [“Pet. Ex.”] 3, pp. 1-2. The labor and delivery were uncomplicated. *Id.* The first medical record from a treating physician after Jonathan’s birth is dated August 1, 1994, when Jonathan was 7 months old, and documented that Jonathan had a probable viral upper respiratory infection [“URI”]. Pet. Ex. 9, p. 118; Res. Ex. G, p. 17. The medical history in this record referenced an earlier hospitalization for “RSV,” a common abbreviation for respiratory syncytial virus.⁷ No records of treatment for this RSV illness were filed.

The treating physician for the August 1, 1994 visit was Dr. Terry Cone, but the record of this visit was not contained in the records from Dr. Cone’s office (Pet. Ex. 5) filed with the petition.⁸ This record was apparently furnished by Dr. Cone’s office to the National Institutes of Health [“NIH”] in July 2003, and was filed with the NIH records as

⁶ See § 300aa–13(a): “Compensation shall be awarded...if the special master or court finds on the record as a whole...” See also, § 300aa–13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation).

⁷ MED. ABBREV. at 316. RSV causes respiratory diseases, including bronchiolitis and pneumonia, that can be particularly severe in infants. DORLAND’S ILLUSTRATED MEDICAL DICTIONARY [“DORLAND’S”] at 2047 (30th ed. 2003). Mrs. Durden testified that Jonathan was not hospitalized for his RSV infection. Transcript [“Tr.”] at 10.

⁸ Petitioner’s Exhibit 5 is specifically identified as containing only the records from February 2, 2000, through March 11, 2004. The exhibit does not identify how these records were obtained from Dr. Cone, nor why Dr. Cone’s earlier records were not filed with the petition.

part of Pet. Ex. 9.

Chronologically, the next records are from Harrison Family Practice Clinic, in Harrison, Arkansas, where Jonathan was treated twice for otitis media and respiratory complaints in December 1995 and for the same conditions in February 1996. Pet. Ex. 4, p. 1.

Jonathan began seeing Dr. Cone again in May 1996, when he was treated for otitis media. Res. Ex. G, p. 17. On July 10, 1996, there is a handwritten notation of “silvadene cream,” but there is no indication of the underlying condition in the record.⁹

On March 31, 1997, Jonathan was treated for an accidental foot injury. Pet. Ex. 9, p. 117; Res. Ex. G, p. 18. There were two follow-up visits. Pet. Ex. 9, p. 116; Res. Ex. G, p. 15.

Between July 1997 and June 2005, Jonathan visited Dr. Cone’s office many times for warts on his fingers, toes, arm, and knees, which were removed with cautery or cryosurgery. See, e.g., Pet. Ex. 9, pp. 109, 113-115, 119-122; Res. Ex. G, pp. 3, 7; Res. Ex. F, p. 17.

In December 1999, Jonathan was prescribed hydrocortisone cream for psoriatic scalp.¹⁰ Pet. Ex. 9, p. 114; Res. Ex. G, p. 13.

Jonathan’s immunization history began with “pediatric DT and MMR” immunizations¹¹ on October 11, 2000, when he was nearly seven years of age. The medical history indicated that Jonathan had cut his eyebrow on a rusty spring, and that he had never had any immunizations.¹² Pet. Ex. 9, p. 120; Res. Ex. G, p. 19. Jonathan’s medical records reflect that he received another DT vaccination and an IPV vaccination¹³ on November 14, 2000. It does not appear that Jonathan was seen for any reason, other than the vaccination, on that date. He was treated for warts and received an IPV on Jan 23, 2001. Pet. Ex. 9, p. 119; Res. Ex. G, p. 20.

⁹ Silvadene cream is an antimicrobial agent. PHYSICIAN’S DESK REFERENCE [“PDR”] at 1716 (61st ed. 2007). It is generally prescribed for burns. See http://www.pdrhealth.com/drug_info/rxdrugprofiles/drugs/sil1404.shtml (last visited September 14, 2007).

¹⁰ Psoriasis is a common, often chronic, dermatosis. DORLAND’S at 1538.

¹¹ “MMR” is an abbreviation for the measles, mumps, and rubella vaccination.

¹² Mrs. Durden testified that her older children had received their immunizations on time, but that after a discussion with a medical friend about post-vaccination problems, the friend recommended that Jonathan’s vaccinations be postponed. None of her children, however, had previously reacted badly to any vaccination. Tr. at 38-39, 54-56.

¹³ An “IPV” is a polio vaccination.

On February 13, 2001, Jonathan was seen for a three-day illness involving fever, sore throat, cough, and vomiting. He was assessed as suffering from a viral syndrome. Pet. Ex. 9, p. 122; Res. Ex. G, p. 11.

Jonathan's shot record indicates that he received a DT-type vaccination¹⁴ and another IPV vaccination on July 9, 2001 (Pet. Ex. 5, p. 69), but the medical records do not contain any other notation regarding this vaccination.

Although the records from Dr. Cone's office provided to NIH reflect the administration of an influenza vaccination on October 7, 2001, and DT and IPV vaccinations on October 30, 2001, these records appear to be those of Jonathan's brother, Nathanael Durden. Nathanael's name appears at the top of the page. Pet. Ex. 9, p. 112. These three immunizations were transcribed in the signature section of the copy of the Certificate of Immunization found at Pet. Ex. 9, p. 107, in the NIH records, rather than in the immunization section. The fax machine header at the top of the Certificate of Immunization indicates that it was faxed by Dr. Cone's office to NIH on July 21, 2003. Another copy of this form, which does not contain the immunizations in the signature section, was faxed from Dr. Cone's office to NIH on July 30, 2003. Pet. Ex. 9, p. 123. Thus, I conclude that the entries in the signature section of Pet. Ex. 9, p. 107, were erroneously added by someone at NIH, based on the mistaken belief that the record at Pet. Ex. 9, p. 112, pertained to Jonathan. In the absence of any other evidence suggesting that Jonathan also received immunizations on October 7 and October 30, 2001, I find that Jonathan did not receive these immunizations.

The immunization alleged to be causal in this case was purportedly administered on February 12, 2002. The unsigned Certificate of Immunization at Pet. Ex. 5, p. 69, indicates that Jonathan received another DT-type vaccination. There is no medical record entry reflecting that Jonathan was seen at Dr. Cone's office on that date.

The next medical record is also from Dr. Cone's office and is dated May 6, 2002, approximately eleven and one half weeks after the immunization. Jonathan reportedly had a rash on his hands and feet for the prior three to four months, with dryness, skin peeling, and painful fissuring. This placed onset of these symptoms either earlier than, or around the time of, his last vaccination. His father had noted possible Raynaud's

¹⁴ Georgia Form 3231 (Certificate of Immunization) lists DTP, DT, DTaP, and Td vaccinations in the same category. The unsigned copy of the Certificate of Immunization found at Pet. Ex. 5 p. 69, does not indicate which of these four vaccinations Jonathan received. He most likely received a DT vaccination at this time, as the medical records indicate that he had previously received a DT vaccination. See also, Res. Ex. K, p. 1 (indicating that Jonathan received a DT vaccination). Unfortunately, Dr. Cone's office staff failed to record the manufacturer and lot number of Jonathan's vaccines, making it difficult to determine which vaccines he received. See Pet. Ex. 8, p. 36; Pet. Ex. 17, p. 3. However, the Vaccine Table covers each vaccine on Jonathan's immunization record.

phenomenon¹⁵ as well, observing pallor in Jonathan's hands and feet followed by a deep purplish discoloration. Jonathan reported aching and difficulty in flexing his fingers. Doctor Cone observed a thin, shiny appearance on the skin of his fingers, with some skin cracking and healing ulcers. His feet were not as bad as his hands; his ears appeared to be normal. Jonathan reported no gastrointestinal symptoms. Doctor Cone thought Jonathan probably had eczema,¹⁶ but included scleroderma¹⁷ in his differential diagnosis. He prescribed Temovate cream¹⁸ and asked to be notified of the results over the next few weeks. Jonathan returned two days later with only mild improvement, and complaints of fatigue and difficulty swallowing. After Dr. Cone mentioned that there was a possibility that Jonathan might have scleroderma, Mrs. Durden indicated that she had been researching scleroderma and had concerns that Jonathan might have it. Doctor Cone planned to talk with a rheumatologist about Jonathan's symptoms.

Over the next two to three weeks, Jonathan had several serologic tests. One of the tests showed a high antinuclear antibody test¹⁹ (1:2560) ["ANA"] with a nucleolar pattern, which is often associated with scleroderma, polymyositis, or scleroderma overlap syndrome. Res. Ex. G, p. 56.

Jonathan saw Dr. Jaime Vargas, a rheumatologist, for the first time on June 3, 2002. Mr. and Mrs. Durden reported a three month history of Raynaud's phenomenon involving Jonathan's hands and feet, with later development of some joint problems in the hands, elbows, knees, and feet. This would place onset two to three weeks after Jonathan's last vaccination. Jonathan had experienced "a good bit of pain" in his abdomen and chest for about 15 minutes the day before one of his May 2002 visits to Dr. Cone. Jonathan denied having any alopecia, photosensitivity, inflammatory eye problems, difficulty swallowing,²⁰ recent strep throat, shortness of breath, pneumonia,

¹⁵ Raynaud's phenomenon is ischemia of the fingers and toes, characterized by severe pallor and pain, which may be brought on by cold. DORLAND'S at 1420.

¹⁶ Eczema is a pruritic dermatitis characterized by oozing, crusting, and scaling of the dermis. It may include pigmentation changes. DORLAND'S at 588.

¹⁷ Scleroderma is a chronic hardening of the skin. The disease may be localized or a may be a systemic connective tissue disorder. In the systemic form, it may cause fibrotic degenerative changes in many organ systems. DORLAND'S at 1668.

¹⁸ Temovate is the trademark for clobetasol propionate. DORLAND'S at 1863. It is used to treat various forms of dermatitis. PDR at 2668.

¹⁹ ANA testing is used to diagnose systemic lupus erythematosus and other diseases. Kathleen D. Pagona & Timothy J. Pagona, MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS ["MOSBY'S LABS"] at 91 (3d. ed. 2006).

²⁰ This contrasts with the difficulty in swallowing reported by Mrs. Durden to Dr. Cone on May 8, 2002. Pet. Ex. 9, p. 125.

meningitis, constipation, diarrhea, or renal disease. On examination, Jonathan had no facial telangiectasias²¹ or oral ulcers. The examination was remarkable for bilateral synovitis of several finger joints and his inability to make a complete fist. Doctor Vivas found no finger ulcers or sclerodactylia. He noted synovial proliferation in both of Jonathan's elbows, increased temperature in his knees, and an effusion in the infrapatellar bursae. He had synovitis in many of his toe joints. Pet. Ex. 6, pp. 1-2.

Doctor Vivas indicated that his clinical impression was juvenile rheumatoid arthritis ["JRA"] with Raynaud's phenomenon. His differential diagnosis included "an overlap syndrome with systemic sclerosis." He ordered more blood tests, a bone scan, x-rays, and an eye examination,²² and asked Jonathan to return in three weeks. *Id.*, p. 2.

Jonathan saw Dr. Vivas again on June 26, 2002, and reported feeling better, but complained of pain in his right shoulder and occasionally in his hands and both knees. Doctor Vivas reviewed the test results, noting that the bone scan showed no activity in Jonathan's hands, but some in the knees, ankles, and shoulders. Based on the minimal findings, he could not determine if the test results were indicative of a disease process. Jonathan's serologic test results were negative for both lupus and anticardiolipin antibodies. On examination, Jonathan still demonstrated decreased grip strength and his hands looked like those of an adult with rheumatoid arthritis. His skin was normal, showing no signs of sclerodactylia or telangiectasias. Doctor Vivas' assessment was that Jonathan had either JRA, early systemic sclerosis, or overlap syndrome. However, he noted that Jonathan's presentation was "atypical," and indicated that he would likely refer Jonathan to Dr. Larry Vogler for a second opinion. Pet. Ex. 6, p. 3.

Doctor Vogler saw Jonathan with his parents on August 5, 2002. By history, Jonathan was reported to have been well until April 2002, when he began to have dryness, peeling, and cracking of his palms, as well as bleeding in his fingertips. This history placed onset of Jonathan's symptoms six to ten weeks after his last vaccination. In May, during a family trip to Florida, Jonathan was more sensitive to sun than previously and noticeably more sensitive than other family members. He developed pain, swelling, and tenderness in his hands, which were accompanied by an inability to fully extend his fingers. He was fatigued.

Steroid cream improved the swelling and redness significantly. Laboratory findings included a positive ANA and negative findings for anti-DNA, Sjorgren, Smith, and scleroderma antibodies. Oral steroids improved Jonathan's pain, but Dr. Vogler

²¹ Telangiectasias are permanently dilated small blood vessels in the skin or mucus membranes, creating small focal red lesions. DORLAND'S at 1861.

²² Jonathan's eye examination on June 24, 2002, was normal. Pet. Ex. 7, pp. 1-2.

noted that Jonathan still had marked restriction in his ability to fully extend his fingers and still had thick, dry skin over his hands. Doctor Vogler noted that Jonathan had a serious bout of RSV as an infant, as well as a serious nasopharyngeal staph infection. Pet. Ex. 8, pp. 1-2.

Jonathan's examination disclosed redness over several joints, thickened skin on his palms and soles, some ulcerations on fingers, bilateral finger swelling and contractures, and mild right knee pain on flexion. There was no synovial thickening in his lower extremities. Doctor Vogler observed possible Gottron papules over Jonathan's fingers²³ and a rash in a pattern characteristic of dermatomyositis. His findings were suggestive of "an overlap syndrome with Raynaud's phenomenon." Jonathan's one episode of dysphagia suggested there might be some esophageal dysfunction, which might be a partial manifestation of CREST syndrome.²⁴ He ordered a number of tests, including a barium swallow, a biopsy of Jonathan's right hand, an electrocardiogram, and blood tests. *Id.*, pp. 3-5.

The punch biopsy showed acanthosis with hyperkeratosis,²⁵ parakeratosis,²⁶ and focal exocytosis²⁷ in the epidermal layer, normal findings in the dermal layer, and areas of mild to moderate infiltration of lymphocytes and neutrophils.²⁸ There was no evidence of scleroderma. Pet. Ex. 5, p. 38. On September 12, 2002, after reviewing the test results, Dr. Vogler diagnosed Jonathan as suffering from overlap syndrome. Pet. Ex. 8, pp. 10-11. He prescribed methotrexate and directed tapering Jonathan off prednisone.

Mrs. Durden reported Dr. Vogler's findings to Dr. Cone on September 16, 2002, characterizing the diagnosis as "a combination of systemic sclerosis and Dermatomyositis." Res. Ex. G, p. 10. Two days later, the Durdens indicated to Dr. Cone that they intended to follow Dr. Vogler's treatment plan, but that they also intended to take Jonathan to California for an alternative herbal treatment. *Id.*, p. 9.

²³ Gottron papules are flat-topped, solid elevations of skin on the dorsal aspect of the finger joints. They are considered pathognomonic of dermatomyositis. DORLAND'S at 1360.

²⁴ CREST syndrome is a constellation of symptoms representing calcinosis, Raynaud's disease, esophageal dysmotility, sclerodactyly, and telangiectasia. MED. ABBREV. at 100.

²⁵ Acanthosis is a diffuse hyperplasia (abnormal increase in the number of cells). DORLAND'S at 10, 886.

²⁶ Parakeratosis is the persistence of the nuclei of certain skin cells into the horny layer of the skin. *Id.* at 1363.

²⁷ Exocytosis is the aggregation of leukocytes in the epidermal skin layer as a part of an inflammatory response. *Id.* at 655.

²⁸ Neutrophils and lymphocytes are types of white blood cells involved in fighting pathogens.

No records from any California treatment were filed.

Over the next ten months, both Dr. Cone and Dr. Vogler continued to treat Jonathan's symptoms of joint pain, rash, and abdominal pain. Pet. Ex. 5, pp. 4-5; Pet. Ex. 8, pp. 14-26. Doctor Vogler recorded his primary diagnoses as overlap syndrome, juvenile dermatomyositis, and scleroderma. Pet. Ex. 8, pp. 16-17. Doctor Cone's office administered an influenza vaccination and treated Jonathan again for warts during this time frame. Pet. Ex. 5, pp. 4, 6.

On June 23, 2003, Dr. Cone recorded the first connection between Jonathan's "DPT" vaccination and his disease. After a heading of "S"²⁹ on Pet. Ex. 5, p. 6, Dr. Cone noted:

Jonathan's mom states that in thinking carefully about the history of his disease, it is her recollection that he got a DPT shot on the 12 of February 2002. Two days late (sic) on the 14 (sic) he came down with fever and chills, sore throat, and prostration that was marked and lasted a week. She called to notify the office and was informed a lot of flu was going around and to treat it symptomatically and notify if it got worse. It was a number of weeks to a month after that he began having symptoms that have now been diagnosed as SS adn (sic) polymyositis. She has talked to a physician who has taken interest in autoimmune diseases and in Jonathan's case would like to know the lot number of the DPT and is concerned he may have developed diptheria (sic). I have informed her no organism is administered in that immunization but rather toxoid is the diptheria (sic) portion of it.

In late June or early July 2003, Mrs. Durden contacted NIH about enrolling Jonathan in a study. Petitioner's Exhibit 8, pp. 29-30, contains an email message from Dr. Lisa Rider, the senior clinical investigator with the Environmental Autoimmunity Group at NIH, discussing the studies and the medical statements required for enrollment.

Jonathan was seen by an allergist at Emory Children's Center on August 6, 2003. The primary diagnosis recorded was overlap syndrome; the secondary was "possible hyper immune response to ? vaccine ? virus." The history indicated that Jonathan received a DPT or DT vaccination in February 2002, and became very ill on the second day after the vaccination, with fever, nausea, and sore throat. The illness lasted for several weeks. Subsequently, he developed Raynaud's sign and sores on

²⁹ "S" is a common medical abbreviation for "subjective findings." MED. ABBREV. at 318.

his fingers in April 2002³⁰ and sun sensitivity in May 2002. Mrs. Durden's concern about a relationship between the vaccine and the onset of Jonathan's symptoms was noted. Pet. Ex. 8, pp. 34-37. Jonathan was tested for antibodies to diphtheria, pertussis, Epstein-Barr virus ["EBV"], and immunoglobulin levels. Other than a slightly elevated white blood cell count, the laboratory tests were all normal. The EBV test was negative. Pet Ex. 9, pp. 84-86.

Jonathan saw Dr. Cone for a viral syndrome on August 11, 2003, and for an influenza vaccination on October 29, 2003. Pet. Ex. 5, pp. 6-8.

He was evaluated at NIH in December 2003, where he was seen by several specialists. He was diagnosed with juvenile dermatomyositis overlap and enrolled in a twin-sibling study with his brother, Nathanael. Jonathan was classified as having scleroderma for purposes of the study. He was also diagnosed with iron deficiency, osteopenia, gastroesophageal reflux, and ichthyosis with keratosis pilaris. Pet. Ex. 8, pp. 2-11. The history of his illness indicated that after receiving a DPT booster in February 2002, he did not feel well that evening. The next day, he developed a 103-104 degree fever, sore throat, lethargy, and malaise, and subsequently missed a week of school.³¹ Raynaud's sign and finger ulcers developed in March and April 2002. *Id.*, p. 7.

The last medical records filed are dated August 2006. The more recent records indicate that Jonathan continues to suffer from the overlap syndrome and normal childhood illnesses. See *generally*, Res. Ex. F, pp. 9-20.

II. Issues Regarding Jonathan's Medical History.

Two issues must be resolved before considering the expert testimony regarding causation. The first issue is whether Jonathan actually received a DT-type vaccination on February 12, 2002. The second issue involves the nature of Jonathan's symptoms between the February 12, 2002 vaccination and the manifestation of his disease. For the reasons indicated below, I find adequate evidence that Jonathan had the vaccination alleged to be causal, but I find inadequate evidence of a severe febrile illness in close temporal relationship to the vaccination. Shortly after the vaccination in either late February or early March of 2002, I conclude that Jonathan developed the initial symptoms of his overlap syndrome.

³⁰ This onset date contrasts with Mr. Durden's testimony that Jonathan began displaying Raynaud's sign and hand problems in March 2002. Tr. at 69-71.

³¹ Jonathan was home schooled. Mrs. Durden testified that she kept attendance records and that Jonathan missed about a week of school after his vaccination. She no longer had those records. Tr. at 57-59. She could not verify that Jonathan was reported as absent during that week on the records she sent to the county. *Id.* at 59-60.

A. Did Jonathan Receive a DT-type Vaccination on February 12, 2002?

Jonathan's Georgia Certificate of Immunization, initially filed as Pet. Ex. 5, p. 69, did not identify the type of vaccination Jonathan received on February 12, 2002; it merely recorded that date under the row for DTP-type immunizations. No lot number or manufacturer data was recorded, and the form did not indicate who made the entries or maintained the Certificate of Immunization.³² Jonathan's medical records did not reflect that an immunization was administered that day, unlike entries for almost all of Jonathan's other immunizations. Because Jonathan had not received immunizations on a regular schedule (much less under the typical childhood immunization schedule), there was no "due date" established for an immunization on February 12, 2002. Typically, DPT-type immunizations are administered at two, four, and six months of age, followed by a 4th vaccination at 15-18 months of age, and a 5th between four to six years of age. Between ages 11-18 (preferably at ages 11 or 12), an adolescent preparation of the vaccine known as Tdap, should be administered, and thereafter the vaccinee should receive a Td vaccination every 10 years.³³ Jonathan received his first DT vaccination on October 11, 2000, the second vaccination a month later (November 14, 2000), the third vaccination eight months after the second (July 9, 2001), and his last DT vaccination on February 12, 2002, seven months after the third. The medical records contain no explanation for this "schedule" and no indication that Jonathan was "due" for a vaccination on the date reflected in the records.

The issue is further complicated by two of the three documents that comprise Pet. Ex. 17. Page 1 is an immunization schedule for Jonathan reflecting that Jonathan received DT-type vaccinations on October 11, 2000, November 14, 2000, and July 9, 2001. The first three vaccinations track those on the Georgia Certificate of Immunization at page 2 of Pet. Ex. 17. However, the Certificate of Immunization reflects a fourth vaccination not present on page 1 of the exhibit, the vaccination in question in this case. In a letter from Dr. Cone to Mrs. Durden dated September 16, 2003, Dr. Cone apologized for the fact that Jonathan's records do not reflect the required information regarding his immunizations, presumably referring to the specific type of vaccine, the lot number, and the manufacturer's data. Pet. Ex. 17, p. 3. Complicating the situation further, all copies of the Georgia Certificate of Immunization originally furnished as exhibits (Pet. Ex. 5, p. 69, Pet. Ex. 9, pp. 107, 123) and Pet. Ex. 17, p. 2, are unsigned and undated. In contrast, Pet. Ex. 19, another copy of the Georgia Certificate of Immunization pertaining to Jonathan, is signed by Dr. Terry Cone

³² The medical records from Dr. Cone's office (Res. Exs. G and H) obtained by subpoena after the hearing did not contain a copy of the Georgia Certificate of Immunization. At the hearing, Mrs. Durden indicated that she had obtained the original form from Dr. Cone. Tr. at 16-17. Res. Ex. K, p. 3, indicates that Jonathan had a DT vaccination on February 12, 2002.

³³ The recommended childhood immunization schedule may be found at www.cdc.gov/vaccines/recs/schedules/downloads/child/2007/child-schedule-bw-print.pdf at pp. 1-2 (last visited September 17, 2007).

and dated September 17, 2006. Petitioner's Exhibit 19 was first produced at the hearing on October 19, 2006. Mrs. Durden testified that Dr. Cone dropped the original signed immunization form at her home when he came by to drop off a present for her grandchild.³⁴ Tr. at 17.

Efforts to obtain billing or insurance records to substantiate that Jonathan received a vaccination on February 12, 2002, were uniformly unsuccessful. The Durden family did not have health insurance during 2002. In telephonic testimony taken on March 23, 2007, Dr. Cone³⁵ stated that he had no recollection of signing Pet. Ex. 19, the Georgia Certificate of Immunization (Second Transcript ["2d Tr."] at 5), no knowledge of how the vaccinations on the form were recorded (2d Tr. at 6), and that, absent a medical chart entry indicating receipt of a vaccine, the Certificate entries might be based on information from the patient. 2d Tr. at 8. He was aware that his staff had failed to record lot numbers of immunizations, but was unaware that his staff had failed to chart an immunization in the health records. 2d Tr. at 7-9; Pet. Ex. 17, p.3. Doctor Cone also testified that he had not required the Durden family to pay for medical treatment during the entirety of 2002 because he knew them, the significant problems facing the family, and that Mr. Durden was a minister. 2d Tr. at 9-11; Pet. Ex. 17, p.3. He did not bill any Georgia state fund for the immunizations he supplied to the Durden family. 2d Tr. at 11. He also testified that there might be circumstances in which he would take a family's word about receipt of a vaccination, even if he or his staff was unable to confirm receipt of that vaccination. 2d Tr. at 18-20.

Section 300aa-11(c)(1)(A) of the Vaccine Act requires supporting documentation demonstrating that a vaccine on the Vaccine Injury Table was actually administered. However, a vaccine record or a chart entry reflecting administration of a vaccination is not required. See *Centmehaiey v. Sec'y, HHS*, 32 Fed. Cl. 612, 621 (1995). While the evidence is not overwhelming, I conclude that there is preponderant evidence that Jonathan received a vaccination on February 12, 2002. On two different dates in July 2003, the vaccination certificate was in the possession of Dr. Cone's office staff, as indicated by the fax headers on Pet. Ex. 9, pp. 107 and 123. This substantiates Mrs. Durden's testimony that she obtained Pet. Ex. 19 from Dr. Cone. While there is ample evidence that the record-keeping practices at Dr. Cone's office were not exemplary, and the absence of a chart entry indicating administration of the vaccination is troubling, Jonathan received at least one other set of vaccinations—ones not at issue in this case—that were not entered into his medical chart. See Pet. Ex. 5, p. 69 and IPV

³⁴ The relationship between Dr. Cone and the Durden family was closer than most doctor-patient relationships. At least one of Jonathan's older sisters, Carla, worked for Dr. Cone for two or three years, which included the time period when the final vaccination was recorded and when Jonathan first saw Dr. Cone with symptoms of his current illness. Tr. at 78-79, 83. Mr. Durden described Dr. Cone as a friend. Tr. 72.

³⁵ Doctor Cone's name is misspelled as "Cohen" throughout the entire transcript of this telephonic testimony.

vaccinations on July 9, 2001). Several subsequent records reference the vaccination; these records were all made over a year before the Durdens filed this petition on Jonathan's behalf.

B. The Nature of Jonathan's Symptoms After the February 12, 2002 Vaccination.

The medical records and testimony regarding what transpired after Jonathan's February 2002 vaccination are discordant. Conflicts such as these between contemporaneous medical records and subsequent statements, testimony, and medical histories are common in vaccine cases.

Two general legal principles guide the resolution of conflicts between contemporaneous records and later-adduced evidence. The first is that the absence of a reference to specific symptoms in a medical record does not conclusively establish the absence of symptoms during that time frame. *See, e.g., Murphy v. Sec'y, HHS*, 23 Cl. Ct. 726, 733 (1991) *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 506 U.S. 974 (1992) (“[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.”)

The second principle addresses the degree of reliance commonly accorded to contemporaneous records. Special masters frequently accord more weight to contemporaneously recorded medical symptoms than those recounted in later medical histories, affidavits, or trial testimony. “It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.” *Murphy*, 23 Cl. Ct. at 733 (1991). *See also, Cucuras v. Sec'y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993). Inconsistencies between testimony and contemporaneous records may be overcome by “clear, cogent, and consistent testimony” explaining the discrepancies. *Stevens v. Sec'y, HHS*, No. 90-221V, 1990 WL 608693 at *3 (Fed. Cl. Spec. Mstr., Dec. 21, 1990). With these legal principles in mind, I turn to the specific area of conflict.

Mrs. Durden testified that Jonathan became ill the afternoon of his February 12, 2002 vaccination, experiencing a low grade fever and malaise. Tr. at 18. When he awoke during the night, he complained that he was sick, hot, lethargic, nauseated, and had a sore throat. After a fretful night of sleep, his condition appeared to worsen the next day. That day his temperature was 103-04 degrees. Tr. at 18-19.

Mrs. Durden testified that she called Dr. Cone's office to say that Jonathan was running a temperature and was really sick. She was told by an unidentified staff member that the “flu” was going around and that she should not to bring Jonathan in to the office. In accordance with the instructions she received from Dr. Cone's office staff, she gave him Tylenol and kept him home. Tr. at 19. Mrs. Durden described Jonathan

as the sickest she had seen of any of her children, and that he was ill for about a week, followed by another week during which he remained weak. Tr. at 19-20. None of the other family members came down with any illness after Jonathan. *Id.* Jonathan missed a week of home schooling during his illness. Tr. at 20.

Sometime around mid-March of 2002, Mr. Durden noticed discoloration in Jonathan's hands and feet after a shower. Also, Jonathan, his father, and his brothers liked to ride bicycles, and Jonathan began having trouble gripping the handles and applying the hand brakes. Tr. at 20-21, 69-71. Jonathan's hands became chapped and his parents applied various lotions, including those suggested by the doctor's office during a telephone call, to reduce the chapping and sores he developed. *Id.* at 22, 68-69. During a beach trip to Florida, Jonathan was very lethargic.³⁶ *Id.* at 23, 73. After several weeks without improvement of his symptoms, Mr. and Mrs. Durden took Jonathan to see Dr. Cone during the first week of May 2002. *Id.* at 22-23. Mr. Durden recalled discussing Jonathan's symptoms with Dr. Cone before the office visit in May, and testified that he had mentioned Raynaud's phenomenon to Dr. Cone during their conversation. Tr. at 72, 79-81. According to Mr. Durden, Dr. Cone discounted the likelihood of Raynaud's phenomenon. *Id.*

Mrs. Durden could not recall discussing the proximity of Jonathan's symptoms to his immunization with Dr. Cone at the May 2002 visit. She mentioned it to Dr. Cone over a year later, because, after researching the nature of Jonathan's illness, she sought an explanation for his condition. Tr. at 24-25. She testified that she identified Jonathan as becoming ill two days after the vaccination because that was Valentine's Day, and Jonathan was too ill to participate in an annual family Valentine's Day scavenger hunt. It was the first and only time one of her children was too ill to participate in the scavenger hunt on his own. Tr. at 33-34. Upon being shown Pet. Ex. 5, p. 2 (Dr. Cone's records), Mrs. Durden recalled taking Jonathan to the doctor's office on February 13, 2001, with symptoms similar to those she described Jonathan as experiencing on February 13-14, 2002, but she was firm that Jonathan missed participating in the scavenger hunt in 2002, not 2001. Mr. Durden also testified that Jonathan missed the 2002 Valentine's Day event. Tr. at 76-77.

Mrs. Durden was unable to account for the lack of entries in Jonathan's records regarding her telephone call to Dr. Cone's office after the vaccination and the call about lotions for dry skin. Tr. at 37, 40-41. Doctor Cone testified that in 2002, it was his practice to document all telephone calls from patients. 2d Tr. at 23. Mrs. Durden explained the discrepancy between her testimony that Jonathan became ill the afternoon of the vaccination and the June 2003 reports to Dr. Cone and Dr. Vivas that Jonathan became ill two days after the vaccination as a difference in the degree of

³⁶ Mrs. Durden's testimony suggested that the beach trip happened before the first visit to Dr. Cone in early May 2002; Mr. Durden's testimony was that the trip was in mid-May, the weekend before his daughter's wedding. Tr. at 22-23, 73-74. I adopt Mr. Durden's dates for the beach trip.

illness he experienced. Tr. at 46-47. She could not explain why Dr. Vogler would record information about Jonathan's RSV and staph infections as an infant, but fail to record the Durden's mention of the severe illness that Jonathan experienced soon after the vaccination. Tr. at 48-49.

Considering all the evidence, I find that the May 6, 2002 medical record is the most reliable account of the onset of Jonathan's overlap syndrome. Doctor Cone recorded an onset of symptoms of chapping, peeling, and fissuring skin on Jonathan's hands and feet about three to four months prior to that appointment, placing onset of Jonathan's symptoms sometime between January and March 2002. The history taken by Dr. Vivas at the June 2002 appointment placed the onset of the Raynaud's phenomenon in March 2002, about three months prior to the appointment. The history provided to Dr. Vogler in August 2002 reflects an April 2002 onset of Jonathan's symptoms.

It is striking that none of the contemporaneous medical records reflect Jonathan having a severe illness around Valentine's Day, at approximately the same time the symptoms of his overlap syndrome began appearing. If Jonathan was truly more ill than any of Mrs. Durden's other six children had ever been, running a high fever, and experiencing the degree of malaise and fatigue she described, it is highly probable that she or her husband would have reported it to one of these physicians. Although one doctor might fail to record such symptoms, it is extremely unlikely that all three would have failed to record Mr. or Mrs. Durden's account of this illness. The concerns that Mrs. Durden had about vaccine reactions, which caused her to delay Jonathan's vaccinations until an injury placed him at risk of tetanus, would make her even more likely than others to attribute an illness immediately following a vaccination to the vaccine.

Although Dr. Cone's immunization record-keeping may have been deficient, Jonathan's records reflect several telephone calls concerning other illnesses or problems. Therefore, I find it unlikely that a telephone call regarding Jonathan's severe flu-like symptoms and a call regarding hand cream recommendations would both be unrecorded in the mid-February to early May 2002 records.

The medical record concerning a flu-like illness in February 2001, almost exactly one year before the vaccination in question, is the final piece of evidence that convinces me that both Mr. and Mrs. Durden were mistaken in their assertions that Jonathan became severely ill after the February 12, 2002 vaccination. The reports in June 2003 that Jonathan was severely ill in February 2002 reflect a conflation of his February 2001 illness, rather than an unreported and unrecorded illness in February 2002. Mrs. Durden took Jonathan to the doctor for a viral-type illness in February 2001, with symptoms virtually identical to those she identified as having occurred in February 2002. A mother with seven children would see a significant number of children's illnesses; a description that Jonathan was sicker than any child she had ever seen is inconsistent with merely a telephone call. It is consistent with a doctor's visit.

Based on the contemporaneous records and the Durden's testimony, I conclude that Jonathan's first symptoms of dry, cracked, fissured, and ulcerated skin on his hands, feet, and ears occurred in late February or early March of 2002. His father observed Raynaud's phenomenon at approximately the same time. Further, I find that Jonathan began experiencing hand pain and difficulty in closing his hands by March 2002. His fatigue began around the same time frame and had become more obvious by the time of the family vacation in Florida in mid-May.

III. Expert Testimony on Causation.

Petitioners presented the testimony of Dr. Levin to establish that the DT vaccination caused Jonathan's overlap syndrome. In essence, Dr. Levin opined that the vaccination caused Jonathan to experience a "cytokine storm" which led to the development of an "immune mediated inflammatory disease" that is "pigeonholed" as overlap syndrome. Respondent presented the testimony of Dr. Rosé, a pediatric rheumatologist, who opined that Jonathan has sclerodermatomyositis overlap syndrome, which is not an immune mediated inflammatory disease. He explained that although a cause for this disease is not known, a genetic basis is strongly suspected. He strenuously disagreed with Dr. Levin's attempts to analogize from conditions with symptoms similar to overlap syndrome and to attribute the causes of those conditions to Jonathan's disease. I found Dr. Rosé's testimony on causation to be more reliable and more persuasive than Dr. Levin's.

A. The Reliability and Credibility of the Experts.

Dr. Levin's letterhead indicates that he is board certified in allergy and immunology, pathology, and emergency medicine. However, he is not primarily engaged in the practice of medicine. Pet. Ex. 10, p. 1. At the time of the hearing, Dr. Levin was treating only four patients (none of whom had overlap syndrome). He indicated that the practice of medicine involved only about 2% of his time. Tr. at 118. His primary profession is law, although he testified that he is also involved in a biotechnology company in China exploring the therapeutic use of cytokines³⁷ to treat cancer, infectious diseases, and obesity. Tr. at 119. He acknowledged that this company might have a financial interest in developing treatments for diseases caused by cytokines with "designer nucleotides." Tr. at 88, 120. He holds two patents for immunotherapy for diseases. Tr. at 122. Although he cited a New England Journal of

³⁷ Cytokines are, as Dr. Levin testified, small proteins that act as messengers. Tr. 94. "Cytokine" is a generic term; there are many different cytokines. They are released by macrophages in response to bacterial, viral, or fungal pathogens. Those made by lymphocytes are called interleukins ["IL"]. Cytokines interact with the cells that have a receptor that recognizes them; the actions that they introduce vary markedly. For example, IL-2 causes T-cell proliferation; IL-13 is responsible for B cell growth and differentiation, inhibits macrophage inflammatory cytokine production, and induces allergies and asthma. IMMUNOBIOLOGY, App. III, p. 746-47. See also, Dr. Rosé's testimony discussing types of cytokines seen in lupus flares. Tr. at 235-36.

Medicine article as support for his opinion regarding causation, Dr. Levin admitted that, in the past, he had equated that particular medical journal as the equivalent of the “National Enquirer.” *Id.* He acknowledged that he had been referred to as a “junk scientist.” Tr. at 125. He disavowed any knowledge that any other court had excluded his testimony as lacking scientific acceptability.³⁸ Tr. at 125-26.

In contrast, Dr. Rosé is one of approximately 170 board certified pediatric rheumatologists in the country. He is also board certified in pediatrics. Res. Ex. B; Tr. at 155. He has an active clinical practice and actually treats children with Jonathan’s condition. Tr. at 156, 160. He was listed among the best doctors in America in 2003-2004 and 2005-2006. Res. Ex. B, p. 2. He currently serves as the head of the Rheumatology Division at Thomas Jefferson University. He treats approximately 180 children with rheumatic diseases each month. Tr. at 153, 156. His curriculum vitae includes over 50 publications dealing primarily with the causes, diagnosis, and treatment of rheumatic disease. Res. Ex. B, pp. 11-15.

Based on the qualifications of the two medical witnesses, there is no question that Dr. Rosé’s qualifications to opine on the nature of Jonathan’s disease are far superior to those of Dr. Levin. Doctor Rosé actually treats children with Jonathan’s condition, knows two of the doctors who have evaluated and treated Jonathan (Dr. Vogler and Dr. Rider), and is well-versed in current medical research regarding overlap syndrome. In contrast, Dr. Levin is primarily a lawyer, albeit one with a medical degree. He does not treat patients with Jonathan’s condition. Furthermore, he acknowledged an economic interest in developing drugs to treat cytokine-induced conditions.

Equally compelling in determining credibility, reliability, and ultimately, causation, was the quality of the testimony of the two witnesses. Doctor Rosé provided thoughtful, careful answers to questions. He grounded his testimony in clinical practice and research. He cogently explained the overlap syndromes, including why and how Jonathan’s condition differed from rheumatoid arthritis, dermatomyositis, and scleroderma.

On the other hand, Dr. Levin’s testimony was confusing at best, and disingenuous at worst. He re-diagnosed Jonathan’s condition to fit his theory of an inflammatory response to vaccination. He used words in unusual ways. For example, Dr. Levin testified that the human immunodeficiency virus (HIV) can “cause” Kaposi’s sarcoma in one patient and pneumocystis pneumonia in another. Tr. at 129. Upon closer questioning, Dr. Levin acknowledged that Kaposi’s sarcoma is actually caused by a virus other than HIV³⁹ (Tr. at 145-46), but nevertheless stated that the biological

³⁸ Respondent did not offer any evidence that Dr. Levin had been rejected as an expert by any other court.

³⁹ In HIV patients with Kaposi’s sarcoma, the causal herpes virus takes advantage of the HIV-weakened immune system. IMMUNOBIOLOGY at 505.

mechanism of the disease would be “immune disregulation,”⁴⁰ caused in one case by the virus and in another case by other disorders. He opined that ten people with the diagnoses of diabetes actually have different diseases because the sequelae differ, with some patients developing eye problems, for example, while others develop gangrene of the toe. When I questioned him about whether this meant that the patients truly had different diseases or merely displayed different clinical manifestations of the same disease, he referred to my question as “semantics.” Much of his testimony was based on these unusual semantic constructions and much of it involved circular reasoning. He indicated that if the same drug could be used to treat two diseases, the diseases were the same. As Dr. Rosé noted, the fallacy is obvious: aspirin is used to treat toothache and stroke, but the two conditions are not the same disease. Tr. at 167. To say I found Dr. Levin’s testimony to be less than convincing would be a significant understatement. He was witty, entertaining, engaging, and “talked a good game,” but his testimony was not grounded in science accepted by the medical community at large, lacked support in medical research,⁴¹ and ultimately rested on his own characterization of Jonathan’s condition as an immune disease.

B. What Disease Does Jonathan Have and How Should It be Characterized?

Jonathan’s medical records reflect a diagnostic process. Doctor Cone thought he might have scleroderma and referred Jonathan to a rheumatologist, Dr. Vivas, who thought he might have polyarticular juvenile rheumatoid arthritis with Raynaud’s phenomenon. Doctor Vivas considered overlap syndrome in his differential diagnosis. Doctor Vogler, with the benefit of several more laboratory studies and his pediatric rheumatology training, initially noted that the findings were suggestive of an overlap syndrome with Raynaud’s phenomenon and scleroderma-like changes. He diagnosed Jonathan with overlap syndrome a month after first seeing him.

⁴⁰ Doctor Rosé expressed concern about the use of the term “immune disregulation,” indicating that this term did not have a commonly understood meaning among medical professionals. Tr. at 222. Doctor Levin cited Jonathan’s history of warts as evidence of this disregulation and asserted that only a small percentage of children develop warts. Tr. at 126-27. Doctor Rose challenged this statement. Tr. at 169, 222. In the absence of any support for Dr. Levin’s assertions and the fact that no other doctor treating Jonathan attached any importance to Jonathan’s repeated treatment for warts, I did not find Jonathan’s history of treatment to be evidence of “immune disregulation.”

⁴¹ Medical literature may not be required as a condition precedent to finding vaccine causation. *Althen*, 418 F.3d at 1281. However, when medical literature is submitted as evidence, the type of medical literature submitted may be weighed and evaluated in determining what weight should be accorded to that evidence. The Supreme Court has noted:

[S]ubmission to the scrutiny of the scientific community is a component of “good science,” in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U. S. 593-94 (1993).

Doctor Rosé explained that there are actually three “overlap syndromes.” Tr. at 156-57. These syndromes are diagnosed based on a combination of the clinical symptoms and laboratory findings. Tr. at 209-10. The type of overlap syndrome Jonathan has is called sclerodermatomyositis, a disease with some (but not all) of the characteristics of both scleroderma and dermatomyositis. Raynaud’s phenomenon, which Jonathan has, is a symptom of scleroderma, but Jonathan does not have many of scleroderma’s other symptoms. Jonathan has some symptoms of dermatomyositis, such as Gottron’s papules and a heliotrope rash, but is missing other symptoms diagnostic of dermatomyositis. He has a positive ANA with an homogeneous pattern, which is present in 100% of the patients with sclerodermatomyositis. Tr. at 158-160. At the time Jonathan was seen by Dr. Vivas, he might have been diagnosed with any of several diseases, but by the time Dr. Vogler saw Jonathan, it was clear that he had this overlap syndrome. Tr. at 210-11.

In stark contrast to the diagnosis of all the treating doctors, Dr. Levin testified that Jonathan has an “immune mediated inflammatory disease.” Tr. at 89. This class of diseases, according to Dr. Levin, is caused by common triggers. He acknowledged that there were no specific tests conducted to show that Jonathan’s condition was cytokine-triggered, and that there was no research associating cytokines with overlap syndrome. Tr. at 143-45. In another example of his circular reasoning, Dr. Levin opined that because cytokines cause immune mediated disorders, and Jonathan has an immune mediated disorder, therefore, his disease process was triggered by cytokines. Amplifying on this circular reasoning, Dr. Levin indicated that Jonathan has responded to treatment used in immune mediated disorders (methotrexate and plaquinil), therefore, he must have an immune mediated disorder. Tr. at 144-45.

According to Dr. Rosé, overlap syndrome has no known cause. There is no evidence that the children with this disease develop it as the result of any triggering event. Tr. at 160-162. Dr. Rosé discussed Res. Ex. D, an article by M. Blaszczyk, *et al.*, “*Childhood Scleromyositis: An Overlap Syndrome Associated with PM-Scl Antibody*,” 8 PEDIATRIC DERMATOLOGY 1-8 (1991). This article established the diagnostic criteria for overlap syndrome and discussed 14 case studies, only one of which had sudden onset after a fever. While some rheumatic diseases have documented triggers, such as the relationship between dermatomyositis and sun exposure, overlap syndrome is not among those with any known trigger. Tr. at 161-162.

Dr. Rosé disagreed with Dr. Levin’s characterization of Jonathan’s condition as an autoimmune disorder. While he agreed that some rheumatic conditions have autoimmune components, there is no evidence that there is an autoimmune mechanism behind overlap syndrome. Tr. 162-66. He indicated that the NIH study in which Jonathan is enrolled is trying to determine a cause for the affliction. Tr. at 188. Jonathan’s joints are inflamed, but the Raynaud’s phenomenon he displays is not caused by inflammation. Sclerodermatic skin has bundles of collagen in the thickened skin, but there is no evidence of inflammation. Jonathan’s sedimentation rate, a measure of inflammation, has never been elevated. Tr. at 165-66. Antinuclear

antibodies are measured in overlap syndrome and other rheumatic conditions, but there is no evidence that these antibodies are pathogenic, or disease causing. They are simply a marker showing the type of disease present. Tr. at 163-65.

Doctor Rosé also took issue with Dr. Levin's statement (Tr. at 87-89) that it is old-fashioned to pigeonhole diseases, explaining that splitting diseases into smaller categories is the more modern approach, because it is essential in identifying the genetic basis for diseases and thus developing effective treatment options.⁴² Tr. at 166-67. He also disagreed with Dr. Levin's assertion that if the same drug is used to treat two different conditions, they are the same disease. Tr. at 167-68. The use of methotrexate to treat both JRA and Jonathan's overlap syndrome does not mean that Jonathan has JRA. *Id.* He also took issue with Dr. Levin's assertion that synovial fluid in Jonathan's joints would reflect JRA-consistent findings, noting that there is no evidence that the same process is ongoing in JRA and overlap syndrome because no one biopsies the joints of overlap patients. Tr. at 206-07. Finally, he testified that none of the diseases the DPT vaccination protects against are associated with the development of rheumatic conditions. Tr. at 182-83, 226.

C. Could the DT-type Vaccination Have Caused Jonathan's Condition?

Doctor Levin explained the biological process behind Jonathan's condition as an immediate cytokine production in response to an immunization, with the fever demonstrating the cytokine response. His opinion was not dependent on whether the fever began immediately or two days later. Tr. at 98-100, 148-49. He also opined that Jonathan's fever was not from influenza, because kids with the flu are not out of school for a month with the flu, and no one else in the family became sick. Tr. 100. Therefore, he argued, what Jonathan experienced was a cytokine storm in response to his vaccination. *Id.*

Dr. Levin opined that DPT-type vaccinations can trigger autoimmune disorders, citing Pet. Exs. 12-15. He noted medical literature⁴³ suggested that influenza vaccine can trigger dermatomyositis and that tetanus vaccine can trigger calcifying

⁴² I note Dr. Levin appeared to contradict himself on whether "lumping" or "splitting" diseases was the appropriate approach to disease classification. He referred to "the old days" when acute lymphocytic leukemia was a general diagnosis for what is now recognized as five different diseases treated in different ways. Tr. at 87-89. This would appear to be an example of "splitting" one disease into several different diseases classifications as being the more modern approach.

⁴³ Petitioners' Exhibits 13 and 14 are case reports more than 20 years old. The *Reference Manual on Scientific Evidence*, Federal Judicial Center, 2000 (2d ed.), notes that, in determining medical causation, "[c]ausal attribution based on case studies must be regarded with caution," largely because they lack controls and thus do not provide the level of information or detail found in epidemiologic studies. *Id.* at 475.

dermatomyositis. Petitioner's Exhibit 13⁴⁴ is a 1983 case study involving a 59 year old woman who developed calcifying dermatomyositis after a tetanus vaccination that appears to demonstrate a rechallenge scenario. However, the authors of the case study did not opine that the vaccination was causal, noting that epidemiologic studies had failed to demonstrate any link between such conditions and tetanus vaccine. Petitioner's Exhibit 14⁴⁵ is a letter to the editor regarding association between dermatomyositis and vaccination in several cases. Doctor Rosé questioned the applicability of either exhibit to Jonathan's situation because the case reports involved different vaccines and different diseases. Tr. at 217-18.

An article submitted by Dr. Rosé (Res. Ex. C), T. Mimori, "Scleroderma-Polymyositis Overlap Syndrome," 26 INT'L J. DERMATOLOGY, 419-25 (1987), supported Dr. Rosé's characterization of overlap syndrome as a disease distinct from dermatomyositis and scleroderma, despite his having some symptoms in common with both. The article explored whether autoantibodies could be used to distinguish the type of disease. Dr. Rosé amplified on the conclusions in this article when he explained the differences in the classification of the overlap syndromes and the role autoantibodies play in making a specific diagnosis. Tr. at 157-60. This "pigeon-holing" appears to be the current practice, notwithstanding Dr. Levin's characterization of it as old-fashioned.

IV. Legal Standards to be Applied.

A. In General.

Petitioners must establish each of the three *Althen* factors: (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. 418 F. 3d at 1278. Circumstantial evidence and medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006).

The medical theory factor does not require petitioners to establish identification and proof of specific biological mechanisms, as "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F. 3d at 1280. The petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the injury or condition; showing that the vaccination was a

⁴⁴ J. Albert, et al., "Calcifying Dermatomyositis Following Antitetanus Vaccination," 143 ARCH. INTERN. MED., 1457-58 (1983).

⁴⁵ W. Ehrengut, "Dermatomyositis and Vaccination," published in LANCET, May 13, 1978. In the one report cited by the author that involved the DPT vaccination, the author opined that the pertussis component of the vaccination was the likely culprit. According to Dr. Cone, Jonathan received a DT vaccination, or one without a pertussis component. Res. Ex. K, p. 1.

“substantial factor” in causing the condition and was a “but for” cause are sufficient for recovery. *Shyface v. Sec’y, HHS*, 165 F. 3d 1344, 1352 (Fed. Cir. 1999). See also, *Pafford v. Sec’y, HHS*, 451 F. 3d 1352, 1355 (Fed. Cir. 2006) (petitioner must establish that vaccinations were a substantial factor and that harm would not have occurred in the absence of vaccination). Petitioners may not be required to show “epidemiologic studies, rechallenge, the presence of pathologic markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect....” *Capizzano v. Sec’y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Causation is determined on a case by case basis, with “no hard and fast *per se* scientific or medical rules.” *Knudsen v. Sec’y, HHS* 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. *But see, Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof failed to meet that burden).

When a petitioner alleges an “off-Table” injury, eligibility for compensation is established when, by a preponderance of the evidence, petitioner demonstrates that he: (1) received a vaccine set forth on the Vaccine Injury Table; (2) received the vaccine in the United States; (3) sustained an illness, disease, disability, or condition caused by the vaccine (or experienced a significant aggravation of an illness); and (4) the problem has persisted for more than six months.⁴⁶ Vaccine litigation rarely concerns whether the vaccine appears on the Table, the situs for administration, or whether the symptoms have persisted for the requisite time. In this case, the focus, as in most vaccine litigation, is on the issue of whether the injury alleged was caused by the vaccine; all of the other requirements of the Vaccine Act were established.

The special master determines the reliability and plausibility of the expert medical opinions offered and the credibility of the experts offering them. Not all evidence carries equal weight with a trier of fact. A medical opinion on causation may be based on factually incorrect medical histories or it may be offered by someone without the necessary training, education, or experience to offer a reliable opinion. An expert’s opinion may be unpersuasive for a variety of reasons. Courts, whether they deal with vaccine injuries, medical malpractice claims, toxic torts, or accident reconstruction, must base their decisions on reliable evidence. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594-96 (1993). *Daubert* provides a useful framework for evaluating scientific evidence in Vaccine Act cases. *Terran v. Sec’y, HHS*, 41 Fed. Cl. 330, 336 (1998), *aff’d* 195 F.3d 1302, 1316 (Fed. Cir. 1999), *cert. denied*, *Terran v. Shalala*, 531 U.S. 812 (2000). See also, *Ryman v. Sec’y, HHS*, 65 Fed. Cl. 35, 40 (2005) (special master performs gatekeeping function when he “determines whether a particular petitioner’s expert medical testimony supporting biologic probability may be admitted or credited or otherwise relied upon”).

⁴⁶ Section 300aa–13(a)(1)(A). This section provides that petitioner must demonstrate “by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1)...” Section 300aa–11(c)(1) contains the four factors listed above, along with others not relevant to this case.

The Vaccine Act clearly contemplates that the special masters will weigh the merits of the evidence presented in making entitlement decisions. Special masters are not bound by any particular “diagnosis, conclusion, judgment, test result, report, or summary,” and in determining the weight to be afforded to these matters, “shall consider the entire record....” § 300aa–13(b)(1). Respondent may challenge the factual underpinnings of a causation opinion, the opinion itself, or both. Special masters weigh the evidence found in the medical records (see, e.g., *Ryman*, 65 Fed. Cl. at 41-42); consider evidence of bias or prejudice on the part of a witness, affiant, or expert (see, e.g., *Baker v. Sec’y, HHS*, No. 99-653V, 2003 WL 22416622, *33-34 (Fed. Cl. Spec. Mstr. Sept. 26, 2003)); weigh opposing medical opinions and the relative qualifications of experts (see, e.g., *Epstein v. Sec’y, HHS*, 35 Fed. Cl. 467, 477 (1996) and *Lankford v. Sec’y, HHS*, 37 Fed. Cl. 723, 726-27 (1997)); examine medical literature, studies, reports, and tests submitted by both sides (see, e.g., *Sharpnack v. Sec’y, HHS*, 27 Fed. Cl. 457 (1993), *aff’d*, 17 F.3d 1442 (Fed. Cir. 1994)); and may consider a myriad of other factors in determining the facts of the case and the mixed questions of law and fact that arise in causation determinations. Special masters decide questions of credibility, plausibility, reliability, and ultimately determine to which side the balance of the evidence is tipped. See *Pafford*, 451 F.3d at 1359 (“Notably, this court accords great deference to a Special Master’s determination on the probative value of evidence and the credibility of witnesses”).

In an off-Table case, if the special master concludes that petitioner’s evidence of causation is lacking, then the burden never shifts to respondent to demonstrate the “factors unrelated” as an alternative cause for petitioner’s injury. See *Bradley*, 991 F.2d at 1575 (when petitioner has failed to demonstrate causation by a preponderance, alternative theories of causation need not be addressed) and *Johnson v. Sec’y, HHS*, 33 Fed. Cl. 712, 721-22 (1995), *aff’d*, 99 F.3d 1160 (Fed. Cir. 1996) (even in idiopathic disease claims, the special master may conclude petitioner has failed to establish a *prima facie* case).⁴⁷ If a petitioner fails to establish one or more of the *Althen* factors, then the petitioner has failed to establish causation. By challenging any of *Althen*’s three causation factors through cross-examination, introduction of medical literature, contrary testimony of well-qualified experts, or by some other method, respondent may stymie petitioners’ efforts to establish causation without the necessity of establishing an alternate cause.

B. Applying *Althen*.

1. *Medical Theory*. Reduced to its essence, Dr. Levin’s medical theory is that

⁴⁷ If the respondent were limited to presenting the matters set forth in § 300aa-13(a)(1)(B)—proving by a preponderance of the evidence that the petitioner’s condition is due to a factor unrelated to the vaccine—any petitioner with a disease for which medical science has not yet discovered a cause would be at a distinct advantage in Vaccine Act litigation. Section 300aa–13(a)(1)(B) indicates that respondent may not rely upon “idiopathic, unexplained, unknown, hypothetical, or undocumentable” causes as a “factor unrelated.”

the DT vaccination caused the release of cytokines; the cytokines provoked a fever within hours to two days of the vaccination (demonstrating a cytokine release); and the cytokine release triggered an immune mediated inflammatory disease in Jonathan, who had a genetic propensity to develop such a condition.

As Dr. Levin noted, cytokine release can be triggered by vaccination, infection, malignancy, chemicals, or even a hot bath. Tr. at 95. Cytokines are a normal part of the innate immune system. What Dr. Levin postulated, however, is that because of Jonathan's genetic predisposition to develop autoimmune disease, the DT vaccination caused cytokines to trigger a disease process that resulted in his overlap syndrome. It did so by what Dr. Levin called "epitope spreading." He explained that, as the immune system reacts to a specific antigen, the reaction process spreads to similar antigens, some of which mimic the individual's own tissue. This process is sometimes described as "molecular mimicry." Tr. at 107-09. The antigen that triggers the first reaction need not resemble the self-antigen at the end of the process, so long as the cytokines stimulate the promotion of autoreactive cells. Tr. at 110. In the absence of any evidence of another triggering event, Dr. Levin believed the vaccination was the cause of the subsequent illness. Tr. at 114. He acknowledged that various pesticides could trigger cytokine release, and that Jonathan had been exposed to lindane in flea soap as well as to other pesticides, but the timing of those exposures were not pinpointed. Tr. at 82-83, 95, 137-39. The vaccination occurred in close proximity to the onset of symptoms. Tr. at 106-07.

2. *Logical sequence of cause and effect.* Although Dr. Levin did not directly address this *Althen* factor, he testified that the fever Jonathan had after the vaccination demonstrated cytokine release and the degree of his illness demonstrated a hyper-response, or a cytokine storm. He relied on the biological theory and timing to link the vaccination to the disease.

3. *Proximate temporal relationship.* There were actually two temporal relationships encompassed in Dr. Levin's causation opinion. The first involved the hours-to-two-day window for fever as evidence of an overly robust cytokine response. The second involved the appearance of rheumatologic or autoimmune symptoms within one month to two or three months of the immunization. He based his opinion that this constituted an appropriate time frame partly on a medical journal article not filed as an exhibit in this case,⁴⁸ and partly on a general belief that a connection would be more tenuous after the passage of more time. Tr. at 111-13. When I asked him how early he would expect an autoimmune disorder to manifest, he answered, "I'm guessing it would be about a month plus or minus a few days." Tr. at 149. Asked for support for that time frame, he indicated that he would supply references. Tr. at 150-51. He did not.

⁴⁸ His opinion on the temporal association between the two events, however, was independent of the article he referenced. Tr. at 117.

4. *Discussion.* In the instant case, my factual determinations undercut the basis for Dr. Levin's opinion that Jonathan's condition was caused by a cytokine storm manifested by a very severe febrile illness after his vaccination. Without evidence of an overly robust reaction to the vaccination, the support for the theory that a cytokine storm induced an autoimmune or immune mediated inflammatory disease is considerably reduced.

Even if I conclude that Jonathan experienced the post-vaccination illness his parents belatedly described to Dr. Cone and others, I would, nevertheless, conclude that petitioners failed to establish causation by a preponderance of the evidence. Doctor Levin's opinion on causation was not persuasive. It was predicated on characterizing Jonathan's disease as an immune mediated inflammatory condition, a conclusion or characterization not made by any of the treating physicians, unsupported by any medical reference, and drawn by a witness without any recent personal experience in treating children with Jonathan's condition or training and expertise in rheumatology.

Doctor Levin testified that anything that could invoke an immune response could cause a cytokine storm. Tr. at 146-47. In the absence of any evidence contradicting this statement, I conclude that the theory is biologically plausible, albeit on the extreme limits of plausibility. Under Dr. Levine's formulation, virtually any disease is caused by genetic susceptibility plus a cytokine reaction, resulting in an immune dysregulation. Therefore, virtually all diseases are autoimmune diseases and, taking his theory to its logical extreme, any trigger can cause any disease. The support for this position in medical literature or among other scientists appears scant.

Nevertheless, the real problem in Dr. Levin's opinion on causation is not biological plausibility, but in precisely what cytokine storms can (and do) trigger—the linkage between theory and the logical sequence of cause and effect. To put it another way, the problem here is the relationship between *Althen's* first two factors. A theory is only a theory, until there is some evidence that the theory is at work in the case. Doctor Levin's theory is based on a conclusion that sclerodermatomyositis overlap syndrome is an autoimmune or immune mediated inflammatory disorder. That evidence is, unfortunately, supplied only by Dr. Levin's characterization. His characterization of Jonathan's disease is countered by the contrary opinion of a well-qualified rheumatologist who is currently engaged in treating that disease. Dr. Rosé's opinion that Jonathan's condition is not recognized as an immune-mediated inflammatory disorder is shared by other pediatric rheumatologists. I conclude that Dr. Rosé's opinion is far more credible than Dr. Levin's.

Finally, there is a dearth of evidence logically or causally linking vaccination to overlap syndrome in general or even to Jonathan's symptoms, in particular. According to Dr. Rosé, neither of the diseases that the DT vaccination protects against is associated with the development of symptoms like those Jonathan displayed. He opined that it is quite unlikely, therefore, that the vaccine would induce an effect not

seen in the natural disease process. Tr. at 226-27. Adding support to Dr. Rosé's contention that the cause is unknown, NIH is studying possible triggers of the disease. Doctor Levin's testimony does not provide a persuasive opinion and none of petitioners' exhibits provide sufficient evidence that a DT vaccination caused his disease. This leaves a *post hoc, ergo propter hoc*, analysis that is insufficient to establish causation. With regard to timing, I note that the earliest report to a medical professional of Jonathan's symptoms placed onset either before his vaccination or very shortly after it. In Dr. Levin's opinion, the earliest appropriate time frame for development of an immune mediated inflammatory disorder would be about a month after the triggering event. The most contemporaneous record places onset of symptoms in the same general time frame as the vaccination, further undercutting Dr. Levin's opinion on causation. Considering the entire record, the evidence of vaccine causation falls far short of the preponderance standard required to succeed in a claim under the Program.

V. Conclusion

Petitioners have not demonstrated by a preponderance of the evidence that Jonathan's condition was either caused or significantly aggravated by the DT vaccination on February 12, 2002. Thus, they have failed to establish entitlement to compensation and the petition for compensation is therefore DENIED. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.⁴⁹

IT IS SO ORDERED.

Denise K. Vowell
Special Master

⁴⁹ 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.