

IN THE UNITED STATES COURT OF FEDERAL CLAIMS  
OFFICE OF SPECIAL MASTERS  
No. 04-503V  
Filed: April 30, 2007  
To be Published

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YVONNE WALTON, \*  
\*  
\* Petitioner, \* Causation; Myocarditis;  
\* MMR Vaccination;  
\* Coxsackie Virus;  
v. \* Factor Unrelated  
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\*  
SECRETARY OF THE DEPARTMENT \*  
OF HEALTH AND HUMAN SERVICES, \*  
\*  
\* Respondent. \*  
\*  
\*\*\*\*\*

James McCarney, Esq., Howrey LLP, Pittsburgh, PA, for petitioner.  
Alexis Babcock, Esq., U.S. Department of Justice, Washington, D.C., for respondent.

**DECISION<sup>1</sup>**

**Vowell**, Special Master

On March 30, 2004, Mrs. Yvonne Walton<sup>2</sup> ["Mrs. Walton" or "petitioner"] timely filed a petition ["Petition"] for compensation under the National Vaccine Injury

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<sup>1</sup> Because I have designated this decision to be published, petitioner has 14 days to request redaction of any material "that includes medical files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be publicly available. 42 U.S.C. § 300aa12(d)(4)(B).

<sup>2</sup> Some of the medical records filed in this case refer to Mrs. Walton by her maiden name, Yvonne Schmitt.

Compensation Act ["Vaccine Act" or "Program"], 42 U.S.C. § 300aa-10 *et. seq.*<sup>3</sup> She alleged that a measles, mumps and rubella ["MMR"] vaccination she received on March 30, 2001 caused her to develop an "acute complication or sequella of illness and vaccine strain measles viral infection... ." Petition at 1. She claimed symptoms of "fever, chest pain, nausea, headaches, dizziness, lightheadedness, racing heart rate, tired feeling, faintness, Coxsackie-carditis with supra-ventricular tachycardia with pronounced exhaustion pathology," which manifested on or about April 2, 2001. She alleged that these symptoms were caused in fact by the MMR vaccination. *Id.* at 1, 3.

To be eligible for compensation under the Vaccine Act, a petitioner must either demonstrate a Vaccine Table<sup>4</sup> 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. 1992). This petition alleged both the "Table" injury of acute vaccine-strain measles viral infection<sup>5</sup> and an actual causation claim. By the time of the hearing, Mrs. Walton had abandoned her "Table" injury claim and was proceeding solely on the theory that the MMR vaccination caused her to develop myocarditis.<sup>6</sup> In order to prevail, she must demonstrate that the MMR vaccination she received on March 30, 2001 either caused or significantly aggravated her condition or injury.

After considering the record as a whole,<sup>7</sup> including the testimony of petitioner and four physicians at a hearing on September 12, 2006, and all the matters introduced after the hearing, I conclude that Mrs. Walton has failed to establish her entitlement to

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<sup>3</sup> 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.).

<sup>4</sup> 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.

<sup>5</sup> "Vaccine Strain Measles Viral Infection in an immunodeficient recipient" is an injury listed on the Vaccine Injury Table for any measles virus-containing vaccine. The Qualifications and Aids to Interpretation ["QAI"] portion of the Vaccine Injury Table defines this injury as "a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests." No such tests were ever introduced. Because Mrs. Walton withdrew her claim of a "Table" injury, I need not address the issues of what constitutes an "immunodeficient recipient" or what evidence is needed to establish a "vaccine-strain" disease.

<sup>6</sup> Myocarditis is an inflammation of the walls of the heart. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] at 1212 (30<sup>th</sup> ed. 2003). *See also*, Respondent's Exhibit ["Res. Ex."] A, Tab 3, Chapter 73, "Pericarditis and Myocarditis," authored by A. M. Lerner, from INFECTIOUS DISEASES, (S.L. Gorbach, *et. al.*, 1992 ed.) [hereinafter "INFECTIOUS DISEASES, Ch. 73"]. The symptoms of myocarditis, and what may cause it, are discussed in greater detail, *infra*.

<sup>7</sup> *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).

compensation and her petition must therefore be denied.

## I. PETITIONER'S BACKGROUND AND MEDICAL HISTORY

Mrs. Walton was born in Saar Louis, Germany on April 29, 1977. Transcript ["Tr."] at 8;<sup>8</sup> Petitioner's Affidavit ["Pet. Aff."], ¶ 2.<sup>9</sup> During a hospitalization for tuberculosis when she was two years old, she contracted measles. Tr. at 19-21. She had a rubella vaccination in November 1989.<sup>10</sup> Petitioner's Exhibits ["Pet. Ex."] 2, p. 2; Tr. at 36. There is no evidence that she ever had mumps. She had childhood vaccinations against polio, diphtheria, and tetanus. Pet. Ex. 2, pp. 1-2.

While working as a kindergarten teacher in Liederprüm, Germany in 1999, she met her future husband, Mr. Thomas Walton ["Mr. Walton"], a Senior Airman stationed at Spangdahlem Air Force Base, Germany. Tr. at 8-9, 13. Approximately six months after they met, Mr. Walton left the Air Force and returned to his home in Texas. Tr. at 10-11.

Petitioner was unhappy after his departure, so her father arranged for her to fly to the U.S. to visit Mr. Walton. Tr. at 12. During an October 2000 visit, they became engaged. *Id.* Mrs. Walton did not provide specific dates for her visits, but medical records<sup>11</sup> reflect that she was under the care of Dr. Michael Jager in Bitburg, Germany, during the period from October 12 through December 19, 2000. Pet. Ex. 9, p. 22; Pet Ex. 2, p. 1. She had a physical examination at Dr. Jager's office on October 13, 2000

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<sup>8</sup> Mrs. Walton testified in English without aid of a translator. I found her fluent in the English language and had no difficulty in understanding her testimony. While she occasionally paused to recall a specific word in English, she appeared to comprehend both my questions and those of counsel for both parties. Her accent and phrasing were very understandable.

<sup>9</sup> Petitioner's Affidavit was designated as Petitioner's Exhibit 22 shortly before the hearing.

<sup>10</sup> Pet. Aff. ¶ 4, indicates that Mrs. Walton had rubella as a child. This conflicts with her hearing testimony that she had a rubella vaccination. Her medical records reflect a rubella vaccination. While it is possible that she had both the disease and a later vaccination, it is more likely that the affidavit is incorrect.

<sup>11</sup> These medical records are contained in Pet. Ex. 9, which, unfortunately, does not conform to the Guidelines for Practice or the Vaccine Rules in that the pages of the exhibit are not sequentially numbered. Instead, the page numbering begins anew with the medical records for each of several health care providers. In order to have reference points for questioning the witnesses at the hearing, I hand-numbered the pages of this exhibit sequentially, resulting in the occasional numbering of one of the blank pages inserted between each provider's records. For the sake of clarity, when referring to any record in Exhibit 9, I will identify the record by the number of pages after the table of contents ["TOC"] and the referenced medical record.

and received some vaccinations in December 2000.<sup>12</sup> This record (Pet. Ex. 9, pp. 22-28, inclusive of translator's certification and the German-language records) is dated July 5, 2004 and is in the form of a medical attestation which does not include the actual records of the physical examination.<sup>13</sup>

When they became engaged, petitioner and her future husband had not yet decided where they would live and work. Mrs. Walton's job with the kindergarten in Germany carried some form of tenure<sup>14</sup> and she hoped to become the manager of the school at some point in the future. However, her husband missed his family and friends while he was stationed in Germany and he wanted to remain in Texas. Mrs. Walton's testimony indicated that they were still struggling with the decision of where to live. Tr. at 33-35.

Petitioner returned to Austin, TX, for another visit a day or two before Christmas, 2000. Tr. at 13, 15. During or shortly before her trip, she suffered from some type of upper respiratory problem, which she variously described as a cold or the flu. Tr. at 16 (cold); 45-46 (flu). She went to Seton Hospital on January 5, 2001 for symptoms of asthma, bronchitis, dizziness, and shortness of breath for two weeks, placing the onset of this illness at around the time of her departure from Germany. Pet. Ex. 10, pp. 1-2. She also complained of chest tightness and nausea while eating. On examination, she had diminished breath sounds bilaterally with occasional rhonchi.<sup>15</sup> She received

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<sup>12</sup> Pet. Ex. 2, p. 1 (also at Pet. Ex. 3, p. 5), shows that Mrs. Walton received a tetanus vaccination from Dr. Hormans on December 2, 2000 and diphtheria and polio vaccinations from Dr. Jager on December 14, 2000. The medical attestation at Pet. Ex. 9, p. 22 reflects that she received a tetanus and diphtheria ["Td"] vaccination on December 14, 2000, but makes no mention of the polio vaccination. The medical history at Pet. Ex. 9, p. 14 (from the group practice of N. Nabo and H.J. Dworatzek) refers to tetanus and polio vaccinations in December 2000, but omits the diphtheria vaccination. Pet. Ex. 4, p. 14 (also at Pet. Ex. 1, p. 1), an immigration immunization reporting form, dated April 2, 2001, indicates that Mrs. Walton received a Td vaccination on December 2, 2000. Because the entries on Pet. Ex. 2 appear to be made contemporaneously with the vaccinations and because it contains the most detailed information, including manufacturers and lot numbers, I conclude that this record is the most reliable. I therefore find that Mrs. Walton received a tetanus vaccination on December 2, 2000 and polio and diphtheria vaccinations on December 14, 2000.

<sup>13</sup> Although Dr. Jager's medical attestation indicated that he could ascertain no reaction to the December vaccinations, petitioner left Germany for the U.S. about three weeks after the tetanus vaccination and about one week after the diphtheria and polio vaccinations were administered. There is no evidence that she was examined again by Dr. Jager between the time he administered the December 14, 2000 vaccinations and her departure for the United States on or about December 23, 2000. His conclusion is thus of limited value, as it appears to be based on Mrs. Walton's reports, rather than on his personal observation.

<sup>14</sup> Mrs. Walton described this as a "life term contract" and explained that she could work at this particular school until she retired. Tr. at 13.

<sup>15</sup> Rhonchi are low-pitched snoring sounds produced in the throat or bronchial tubes as the result of partial obstruction of breathing. DORLAND'S at 1630.

breathing treatments and was released with antibiotics and an albuterol inhaler.<sup>16</sup> Pet. Ex. 4, pp. 2-5; 10, pp. 2, 4, and 6. She was advised to follow up with a doctor in 7-10 days, if needed. Pet. Ex. 10, p. 10. Mrs. Walton testified that she had respiratory symptoms, shortness of breath, tiredness, and dizziness persisting from her December flight to the U.S. through March 2001. Tr. 45-47.

Although her December 2000 trip was planned as a visit, petitioner and Mr. Walton were married in Austin in February 2001. Tr. at 13-14. It was apparent from Mrs. Walton's voice and demeanor on the witness stand that the decision to remain in the U.S. was a difficult one for her, made even more difficult by the problems she encountered in changing her immigration status with U.S. authorities.

She described her experience with immigration authorities as "horrible." Tr. at 14. She was nearly as uncomplimentary about Pro Med, the medical clinic where her MMR vaccination was administered. *Id.* At this point in her testimony, Mrs. Walton began crying and testified through her tears, "I was just married. We had different plans. I didn't want to be in America. I never planned to get married to [an] American." *Id.*

Mrs. Walton attributed the impetus for her MMR vaccination to employees of the medical clinic where she received the vaccination. Although she testified that "they told me that I should get this damn shot or I had to leave the country" (*id.* at 14), it is reasonably clear from the record that the requirement to demonstrate either prior MMR vaccination or immunity to measles, mumps, and rubella came from U.S. immigration rules, not the medical clinic.<sup>17</sup> When Mrs. Walton entered the U.S. in December 2000, she did so under a tourist visa that limited her stay to three months. Tr. at 15. In order to lawfully extend her stay after her marriage on February 18, 2001, she had approximately a month to obtain another visa, one that required proof of vaccination. *Id.*, at 15-16.

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<sup>16</sup> Many asthma medications, including albuterol (a bronchodilator marketed under the trade name "Proventil"), can cause heart palpitations or tachycardia (a heart rate above 100 beats per minute) See PHYSICIAN'S DESK REFERENCE ["PDR"] at 1194 (58<sup>th</sup> ed. 2004); DORLAND'S at 45, 1850. See also, Pet. Ex. 4, pp. 3-4, a patient handout from Seton Hospital indicating that Proventil's common side effects include increased heart rate and shakiness. The handout also advised patients to seek immediate medical attention if they developed "increased shortness of breath, chest pain, palpitations, continued shakiness, or severe headache." *Id.* Mrs. Walton sought medical attention on April 30, 2001 for severe headache, syncope, and dizziness, but did not mention any other of these symptoms. Pet. Ex. 5, p. 1. Mrs. Walton testified that the use of her inhaler made her heart palpitations worse. Tr. at 25. She continued to use her inhaler over the next few months. Tr. at 48.

<sup>17</sup> Petitioner's Exhibit 6, p. 1, is a Pro Med form. At the top left hand corner of the form the words "Immigration and Naturalization" appear and the words "immigration phy" (likely meaning "physical") appear on the triage section of the form. Res. Ex. A, Tab 2, *Morbidity and Mortality Weekly Report* ["MMWR"], No. 47, dated May 22, 1998, contains the recommendations of the Advisory Committee on Immunization Practices. It states: "Persons who may be immune to measles, mumps, or rubella, but who lack either adequate documentation of vaccination or other acceptable evidence of immunity should be vaccinated." *Id.* at 10 (reference omitted).

Being informed that she did not qualify for a religious exemption to the vaccination requirement<sup>18</sup> and that there was inadequate time remaining to obtain evidence of her prior vaccinations or disease exposure, Mrs. Walton agreed to be vaccinated. Tr. at 16-17.

## II. The MMR VACCINATION AND SUBSEQUENT TREATMENT IN THE U.S.

Mrs. Walton received the MMR vaccination along with her immigration physical at Pro Med on March 30, 2001.<sup>19</sup> Pet. Ex. 3, p. 1. Prior to receiving the vaccination, Mrs. Walton provided a medical history that reflected that she had measles and rubella as a child. Pet. Ex. 3, p. 10; Tr. 19. She also reported a history of asthma, allergies, tuberculosis, and meningitis. Pet. Ex. 3, p. 10; Tr. at 19, 20, 22. In addition to the MMR vaccination, Mrs. Walton had a chest x-ray to rule out tuberculosis. Pet. Ex. 3, p. 11. Although she testified that she was still ill from the flu she had in December 2000 (Tr. at 47), the physical examination on March 30, 2000 recorded no illness. Her temperature, blood pressure, pulse, and respiration were all normal.

Consistent with her affidavit, Mrs. Walton testified that she began feeling sick, tired, and suffered from headache and a rash, within a few days of the vaccination. Tr. at 17-18, 22. Her affidavit indicated that she began feeling weak and developed itchy red spots on her abdomen by about April 2, 2001, two days after the vaccination.<sup>20</sup> Pet. Aff. ¶ 6. Later in her testimony, she indicated that she began having heart palpitations within a few days of the vaccination. Tr. at 24. She described a long list of symptoms in her affidavit: “fever, chest pain, nausea, headaches, dizziness, lightheadedness, racing heart rate, tired feeling and faintness,” but the affidavit did not pinpoint when these symptoms began. Pet. Aff. ¶ 6. She testified that she was tired and suffered from shortness of breath and dizziness before the MMR vaccination, but that the rash began a few days after the vaccination. Tr. at 47-50. While she could not recall when the rash resolved, it was still present in July and September 2001. Tr. at 49-51. She mentioned her symptoms to her husband, who advised her to go back to the doctor. She declined his suggestion. *Id.* at 22.

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<sup>18</sup> Although Mrs. Walton testified that the clinic personnel told her she did not qualify for a religious exception based on her Roman Catholic faith, she had either a copy or the original of her vaccine record from Germany with her, which reflected many other vaccinations. Pet. Ex. 2, pp 1-2. A “Pro Med” stamp appears after the entry on Pet. Ex. 2, p. 9, recording the MMR vaccination in question in this case. Given her previous vaccination history (including three vaccinations in December 2000), it is more likely that she was told that she did not qualify for a religious exception because of her prior history of vaccinations, rather than the nature of her religious faith.

<sup>19</sup> The parties stipulated that petitioner received an MMR vaccination on this date. Joint Status Report, filed July 31, 2006.

<sup>20</sup> This is the same date that Pet. Ex. 1, pp. 1-2, an immigration immunization form, was completed by a doctor whose signature is illegible.

She had been scheduled to receive her second MMR vaccination four weeks after the first one, and she did not see a doctor again until she returned to Pro Med for this vaccination. *Id.* While she could not recall dates, her description of the return visit to Pro Med is generally consistent with the visit on Monday, April 30, 2001, documented at Pet. Ex. 5, p. 1.

The medical records from this second Pro Med visit state that Mrs. Walton was there for her second MMR vaccination and for treatment of a headache that had persisted for one week, with dizziness and a brief period of syncope<sup>21</sup> the previous Tuesday or Thursday. There was no mention in this medical record of the symptoms of rash, tiredness, and heart palpitations that Mrs. Walton related in her testimony.<sup>22</sup> Her temperature was normal. Pet. Ex. 5, p. 1; Tr. at 38. Instead of administering the second MMR vaccination, Pro Med personnel referred Mrs. Walton to her hospital of choice for further examination for her headache. Pet. Ex. 5, p.1.

Mrs. Walton returned to Seton Hospital. The emergency room records indicated that she had suffered from severe headache, blurred vision, and dizziness “since Thursday.” Her temperature was very slightly (half of one degree) elevated. Her childhood medical history of tuberculosis, meningitis, and abdominal problems were recorded. Mrs. Walton was described as “anxious.” Although the handwriting is difficult to read and part of the page is cut off (Pet. Ex. 10, p.15), it appears that her anxiety might have been related to the intravenous line established at Seton Hospital. *Id.*, pp. 15-17. The treating physician ordered a brain computed tomograph [“CT”]<sup>23</sup> which was essentially normal. Pet. Ex. 10, p. 18. She was released later that day when her headache improved after treatment with Phenergan and Reglan.<sup>24</sup> She had instructions to make a follow-up appointment within two days. Although she testified that hospital personnel wanted to admit her (Tr. at 22), there is no indication of this in the records, which reflect that Mrs. Walton was released when her pain was relieved. Pet. Ex. 10, p. 15.

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<sup>21</sup> “Syncope” is a temporary loss of consciousness, sometimes referred to as fainting. DORLAND’S at 1807.

<sup>22</sup> Mrs. Walton also testified about a problem with her blood sugar in relation to this visit (Tr. at 22-23), but other records indicate that she had low blood sugar at the June 2001 visit to Pro Med, discussed, *infra.* Pet. Ex. 7, p. 2. The laboratory reports from Seton Hospital indicate that her blood sugar was normal at the April visit. Pet. Ex. 10, p. 20.

<sup>23</sup> A brain CT scan “consists of a computerized analysis of multiple tomographic x-ray films taken of the brain tissue at successive layers, providing a three dimensional view of the cranial contents.” MOSBY’S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS [“MOSBY’S LABS”] at 1096 (3d ed. 2006). A brain CT is used in the diagnosis of brain tumors, bleeding, and other central nervous system problems. It may also be used in the diagnosis of multiple sclerosis. *Id.* at 1095. Mrs. Walton’s CT scan was normal, other than incidental calcifications not considered to be of significance. Pet. Ex. 10, p. 18.

<sup>24</sup> Patient handouts at Pet. Ex. 10, p. 22 indicate that Phenergan is used to treat vertigo and nausea and Reglan is used to treat nausea.

Mrs. Walton testified that she and her husband discussed information provided by Pro Med on possible adverse effects from vaccination after this visit to Seton Hospital and that they “went back” (Tr. at 23), but there are no records of any other visits to Seton Hospital.<sup>25</sup> She later testified that she was not seen by a physician again between treatment at Seton Hospital and her return to Pro Med on June 6, 2001. Tr. at 39.

At the June 6, 2001 visit to Pro Med, her complaints were a tickling or choking sensation in her throat, shortness of breath, and heart palpitations. Her heart rate was recorded as 100 beats per minute.<sup>26</sup> Pet. Ex. 7, p.1. An electrocardiogram<sup>27</sup> [“EKG”] was normal.<sup>28</sup> Blood tests revealed an extremely low glucose level, but all other serologic tests were normal. Pet Ex. 7, p. 2. Mrs. Walton called the clinic on June 8, 2001 to report that she had episodes of feeling as if her throat were swelling shut and that she was experiencing periodic heart palpitations. She was urged to go to the nearby Seton Hospital emergency room if her symptoms returned. Pet. Ex. 11, p. 4. She called Pro Med again during the early morning hours of June 9, 2001, connecting with an answering service. She identified the call as an emergency and asked the answering service to wake up the doctor. Pet. Ex. 7, p. 10; Pet. Ex. 15, p. 1 (a transcription of the machine-printed entry regarding her call). While there is no record of what else transpired during or immediately after this call, a Pro Med employee documented a call to Mrs. Walton at 10:15 AM on June 9, 2001, to encourage her to return to the clinic for a fasting blood sugar test. Pet. Ex. 11, p. 4.

She was signed in to Pro Med on June 9, 2001 at 10:58 AM. Upon arrival, she reported that she often felt light-headed and dizzy, had sweaty palms, and had the sensation of having something in her throat. Pet. Ex. 7, p. 8; Pet. Ex. 11, p. 1. The follow up glucose check was normal. No other records from U.S. health care providers were filed.

Mrs. Walton acknowledged that she did not mention a rash to her health care providers during her treatment in the U.S. Tr. at 50. She explained this by saying that she was young and newly married and did not want to appear to be sicker than she was. *Id.* at 51.

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<sup>25</sup> On November 13, 2006, I ordered respondent to subpoena all records from Seton Hospital pertaining to petitioner under either her maiden or married name. Those records were filed as Respondent’s Exhibits [“Res. Ex.”] G and H. They do not show any visits after April 30, 2001.

<sup>26</sup> A heart rate of over 100 beats per minute is classified as tachycardia. DORLAND’S at 1850.

<sup>27</sup> An electrocardiogram is a view of the heart’s electrical impulses. It “is used to evaluate arrhythmias, conduction defects, myocardial injury and damage” to the heart. MOSBY’S LABS at 560-61. The EKG tracing is found at Pet. Ex. 7, p. 4, and is hand-dated “6/6/01.”

<sup>28</sup> Mrs. Walton’s affidavit records this EKG as occurring during the April 2001 visit to Pro Med. Pet. Aff. ¶ 7. Based on all the evidence submitted, I conclude that Mrs. Walton was mistaken; her only EKG at Pro Med was performed on June 6, 2001 in response to her complaints of heart palpitations.



### III. TREATMENT IN GERMANY

Sometime in June 2001, Mrs. Walton and her husband returned to Germany, where Mr. Walton secured employment after losing his job in Austin, TX. Pet. Aff. ¶ 9; Tr. at 25. Mrs. Walton testified that she went from the airport to a doctor (*id.* at 26), but there is no record of this visit.<sup>29</sup> The first German medical record filed after her June 2001 return is dated July 11, 2001 and contains test results: measles, mumps, and rubella titers demonstrating seropositivity to all three viruses. Pet. Ex. 8, p. 1.

On July 30, 2001, Mrs. Walton visited a dermatologist and allergist, Dr. L. Weigl, for complaints of a skin rash. Pet. Ex. 9, 4<sup>th</sup> page after table of contents [“TOC”]. Doctor Weigl recorded the visit as a consultation for contact dermatitis,<sup>30</sup> with lichen ruber planus<sup>31</sup> as the differential diagnosis. He took a history of partially pruritic skin changes on belly, arms, and chest after a stay in Texas. The skin rash was apparently present at the time of the visit, because Dr. Weigl noted plans for a future skin biopsy. *Id.* The results of this biopsy are not in any of the exhibits filed and Mrs. Walton testified that the biopsy was never performed. Tr. at 41.

Doctor Weigl noted “Koebner phenomenon” on the skin, referring to a skin eruption similar to the rash at a pressure point or a scratch, often found in lichen ruber planus and infectious dermatitis.<sup>32</sup> The records regarding diagnosis and treatment of

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<sup>29</sup> The records from Dr. W. Kauffman’s office at Pet. Ex. 9, 18<sup>th</sup> page of records after TOC, indicated that Mrs. Walton had a consultation at an emergency room in Munich in July 2001 for complaints of a rapid pulse rate, drop in performance, and heat intolerance. The hospital records from this visit were not filed as an exhibit. There are references to blood pressure and ultrasound examinations at the emergency room, followed by “NAD.” In this context (including subsequent uses of the abbreviation at other places in Dr. Kauffman’s records), this abbreviation likely means either “no appreciable disease” or “nothing abnormal detected.” See N. Davis, MEDICAL ABBREVIATIONS [“MED. ABBREVIATIONS”], pp. 241-42 (12<sup>th</sup> ed. 2005). Mrs. Walton’s affidavit indicated that “she continued to seek medical assistance, including a visit to a Dr. Boschert on July 11, 2001.” She did not mention an emergency room visit immediately after her arrival. Pet. Aff., ¶ 9.

<sup>30</sup> Contact dermatitis is a skin inflammation caused by materials or substances coming into contact with the skin. DORLAND’S at 496.

<sup>31</sup> Lichen ruber planus is an inflammatory pruritic skin disease characterized by violet, scaly papules with white lines. DORLAND’S at 1026 (contains a picture of lichen ruber planus). It would not ordinarily be confused with the characteristic rash of measles. A measles rash infection would not ordinarily present with a rash lasting for three or four months. R. Summit, INFECTIOUS DISEASES at 874-76 (1990) indicates that the measles rash generally clears within one week of its appearance, leading to the name “7-day measles” for rubeola. Examples of the characteristic measles rash may be found in C. Simon and M. Jänner, COLOR ATLAS OF PEDIATRIC DISEASES at 344-45 (2d ed. 1990). This textbook also indicates that the coxsackie virus can produce rashes resembling rubella and rubeola (measles). *Id.*

<sup>32</sup> Koebner phenomenon is a cutaneous response founds in some forms of dermatitis; pressure at an uninvolved area of the skin by a belt or waistband or from trauma may result in similar lesions at the pressure points. DORLAND’S at 1419 (includes an illustration).

this rash do not indicate when the rash first manifested. Mrs. Walton testified that this rash began within a few days of the MMR vaccination, four months before this visit. Tr. at 17-18, 22.

Doctor Weigl ordered serologic testing for various allergens, hepatitis viruses, and borreliosis. Pet. Ex. 9.<sup>33</sup> The only positive test was for borrelia burgdorferi. This bacteria is the causal agent of Lyme disease and may cause various skin conditions, including dermatitis and erythema.<sup>34</sup>

Although I was unable to find a medical record indicating why it was ordered, Pet. Ex. 8, pp. 4-7 contain an EKG tracing, machine-dated August 3, 2001, and stamped with the name of Dr. Klaus Strasburg. There is no report accompanying the EKG tracing.

In early September 2001, Mrs. Walton saw a doctor who ordered a number of laboratory tests. No record explains why the tests were ordered or who ordered them. Petitioner's Exhibit 8, p. 8, consists of two pages, the second page of which is a continuation sheet of test results from the previous page.<sup>35</sup> Mrs. Walton tested positive for the coxsackie virus at a 1:80 level on a complement fixation reaction test. The virus was typed as A9 and B1-B6. The report contains the following comment in reference to the coxsackie virus test: "conspicuous titer-value: serologic indication for acute or shortly suffered infection," and suggested obtaining another sample to permit sub-typing the coxsackie B virus. *Id.* (second p. 8).

An EKG was performed on September 11, 2001 and reflects that Mrs. Walton was experiencing some atrial tachycardia.<sup>36</sup> Pet. Ex. 8, pp. 11-12. The atrial tachycardia all occurred between 5-6 PM, one hour of the nearly 19 hours of testing. Her highest recorded heart rate occurred at 4:57, just before the atrial tachycardia began, which would place onset of her tachycardia during the morning hours of September 11, 2001 in the New York and Washington, D.C., time zones.

She saw Dr. W. Kaufmann, an internist, sometime on or before September 28, 2001. Pet. Ex. 8, p. 18. He diagnosed left upper gastric pain, paroxysmal

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<sup>33</sup> Found at 4<sup>th</sup>-7<sup>th</sup> pages of medical records after the TOC.

<sup>34</sup> DORLAND'S at 242 (borrelia burgdorferi), 20 (acrodermatitis), and 638 (erythema).

<sup>35</sup> This exhibit is a translation of the German medical report, as are most of the documents appearing in Pet. Exs. 8 and 9. I note that European standard paper sizes are slightly longer than the American standard of 11 inches. Thus, the translator may have attempted to keep the original page numbering with regard to these exhibits, resulting in two pages being numbered as page 8.

<sup>36</sup> Atrial tachycardia is a rapid heartbeat, usually between 160 and 190 beats per minute, originating from the heart's atrium, or upper chamber. DORLAND'S at 1850, 818-19.

supraventricular tachycardia ["PSVT"],<sup>37</sup> and an increased resting heart rate. Underneath these two diagnoses appear underlined "possible" diagnoses: a coxsackie viral infection with myocardial involvement and myocarditis caused by receiving a "vaccination in an influenza infection." Pet. Ex. 8, p. 18. As the immigration physical examination and medical history taken at the time of Mrs. Walton's MMR vaccination contain no mention of a current illness, I conclude that the information regarding influenza infection must have come from Mrs. Walton or a medical record made after her return to Germany. Doctor Kaufmann also recorded current symptoms, including heart palpitations, chest tightness, weight loss, anxiety, and dizziness. *Id.*

The history Mrs. Walton provided to Dr. Kaufmann indicated that after the MMR vaccination on March 30, 2001, she had temperatures of between 37 and 38 degrees Celsius (which convert to 98.6-100.4 degrees Fahrenheit),<sup>38</sup> a skin rash on her stomach and on her left side eight to ten days after the vaccination, a left-sided headache, and left axillary pain. She also reported experiencing tachycardia, anorexia, heat intolerance, and a drop in performance. Pet. Ex. 8, p. 18. Other than the headache, none of these symptoms appears on the records generated on April 30, 2001 at Pro Med when she returned for the second MMR vaccination or on the Seton Hospital records for the same date.

Doctor Kaufmann also noted a "timely correlation with symptoms following vaccination" and that a skin rash was "still" present. *Id.* He had Mrs. Walton perform an exercise EKG. After only one minute of exercise, her heart rate increased to 160 beats per minute, then fell slowly when she was permitted to rest. *Id.*, p. 19. Doctor Kaufmann considered this EKG indicative of "hemodynamic coronary cardiopathy or myocarditis." *Id.* He indicated that healing from "an existing" viral infection might take anywhere from four weeks to several years. *Id.*, p. 20. He also ordered a 24-hour EKG. *Id.*, p. 19. He referred to an echocardiogram<sup>39</sup> ["ECG"] performed on September 6,

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<sup>37</sup> PSVT is a periodically occurring attack of rapid heartbeat with both sudden onset and sudden cessation. DORLAND'S at 1850.

<sup>38</sup> I checked my conversion of degrees Celsius to degrees Fahrenheit with two on-line conversion programs with both yielding results identical to my calculations.

<sup>39</sup> An echocardiogram is an "ultrasound procedure used to evaluate the structure and function of the heart." It is used to diagnose a variety of cardiac ailments. MOSBY'S LABS at 927-29. Many of the German medical records use the abbreviation "ECG" for electrocardiogram. An echocardiogram and an electrocardiogram are different tests. An electrocardiogram measures, as its name implies, electrical impulses of the heart. An echocardiogram uses sound waves to graph heart activity. DORLAND'S at 585 (echocardiography) and 595 (electrocardiogram and electrocardiography). When I use either the "EKG" or the "ECG" abbreviation, I have ascertained which test was actually performed from the description in the records or have relied upon the testimony of a cardiologist about the test.

2001, which was normal,<sup>40</sup> a 24 hour EKG on September 11, 2001, which showed intermittent PSVT, and yet another EKG on September 20, 2001, which was normal. *Id.*

Petitioner's Exhibit 9 contains a "medical attestation" on the letterhead of N. Nabo and H. Dworatzek.<sup>41</sup> The letterhead identifies them as "Medical Practitioners, Naturopathic Treatment, Spa-Doctors" in Bad Abbach, Germany. The attestation reflected a medical history, the dates Mrs. Walton was seen, and a recommendation for part-time work. The dates of treatment were listed as October 1 and 12, 2001; June 14, 2002; July 2, 2002; and July 21, 2003. The form is dated October 2001, which is obviously an error, considering the dates of treatment listed. The diagnosis appears to have been a "strong suspicion of Coxsackie-carditis (B33.2, V) with paroxysmal supra-ventricular arrhythmia (tachycardia) with pronounced exhaustion pathology in October 2001"; the code "B33.2, V" is not explained.

The history reflected Mrs. Walton's trip to the U.S. in December 2000, during which Mrs. Walton had influenza. It recorded her January 5, 2001 treatment at Seton Hospital in Austin for bronchial asthma. It recited the history of the MMR vaccination, followed by fever of 37-38 degrees Celsius, a skin rash after 8-10 days, left sided headache, tachycardia, and drop in performance. The history indicated that the second MMR vaccination was not given because of a reaction to the first vaccination, and recorded that reaction as neck pain, headache, drop in performance, continued tachycardia, inability to drive a car, skin rash (occurring two weeks post-vaccination), high heart rate, and a "long-time" EKG with a pulse rate of 160 beats per minute in the first minute. It noted a "skin rash still there." It appears that at least part of this history was taken from Dr. Kaufmann's records, discussed, *supra*. Given the absence of most of these symptoms in the medical records from Pro Med and Seton Hospital, it does not appear that the history was drawn from the contemporaneous records of treatment in the U.S; there was no EKG performed in March 2001 and no records of any tachycardia until the September 11, 2001 EKG.

A large gap in the medical records exists between September 2001 and May 9, 2004.<sup>42</sup> Although the signature of the doctor is illegible on the May 9, 2004 record, the letterhead is that of Dr. Kaufmann. He recorded a pulmonary function test on April 21, 2004, which demonstrated a slight obstructive ventilation disorder without clinical significance. A resting EKG on that same date showed a sinus rhythm and a heart rate of 60 beats per minute, no heart valve dysfunction and no pericardial effusion. Pet. Ex. 9, pp. 18-19.

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<sup>40</sup> Doctor Kaufmann did not note any abnormalities in the ECG. Doctor Brinker, respondent's cardiologist, commented on this absence, testifying that there was no evidence of heart muscle disease in the tests Dr. Kaufmann reviewed. Tr. at 152-53.

<sup>41</sup> This exhibit is on the 14<sup>th</sup> page after the TOC.

<sup>42</sup> Found on the 18<sup>th</sup>-19<sup>th</sup> pages from the first record after the TOC.

This record also included the results of a stress EKG on April 26, 2004, which reflected significantly decreased physical performance in comparison to Mrs. Walton's age group. The report concluded that Mrs. Walton's myocarditis was no longer active and recommended a physical conditioning program. *Id.*

In July 2004, Dr. Jürgen Pahnke diagnosed Mrs. Walton with bronchial asthma. Because of her previous tachycardia, he treated her with Atrovent<sup>43</sup> alternating with a short-acting beta-2 agonist. He noted that the prescribed beta-2 agonist (Sultanol DA) could cause cardiac palpitations or tachycardia. Pet. Ex. 9.<sup>44</sup>

The gap between Mrs. Walton's diagnosis with myocarditis in September 2001 and her treatment by Dr. Kaufmann in May 2004 is partially explained by a psychiatric report indicating that Mrs. Walton suffered from depression and panic attacks in the summer of 2002. She was an in-patient in a psychiatric hospital from December 16, 2003 through March 2, 2004. Doctor G. Vogl, the author of the psychiatric report, indicated that he had treated her since March 10, 2003. He opined that her depression was aggravated by the beta blocker (Beloc Zok Mite) she took for her viral myocarditis. A reduction in the beta blocker dosage improved her mood swings and mood. Pet. Ex. 9.<sup>45</sup>

In August 2004, Mrs. Walton was seen again by Dr. Kaufmann, who now opined that her myocarditis had been caused "after vaccination in an influenza infection."<sup>46</sup> He found her to be in stable health, with no cardiopulmonary decompensation while resting, and recommended increased physical conditioning. Pet. Ex. 13, pp. 1-2.

Doctor Kaufmann also provided an opinion supporting the now-abandoned claim of a vaccine-strain measles infection in a letter to petitioner's counsel on December 30, 2004. In the same letter, he stated that Mrs. Walton was weakened by the influenza she suffered in December,<sup>47</sup> and therefore suffered an adverse reaction to the MMR vaccination on March 30, 2001. Doctor Kaufmann also indicated that Mrs. Walton had another MMR vaccination on April 30, 2001, a statement at odds with all the other

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<sup>43</sup> Inhalation aerosol used for maintenance treatment of chronic obstructive pulmonary disease. PDR at 995.

<sup>44</sup> The 32<sup>nd</sup> page of medical records following the TOC .

<sup>45</sup> The 36<sup>th</sup> page of medical records following the TOC.

<sup>46</sup> While the signature is illegible, the letterhead is that of Dr. Kaufmann. His earlier diagnosis had been less definitive. He had opined in September 2001 that she had PSVT, with two "possible" additional or differential diagnoses: coxsackie viral infection with myocardial involvement or myocarditis caused by receiving a vaccination while having an influenza infection.

<sup>47</sup> Although the letter indicates that she suffered the infection in December 2004, it is clear from the context that Dr. Kaufmann was referring to the December 2000 illness.

evidence in this case. He suggested that the headache that led to her CT scan on April 30, 2001 could have been an encephalopathy.<sup>48</sup> Pet. Ex. 16, pp. 1-2.

It is obvious that Dr. Kaufmann was attempting to place Mrs. Walton's symptoms and diagnosis into one of the Vaccine Table injuries for the MMR vaccine. His opinion addressed each of the Table injuries for the MMR vaccine, opining that the vaccine did not cause three of the Table injuries: anaphylaxis, chronic arthritis, or thrombocytopenic purpura. The central theme of the letter, however, was the possibility that the vaccine caused the Table injuries of vaccine-strain measles and encephalopathy.

No subsequent medical records were filed. At the hearing, Mrs. Walton testified that she was currently in good health. Tr. at 35.

#### **IV. RESOLVING CONFLICTS IN THE MEDICAL EVIDENCE**

This case thus presents two issues common to most off-Table causation cases: (1) conflicts between contemporaneous medical records and petitioner's subsequent statements, testimony, and medical histories; and (2) the weight to be given to expert medical opinions on causation. Because the medical testimony and expert reports are based on certain assumptions regarding the nature of Mrs. Walton's symptoms and when they developed, I must resolve the factual conflicts in the evidence before considering the medical opinions regarding causation upon which they are based.

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 that the symptoms were not present 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, in affidavits, or in trial testimony. "It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little

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<sup>48</sup> Regardless of the medical merits of any diagnosis of encephalopathy in Mrs. Walton's case, her condition never met the Vaccine Table's definition. According to the Table and the QAI, adult petitioners must demonstrate evidence of an "acute encephalopathy," within 5-15 days of an MMR vaccination. Such acute encephalopathy is defined as "one that persists for at least 24 hours and characterized by at least two of the following: (1) A significant change in mental state that is not medication related; specifically a confusional state, or a delirium, or a psychosis; (2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and (3) A seizure associated with loss of consciousness." The QAI further provide that: "Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group." 42 C.F.R. § 100.3 (b)(2)(i)(C).

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 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).

#### A. Discrepancies in the Evidence.

Mrs. Walton’s accounts of the timing and nature of the symptoms she experienced between December 2000 and September 2001 contain numerous—and significant—discrepancies. While no one expects a patient to provide an identical list of symptoms and dates of onset to each and every health care provider, the degree of variation here is striking. In making the following factual findings, I have generally relied on the contemporaneous medical records. Where other factors buttress or cast doubt upon those records, I have attempted to identify the factors, in addition to the contemporaneous nature of the records, that have influenced my findings.

##### 1. Pre-MMR Illnesses and Relevant Medical History.

I find that Mrs. Walton had a tetanus vaccination on December 2, 2000 and diphtheria and polio vaccinations on December 14, 2000. All three of these vaccinations occurred in Germany.

On January 5, 2001, Mrs. Walton and her then-fiancé visited Seton Hospital in Austin, TX. Mrs. Walton was seeking treatment for dizziness and shortness of breath that had persisted for two weeks. She also reported a cough with the production of yellow sputum, congestion for two or three weeks, and tightness in the chest and shortness of breath in the last 24 hours, and nausea. The two week history places onset of these symptoms on or about December 22, 2000, approximately 20 days after her tetanus vaccination and eight days after her diphtheria and polio vaccinations.

I cannot determine how long after January 5, 2001, these symptoms persisted, but if Mrs. Walton had still been ill at the time of her wedding in February 2001, I believe she would have mentioned that in her affidavit or testimony. I am cognizant that she testified that her respiratory symptoms, shortness of breath, tiredness, and dizziness persisted from her December trip to the U.S. through March 2001, but for the reasons indicated below, I do not accept her testimony as factually correct.

##### 2. MMR Vaccination and Post-Vaccination Symptoms.

Mrs. Walton did not only have an MMR vaccination on March 30, 2001; she had an immigration physical as well. The medical history she provided, the vital signs recorded, and the examination did not record any problems regarding respiratory

ailments or shortness of breath (other than asthma, which she treated with an inhaler when needed), tiredness, or dizziness. Thus, the absence of entries is more significant in this record than their absence might otherwise be, because in performing a physical examination, health care providers are looking at the patient's general state of health.

Mrs. Walton did not contend that she told the doctor performing her physical about health problems persisting after her treatment at Seton Hospital. She did, however, testify that she was still ill from the "flu" she had suffered on her trip to the U.S. and which had prompted the trip to Seton Hospital. She later told her German doctors that she had the flu when she received her MMR vaccination. However, the vital signs and findings in the Pro Med and Seton Hospital records are not consistent with such a persistent illness. There is thus no credible evidence to support a finding that Mrs. Walton received her MMR vaccination while suffering from an influenza infection or any other illness.

The contemporaneous medical records contain no mention of any medical problem post-MMR vaccination until about April 23, 2001. When Mrs. Walton returned to Pro Med for her second MMR vaccination on April 30, 2001, she said that she felt dizzy "last week" that she had fainted "last Tuesday" or "Thurs AM", and had a bad headache for one week. Pet. Ex. 5, p.1. "Last Tuesday" would have been April 24, 2001. These records would place onset of post-MMR vaccination medical problems on or about April 23, 2001 (the beginning of the week prior to her visit). At Seton Hospital, Mrs. Walton told health care providers that she had headache and dizziness "since Thursday," which would have been April 26, 2001. The medical staff at the hospital was concerned enough about Mrs. Walton's symptoms to order a CT scan.

There is no mention of a rash in any post-vaccination medical record until after Mrs. Walton returned to Germany. Comparing Mrs. Walton's own statements (her affidavit and her testimony) regarding the genesis of the rash with the medical records from Pro Med, Seton Hospital, and her treatment in Germany reveals the inconsistencies. Her affidavit stated that the rash began on April 2, 2001. She told her doctors in Germany that the rash began later, a week or two weeks after the vaccination. Mrs. Walton acknowledged that she did not mention a rash to health care providers in the U.S.; her stated reason for the omission did not strike me as a credible one. A person who was anxious about her medical condition, who had been referred from a clinic to a hospital, who provided a cogent history of numerous childhood illnesses, who underwent a CT scan, and who remained in the hospital for over four hours, is unlikely to omit mention of other current symptoms simply because she did not want to appear sicker than she was.

The German dermatologist who first recorded the rash in July 2001 did not indicate that the rash had been persistent for three months, only since a visit to Texas (which had ended in late June or early July). He did not indicate that the rash resembled a measles or rubella rash; instead, he called it contact dermatitis with a differential



diagnosis of lichen ruber planus. He noted the presence of Koebner phenomenon,<sup>49</sup> a characteristic of both contact dermatitis and lichen ruber planus.

The other symptoms reported to her German health care providers as occurring within days to two weeks of her MMR vaccination were fatigue, slight fever, tachycardia, and left axillary pain. Her testimony and affidavit contain inconsistencies regarding the timing of these symptoms, as well as their nature. Mrs. Walton testified to feeling sick and tired, and developing a headache and a rash within a few days of the vaccination. She added heart palpitations to the list of symptoms later in her testimony. Later, she corrected her testimony and said that she was tired, short of breath, and dizzy before the vaccination, but that the rash began after the vaccination. The German medical records indicated that her symptoms began two weeks after the vaccination.

Notwithstanding these discrepancies, I am not concluding that Mrs. Walton deliberately or knowingly testified untruthfully. She acknowledged that she had difficulty remembering details from this period, explaining that she had tried to put her cardiac illness out of her mind and to focus on getting well.<sup>50</sup> For example, she confused when she had a low blood glucose level, testifying that she had low blood sugar tests in April, when test results placed this problem in June 2001, and she referred to an April EKG, when it was actually performed in June. Developing a rash after her June 9, 2001 visit to Pro Med would be consistent with her first report to her German doctor that she had the rash “since” a visit to Texas.

I have no doubt that Mrs. Walton was ill on several occasions during the six months she spent in Texas. There were a number of reasons that she may have attributed her subsequent symptoms to the MMR vaccination and her stay in the U.S. in general. She was ill when she arrived in the U.S.; she missed her job and family;<sup>51</sup> she was angry at her treatment by immigration authorities; and she was frustrated by the requirements for a physical examination and vaccination to alter her immigration status, particularly since she had undergone a physical examination and vaccinations in Germany in the two months preceding her trip. Recalling her treatment by immigration authorities in the U.S. at the hearing some five years later brought her to tears. Notwithstanding her testimony, she was clearly under considerable stress during the first months of her marriage, as she and her husband resolved conflicts about where they would work and reside. Under the influence of these stressors, it would not be

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<sup>49</sup> See footnote 32.

<sup>50</sup> Mrs. Walton testified that her memory might be faulty, saying: “I tried to block everything out now because I am working to be a young woman again, a married woman, and I forgot a lot of things.” Tr. at 23.

<sup>51</sup> Her testimony regarding her state of happiness in the U.S. varied. At one point, she said she was very happy even when she began getting ill shortly after the vaccination (Tr. at 18); she later testified that she was calling her mother every day because she was so ill (Tr. at 24).

unreasonable for Mrs. Walton to conflate or confuse the timing and nature of her symptoms as she described them to her health care providers after her return to Germany.

I also recognize that Mrs. Walton was communicating with health care providers in English, not in her native language, and that this could lead to misunderstandings, a reluctance to use terminology with which she was unfamiliar, or other communication difficulties. I note, however, that she provided clear and cogent testimony at the hearing in English, even though she had not resided in the U.S. for several years prior to her testimony. According to the Pro Med records, her husband was with her when she returned on April 30, 2001,<sup>52</sup> and would thus have been available to remark upon symptoms she neglected to mention. She indicated that she and her husband had discussed her health and possible vaccine side effects.

Even if Mrs. Walton had communication difficulties with her U.S. health care providers, those difficulties would not affect the vital signs or examinations recorded by medical personnel, which were all normal on the date of her vaccination. During the April 30, 2001 visits, her temperature was normal (at Pro Med) or only mildly elevated (99.1 degrees—only one half of a degree of elevation—upon arrival at Seton Hospital). Her heart rate was recorded as 89 beats per minute, which was elevated over her March heart rate but not tachycardic.<sup>53</sup> Her other vital signs (blood pressure and respiration) were entirely normal.

### 3. Onset of Cardiac Problems.

While there is no indication that health care providers specifically inquired about cardiac symptoms during either of her April 2001 treatments, nothing in the medical histories Mrs. Walton provided or the examinations performed suggested cardiac problems in a young woman. Had Mrs. Walton mentioned any cardiac complaints to either Pro Med or Seton Hospital health care providers or presented with any symptoms of concern on April 30, 2001, I am reasonably confident that one or both of these medical facilities would have documented and explored them. I base this conclusion in part on what Pro Med did when Mrs. Walton reported cardiac symptoms in June 2001: Pro Med staff performed an EKG. I find that Mrs. Walton did not complain of any cardiac symptoms until June 6, 2001, more than two months after her vaccination. The EKG performed then was normal. She did not have any abnormal cardiac tests before early September 2001, and was not diagnosed with myocarditis until late September 2001.

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<sup>52</sup> Pet Ex. 5, p. 1.

<sup>53</sup> Tachycardia is defined as a heart rate in excess of 100 beats per minute. DORLAND'S at 1850. An elevated heart rate not amounting to tachycardia is not uncommon in an individual who is anxious or stressed.

## B. Summary and Effects of Factual Findings.

In short, I do not find sufficient indicia of reliability in Mrs. Walton's later accounts of her post-vaccinal symptoms to credit those accounts in lieu of or in addition to those described in the contemporaneous medical records. To be more specific, there is no credible evidence that Mrs. Walton suffered either a rash or cardiac symptoms (racing heart, chest pain, or palpitations) within 60 days of her vaccination. There is no credible evidence that she suffered from dizziness, lightheadedness, syncope, or headache within one to three weeks of the MMR vaccination. The probable onset (or return) of these symptoms was on or after April 23, 2001. The symptoms of dizziness, shortness of breath, and chest tightness reported in January 2001 occurred prior to her MMR vaccination and within one to three weeks of her vaccinations in Germany.

To the extent that the doctors who testified in this case relied upon Mrs. Walton's accounts of the nature or timing of symptoms to opine on vaccine causation, I find an insufficient factual basis for their opinions. As the Court of Federal Claims has noted, a doctor's "conclusions...are only as good as the reasons and evidence that support them." *Davis v. Sec'y, HHS*, 20 Cl. Ct. 168, 173 (1990). When an expert's opinion is based upon facts not established by the record, a fact-finder may reject the expert's opinion. *Bradley v. Sec'y, HHS*, 991 F.2d 1570, 1574 (Fed. Cir. 1993).

## V. APPLICABLE LAW

### A. Issues Presented.

This case presents an issue that appears in most actual causation cases arising under the Vaccine Act: the credibility of the experts testifying and the plausibility and reliability of their opinions. This case also presents the issue of what constitutes a *prima facie* case of vaccine causation, including the nature of petitioner's obligation, if any, to rule out alternate causes, and the role that evidence of a factor unrelated to a vaccine may play in determining if petitioner has established a *prima facie* case.

### B. Legal Standards to be Applied.

#### 1. In General.

Petitioner need not show 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 "substantial factor" in causing the condition and was a "but for" cause is 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). Circumstantial evidence and medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano*, 440 F.3d at 1325.

When a petitioner alleges an “off-Table” injury, eligibility for compensation is established when the petitioner demonstrates, by a preponderance of the evidence, that: (1) petitioner received a vaccine set forth on the Vaccine Injury Table; (2) she received the vaccine in the United States; (3) she sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the problem has persisted for more than six months.<sup>54</sup> 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. Currently, vaccine litigation is most often focused on the issue of whether the injury alleged was caused by the vaccine.

## 2. Causation and the *Prima Facie* Case.

Petitioner must present evidence of a reliable medical theory. Thus, the trier of fact must determine the reliability and plausibility of the expert medical opinions offered and the credibility of the experts offering them. When petitioners establish entitlement to compensation, the burden shifts to respondent to establish, “also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.” *Whitcotton v. Sec’y, HHS*, 17 F.3d 374, 376 (Fed Cir. 1994), *rev’d and remanded sub nom. Shalala v. Whitcotton*, 514 U.S. 268 (1995). Determining when the burden shift occurs is complicated by the two meanings that have attached to the term “*prima facie* case” in Vaccine Act decisions.

In its classic sense, a *prima facie* case is a case that could withstand a motion for summary judgment. In the context of the Vaccine Act, this would mean that if the evidence filed established all the statutory requirements, including, in off-Table cases, some evidence that the vaccine was responsible for the injury, petitioner’s case could not be dismissed on motion for summary judgment and the burden of production would shift to respondent.

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<sup>54</sup> 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 second meaning of “*prima facie* case” involves the point at which petitioner’s evidence tips the balance in favor of vaccine causation. The difference between the two meanings of “*prima facie*” rests on the principle that, outside the summary judgment arena, not all evidence carries equal weight with a trier of fact. Medical opinions on causation may be based on medical histories that are factually incorrect or the opinion may be made by someone without the necessary training, education, or experience to offer a reliable opinion. An expert may offer an opinion that is 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”). At this point, the burden is not one of production, but rather one of persuasion.

Thus, in off-table Vaccine Act cases, the term “*prima facie* case” is frequently used to indicate the point at which the trier of fact is sufficiently satisfied that the vaccine is, more likely than not, the cause of the petitioner’s injury. In the language of the Vaccine Act, the burden shifts to respondent to establish by a preponderance of the evidence the existence of causation to “factors unrelated to the administration of the vaccine.”<sup>55</sup>

For those who are the fact-finders, this is a somewhat artificial distinction, because it implies that there is a precise point in a case, other than in a motion for summary judgment, when the burden of production becomes one of persuasion. See *Althen*, 418 F.3d at 1278 (burden shift occurs when there is adequate evidence of each of the three factors). Often, there is no specific point in a case where this occurs, which is in keeping with the Vaccine Act’s requirement that a special master consider all the evidence in determining whether to award compensation. Section 300aa-13(a)(1) provides that the special master shall award compensation when the record as a whole demonstrates entitlement.

The Vaccine Act clearly contemplates that the special masters will weigh the evidence presented in determining 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 before the special master determines whether a *prima facie* case has been established. Special masters

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<sup>55</sup> Section 300aa-13(a)(1)(B).

weigh the evidence found in the medical records (see, e.g., *Ryman*, 65 Fed. Cl. at 40-41); 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)); as well as considering 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, e.g., *Burns v. Sec’y, HHS*, 3 F.3d 415, 417 (Fed. Cir. 1993) (credibility determinations uniquely within the special master’s purview). See also, *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 (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).<sup>56</sup> If petitioner fails to establish one or more of the *Althen* factors, 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 some other method, respondent may stymie petitioner’s efforts to establish a *prima facie* case.

### 3. Burden Shifting.

Even in Table injury cases where there is a statutory presumption of causation, the Vaccine Act contains a requirement to demonstrate “that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine

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<sup>56</sup> 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.”

described in the petition.”<sup>57</sup> Whether this is a requirement placed on petitioners—to prove the absence of causes other than the vaccine—or a means by which respondent may rebut evidence of causation is the subject of some controversy. In Table cases, a petitioner has no obligation to rule out other possible causes. See, e.g., *Whitcotton*, 514 U.S. at 270-71. In *Whitcotton*, a Table case, the U.S. Supreme Court indicated that the Vaccine Act implicitly places the burden to prove an alternate cause on the respondent. *Id.* at 275-76.

In off-Table injuries where the evidence raises the issue of alternate causes, it is less clear who has the burden of proof regarding those alternate causes. Some cases suggest that it is petitioner’s burden to rebut other possible causes as part of petitioner’s requirement to prove causation by a preponderance of the evidence. Others suggest that respondent must offer proof that a factor unrelated to the vaccine was causal.

Both positions have merits. On one hand, it seems unreasonable to require a petitioner to prove a negative, that is, the absence of any explanation for her condition other than the vaccination. See *Wagner v. Sec’y, HHS*, 37 Fed. Cl. 134, 139 (1997) (petitioner could not be required to show absence of an explanation other than the vaccine for her condition). Where the record is silent regarding any other possible cause, requiring a petitioner to affirmatively show nothing more than that silence has obvious attraction. When a petitioner establishes all of the statutory requirements, including reliable evidence of each of *Althen’s* three requirements, demanding that petitioner exclude the universe of other potential causes appears to place an impossibly high burden on petitioners.

On the other hand, when medical records or other evidence in the case suggest possible alternate causes for petitioner’s condition, it seems equally obvious that, in order to establish the vaccine’s role as a “substantial factor” or “but for” cause of the injury, petitioner must address why the vaccine is more likely than the other apparent explanations. *Pafford* indicates that when the record discloses other possible causes for the petitioner’s condition, petitioner must show that it was the vaccine, and not one of the other possible causes, that was responsible for her injury, as part of petitioner’s “but-for” burden. *Pafford* 451 F.3d at 1357-59.

In the instant case, whether I analyze the proof in terms of Mrs. Walton’s obligation to exclude alternate causes or in terms of respondent’s obligation to establish a causal factor unrelated to a vaccination, my conclusion remains the same: Petitioner failed to prove by preponderant evidence that the MMR vaccination she received on March 30, 2001 caused, directly or indirectly, her myocarditis. Although the medical records themselves undercut Mrs. Walton’s claim of a vaccine reaction within two days to two weeks of her MMR vaccination and the development of cardiac injury within two months of that vaccine, the medical testimony coupled with the records—indeed, the

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<sup>57</sup> Section 300aa-13(a)(1)(B).

record as a whole—demonstrates her failure of proof.

## VI. EXPERT REPORTS AND OPINIONS

Two doctors testified on behalf of Mrs. Walton: Dr. Fouad Michael testified telephonically and Dr. Bruce Charash testified in person. Additionally, petitioner pointed to the opinion of one of her treating physicians, Dr. Kaufmann, as evidence of causation. Doctors Paul Glezen and Jeffrey Brinker testified on behalf of respondent, with Dr. Glezen testifying telephonically, and Dr. Brinker testifying in person.

The expert testimony and reports focused on Mrs. Walton's diagnosis of myocarditis,<sup>58</sup> when the disease developed, and what caused it. In summary, petitioner's witnesses testified that she developed myocarditis after her MMR vaccination and that the symptoms she displayed after the vaccination were consistent with a vaccine reaction. They advanced several medical theories causally connecting the MMR vaccination with the subsequent development of myocarditis.

Respondent's experts challenged the evidentiary support for Mrs. Walton's claim of symptoms within two weeks of the MMR vaccination, the role her self-reports played in expert opinions, and the lack of any proximate temporal relationship between the vaccination and Mrs. Walton's cardiac complaints or diagnosis. Respondent's experts rebutted petitioner's theories of causation in general and argued that even if Mrs. Walton had myocarditis, she had evidence of two infections unrelated to the MMR vaccination that were far more likely to be causal of myocarditis than her MMR vaccination. The testimony and reports are addressed in more detail, *infra*.

With regard to Drs. Charash, Glezen, and Brinker, I analyzed their reports and testimony in light of the three factors set forth in *Althen*. With regard to Dr. Michael, I concluded that his lack of qualifications rendered his opinion unreliable for the reasons discussed below. With regard to Dr. Kaufman, I have no evidence regarding his qualifications, but his opinion letter of August 2004 is based on myocarditis caused by vaccination during an influenza infection. Because I found no evidence that Mrs. Walton had an influenza infection at the time of her MMR vaccination, I do not find this "possible" diagnosis compelling. In addition, his opinion letter was of marginal value to the issue of causation in this case because of his obvious (and futile) attempts to place Mrs. Walton's diagnosis on the Vaccine Injury Table in the absence of any medical basis to do so.

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<sup>58</sup> One of respondent's experts, Dr. Brinker opined that the medical records did not conclusively establish myocarditis. Tr. at 139-40. Petitioner's treating doctors were also somewhat equivocal on this subject. Compare, for example, Dr. Kaufman's initial diagnosis of PSVT with a possibility of coxsackie carditis or vaccinal myocarditis with his later definitive diagnosis of myocarditis caused by vaccination during influenza and with the medical attestation of coxsackie carditis with PSVT and exhaustion from Drs. Nabo and Dworatzek. Nevertheless, I will continue to refer to Mrs. Walton's illness as myocarditis, as the exact label for her illness is not critical in this off-Table injury case.



## A. Testimony and Report of Dr. Michael.

Doctor Michael's expert report is at Pet. Ex. 17. His curriculum vitae is found at Pet. Ex. 18. Doctor Michael's speciality, otolaryngology (Tr. at 60), is unrelated to cardiology, immunology, or any other discipline relevant to this case.<sup>59</sup> Both the special master previously assigned to this case<sup>60</sup> and I expressed concern to petitioner's counsel, well in advance of the hearing, that Dr. Michael's qualifications to offer an expert report or testimony on the diagnosis, cause, and treatment of Mrs. Walton's condition, were questionable, based on his report and his curriculum vitae. In an order dated September 23, 2005, Special Master Sweeney noted:

While Dr. Michael is qualified to testify about general medical issues and the submitted medical literature, his training and expertise appear to make him ill-suited to testify about Ms. Walton's alleged injuries. While recognizing that decisions concerning petitioner's expert witnesses for hearing lie within the exclusive province of petitioner and her counsel, the special master strongly encourages petitioner to consider retaining an additional expert capable of addressing her alleged injuries.

After the case was reassigned to me, I also encouraged petitioner to consider an additional expert; Dr. Charash's report was filed on August 3, 2006.

The testimony of Dr. Michael at the causation hearing demonstrated that the concerns about his subject-matter expertise were well-founded. His testimony initially focused on whether Mrs. Walton had a medical need for immunization in view of her history of measles infection. This opinion may have been relevant in a medical malpractice lawsuit, but had no relevance to the issue of vaccine causation of myocarditis in a no-fault context, as he did not provide any linkage between myocarditis and an MMR vaccination of someone with a previous measles infection. His opinion that the MMR vaccination was the cause of Mrs. Walton's myocarditis was seriously undercut by his lack of familiarity with the filed medical records, his reliance on a reference article (Pet. Ex.19) later withdrawn from publication, his primary focus on the temporal connection between vaccination and Mrs. Walton's onset of symptoms, and his unawareness of the relationship between the coxsackie virus and myocarditis.

He testified that Mrs. Walton's symptoms began a couple of weeks after her MMR vaccination. Tr. at 62. He cited dizziness, fever, headache, pain, rash, and a racing heart as the symptoms Mrs. Walton displayed at her medical appointment a month after the vaccination, noting that the symptoms began about two weeks earlier. *Id.* at 62-64. He insisted that the U.S. medical records reflected that she had complained of "itchy red

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<sup>59</sup> Doctor Michael is retired from practice. His only publication is a book dealing with health care reform. Tr. at 54.

<sup>60</sup> This case was reassigned to me on February 8, 2006.

spots on her abdomen.” *Id.* at 63-64. His opinion thus relied in part on symptoms that were not contemporaneously recorded and which conflict with the facts as I have found them. When questioned about whether the absence of these symptoms in the medical records would alter his opinion that the vaccination was responsible, he testified that their absence would not affect his opinion. Tr. at 67. He explained that, because some symptoms occurred two to three weeks post-vaccination, those symptoms (headache, dizziness, and syncope) were reflective of a vaccine reaction,<sup>61</sup> but he also stated that these were not early symptoms of myocarditis. *Id.* at 67-68. Stripped of its reliance on Mrs. Walton’s non-contemporaneous accounts of symptoms, his opinion does not logically connect her vaccination with her subsequent illness.

When asked whether the coxsackie virus with which Mrs. Walton had been diagnosed was a possible alternate cause for her myocarditis, Dr. Michael responded: “I don’t know –We have to ask a cardiologist if really the coxsackie is a cause of myocarditis.” I note that both cardiologists testified that the coxsackie virus is causally associated with myocarditis (Tr. at 89 and 138) and that the filed medical literature discloses numerous references to the causal relationship between coxsackie viral infections and myocarditis.<sup>62</sup> He added that it was immaterial if her condition were caused by the coxsackie virus “because there are other viruses that can be incubated within the vaccine.” Tr. at 59. He provided no support for this speculative statement about vaccine contamination. Even assuming this statement to be correct, given Mrs. Walton’s three vaccinations in Germany in December 2000, with subsequent development of shortness of breath, cough, congestion, and dizziness one to three weeks later, Dr. Michael’s opinion on vaccine contamination failed to exclude these vaccinations as source of viral incubation.

Filed concurrently with Dr. Michael’s report in this case was Pet. Ex. 19, an article from the British medical journal, *Lancet*. This article was filed in support of Dr. Michael’s opinion that the MMR vaccine could cause illnesses such as Mrs. Walton’s myocarditis because it demonstrated that “viruses can be genetically changed by accepting genetic material from cell cultures.” Pet. Ex. 17, p. 4. The article itself discussed chronic enterocolitis in children with autism or other neuropsychiatric diagnoses and did not mention cardiac problems, genetic changes in viruses, or viral contamination of vaccines. When cross-examined about his reliance on this article, Dr. Michael was unaware that ten of the twelve authors of the study had formally retracted their findings. Tr. at 69-70. Their retraction was filed as Res. Ex. E; *Lancet*’s comment on the retraction was filed as Res. Ex. F. While a petitioner need not cite medical literature

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<sup>61</sup> By his reasoning, Mrs. Walton’s symptoms in early January 2001 would therefore be related to the tetanus, polio, and diphtheria vaccination she had received in Germany prior to her departure for the United States, as they began approximately one to three weeks post-vaccination. Following his logic to its conclusion, all subsequent symptoms, including the cardiac complaints, would then relate back to the German vaccinations.

<sup>62</sup> See generally, INFECTIOUS DISEASES, Ch. 73.

supporting vaccine causation, a petitioner who offers withdrawn medical literature does not enhance her position regarding causation.

For the foregoing reasons, I placed virtually no reliance on Dr. Michael's testimony or expert report.

#### B. Qualifications of the Other Experts.

In contrast, petitioner's other expert witness, Dr. Bruce Charash, was well-qualified in the field of cardiology.<sup>63</sup> He has appeared frequently as an expert witness; he estimated that he had reviewed "in the range of 500 cases," for both plaintiffs and defendants. Tr. at 74. Approximately 70% of his reviews were for plaintiffs and approximately 90% of his testimony at deposition or trial was for plaintiffs. He explained this disparity between reviews and testimony by noting that more cases reviewed for the defense resolved without the need for testimony. Tr. at 74-75.

Doctor Charash testified about the onset, symptoms and diagnosis of Mrs. Walton's myocarditis, all areas in which he was well-qualified to render a medical opinion. He also discussed three theories concerning how the MMR vaccination may have caused Mrs. Walton's myocarditis. When discussing these theories, Dr. Charash's opinions appeared, at certain points, to stray outside cardiology and into immunology, virology, or other disciplines. In these areas, his testimony was less compelling, often contradicted by the filed medical literature, and reliant upon petitioner's uncorroborated statements, and I accorded it less weight.<sup>64</sup>

Respondent's first witness was Dr. Glezen, who testified telephonically. He is currently a professor of molecular virology and microbiology and the head of the preventive medicine section, Department of Pediatrics, at Baylor College of Medicine in

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<sup>63</sup> As he testified, and as his curriculum vitae indicated, Dr. Charash graduated from Cornell Medical School and is board-certified in internal medicine and cardiology. He taught at Cornell Medical School from 1987-91, and was the assistant and then associate chief of the Cardiac Care Unit at New York Hospital during the same period. He was the chief of the Cardiac Care Unit at Lennox Hill Hospital and taught at the State University Medical College in Brooklyn from 1991-2005. He is currently in private practice and has maintained a faculty appointment at New York University's medical school since 1991. Tr. at 73-74.

<sup>64</sup> I indicated to Dr. Charash during his testimony that, at times, his opinions seemed to lie outside his specialty. He responded that he was opining on infectious diseases only as they related to cardiology. Tr. at 93. Nevertheless, his opinions on how Mrs. Walton acquired her myocarditis, particularly with regard to the biological mechanisms he postulated, stepped somewhat outside the realm of diagnosis, etiology, or treatment. Nothing in his curriculum vitae or list of publications indicated any degree of expertise in or research involving the mechanisms by which various infectious agents cause heart damage, the nature of atypical vaccine reactions, or any interrelationship between vaccination and coxsackie viral infections.

Houston, TX. Respondent's Exhibit B. He is a board certified pediatrician,<sup>65</sup> with training in field epidemiology. Tr. at 112. His curriculum vitae indicates that he has taught in the Departments of Microbiology and Immunology and Pediatrics at Baylor College of Medicine since 1977, and has been the head of the Preventive Medicine Section there since 1989. Res. Ex. B. He has also worked for the Public Health Service and in the epidemic intelligence service at the Centers for Disease Control. Tr. at 112. At the time of his testimony, Dr. Glezen was working on a large field trial of a vaccine nasal spray in children in Texas. Tr. at 112. His curriculum vitae contains an impressive list of publications, primarily regarding infectious diseases, epidemiology, and vaccinations. Res. Ex. B.

Doctor Jeffery Brinker, respondent's second expert witness, holds three board certifications: internal medicine, cardiovascular disease, and interventional cardiology. Tr. at 130. His primary area of practice is with patients suffering from heart disease. He teaches cardiology to post-graduate fellows, house staff, and medical students. He has a clinical practice, participates in institutional reviews, consults with the Food and Drug Administration, and is currently a professor of Medicine and Radiology and Director of the Adult Pacemaker Laboratory at Johns Hopkins University School of Medicine. *Id.*; Res. Ex. D, p. 1. He has an impressive list of publications, most of which are related to myocardial infarctions or interventional cardiology, but none appear to deal directly with immunology, virology, or vaccinations. Res. Ex. D, pp. 4-45.

### C. Causation: Applying *Althen*.

I conclude that Mrs. Walton failed to establish any of the three *Althen* factors by a preponderance of the evidence. The theories Mrs. Walton advanced in support of vaccine causation were not persuasive, the evidence of a logical sequence of cause and effect between vaccination and illness was lacking, and the temporal relationship between vaccination and cardiac illness was too attenuated. To place these conclusions into perspective, it is first necessary to discuss the symptoms and common causes of myocarditis and the diagnosis of Mrs. Walton's cardiac disease.

#### 1. Symptoms and Diagnostic Testing.

The expert witnesses were in general agreement about the symptoms of myocarditis. Early symptoms may be reflective of the causal infection, but dyspnea (shortness of breath or labored breathing), chest pain, malaise, and fever are common. *Id.* As Dr. Charash testified, myocarditis can be flagrant (involving permanent damage to the heart) or it may present less dramatically. Tr. at 80. Some of the less dramatic presentations involve arrhythmias, fatigue, light headedness, and lack of energy. *Id.* at

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<sup>65</sup> Training in pediatrics has more bearing on the issues of diagnosis and causes of myocarditis in this case than might readily be apparent. Myocarditis in infants is a serious illness, with mortality rates in acute infectious myocarditis approaching 50%. Res. Ex. A, Tab 3, INFECTIOUS DISEASES, Ch. 73, p. 569.

81. Syncope might also be a symptom, according to Dr. Charash.<sup>66</sup> *Id.* at 101. Although Dr. Charash's report (Pet. Ex. 20, p. 2) mentioned fever as one of Mrs. Walton's symptoms indicative of myocarditis, he acknowledged that none of the contemporaneous records mentioned a fever and called his report "incorrect" in recording fever as one of her symptoms. Tr. at 83-84, 106. He agreed that the EKG in June 2001 was entirely normal, but did not explain whether he would expect to find a normal EKG in a person with myocarditis. *Id.* at 86.

Doctor Glezen testified that the symptoms of myocarditis would include malaise, fever, shortness of breath, weakness, rapid heart rate, heart blockage, or heart failure. A chest x-ray would show an enlarged heart, often with fluid in the pericardial sac. Ordinarily, an infection serious enough to cause myocarditis would manifest with symptoms that would cause the patient to see a doctor. Tr. at 121.

Doctor Brinker discussed the spectrum of myocardial disease, from an infection with few symptoms that resolves on its own, to an unrecognized infection that develops into chronic heart failure, to something that is quickly identified as myocardial disease. *Id.* at 152. He emphasized the role that chest pain and shortness of breath would ordinarily play in someone with myocarditis. *Id.* at 143. Other symptoms would include fever and an enlarged heart on chest x-ray. Chest pain is often the inducement for patients to seek medical treatment. *Id.* at 136. While he acknowledged that someone with mild myocarditis might not seek medical attention, dizziness caused by myocarditis would result from a dramatically lowered heart rate and the resulting low blood flow to the brain. He estimated that a heart rate of 35-40 beats per minute as the result of myocarditis would be required to produce significant dizziness and he would not suspect cardiac involvement in dizziness associated with a heart rate of 82 or 83. *Id.* at 143-45. Isolated arrhythmias or palpitations or a rapid resting heart rate would be very uncommon presenting signs of myocarditis. Tr. at 136-37. A heart rhythm disturbance such as Mrs. Walton experienced could be related to panic attacks, anxiety, asthma medications, or psychiatric problems. Tr. at 155.

As might be expected in a physician with extensive training and experience in cardiac testing, Dr. Brinker emphasized the role of cardiac tests in the symptoms and diagnosis of myocarditis. He reviewed the EKG performed in June 2001 and agreed with Dr. Charash that it was entirely normal. Additionally, Dr. Brinker interpreted the EKG found in Pet. Ex. 8, pp. 4-7, performed on August 3, 2001, as showing no significant abnormalities. According to Dr. Brinker, myocarditis would only rarely be diagnosed without an abnormal EKG, one demonstrating non-specific repolarization changes, reflected in changes in "ST signals and T waves." Tr. at 136. Tests looking for evidence of an inflammatory process are also used in the diagnosis of myocarditis.

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<sup>66</sup> While Dr. Charash was concerned that the syncope in April 2001 might have been caused by an arrhythmia or heart palpitations (Tr. at 101-02), I have concluded, that based on the thoroughness of the work-up for Mrs. Walton's principal complaint of headache and dizziness and after her self-report of palpitations in June 2001, it is unlikely that she had any cardiac symptoms in April 2001.

These include C-reactive protein and white blood cell counts. Elevated white blood cell counts may indicate an active infection, although in the case of a viral infection, the white cell counts may be depressed. Tr. at 137-38. According to Dr. Brinker, an ECG would be likely to show a decrease in heart function in viral myocarditis. Tr. at 140. He noted that Dr. Kaufmann referred to an ECG on September 6, 2001 as normal. *Id.* at 152.

## 2. Nature and Causes of Myocarditis.

Myocarditis is a disease of the heart muscle that may be caused by viral, bacterial, fungal, or parasitic infections.<sup>67</sup> Myocarditis has also been observed within 10-14 days of smallpox vaccination. INFECTIOUS DISEASES, Ch. 73, p. 569. A definitive linkage to a specific underlying infection involves analysis of pericardial fluid or a heart tissue biopsy. *Id.*, p. 567. In most cases, this testing is not performed, because regardless of the cause, the treatment is rest, with beta blockers used to relieve cardiac symptoms. Tr. at 94,147-48. Both cardiologists testified that coxsackie viral infections are strongly linked to myocarditis; Dr. Charash opined that this particular virus is causal in a “plurality” of the cases in which a cause is identified (Tr. at 89), while Dr. Brinker testified that it is the most commonly identified viral agent in myocarditis. *Id.* at 138. The medical literature supplied by Dr. Glezen indicates that the major infectious causes of myocarditis are enteroviruses (which include coxsackie viruses), and pyrogenic bacteria, but that Epstein-Barr virus, cytomegalovirus, and Lyme disease are also recognized as causal.<sup>68</sup> At least half of the cases of myocarditis in one study cited were found to be caused by group B coxsackie viruses, with influenza viruses responsible for very few cases. *Id.* at 567. Coxsackie virus type A9 had a low or moderate association with myocarditis, while types B1-B6 had a high association with the disease. *Id.* at 568. Abnormal EKG findings (increased or decreased ST<sup>69</sup> segments and arrhythmias) are very common in coxsackie B myocarditis.<sup>70</sup>

Doctor Charash testified that the mumps virus has been linked to myocarditis,<sup>71</sup>

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<sup>67</sup> INFECTIOUS DISEASES, Ch 73, p. 567, Table 73-2; Res. Ex. C, 3<sup>d</sup> page of Dr. Brinker’s opinion.

<sup>68</sup> INFECTIOUS DISEASES, Ch. 73, p. 565.

<sup>69</sup> The electrical waves measured on an EKG are arbitrarily designated by the letters P, Q, R, S, and T. The ST segment of an EKG “represents the period between the completion of depolarization and the beginning of repolarization of the ventricular muscle,” with an elevation in the ST segment indicative of muscle injury. MOSBY’S LABS at 561, 563.

<sup>70</sup> INFECTIOUS DISEASES, Ch. 73, p. 569, Table 73-4.

<sup>71</sup> In testifying about the biological mechanism of Mrs. Walton’s myocarditis, Dr. Charash indicated that he considered an infection directly caused by the MMR vaccine itself the least likely of the three mechanisms he postulated. Tr. at 79-80, 91. His medical theories of causation are discussed in more detail, *infra*.

although he admitted that in an adult patient, more cases would be associated with coxsackie viruses than the mumps virus. Tr. at 90, 92, 93-96. According to Dr. Charash, Dr. Glezen, and Dr. Brinker, medical literature does not link the MMR vaccination to myocarditis. Tr. at 89-90 (Dr. Charash); Tr. at 119 (Dr. Glezen); 140-41 (Dr. Brinker). Doctor Brinker testified that, in those vaccinations linked to myocarditis (the most common being smallpox vaccination), there is a specific clinical presentation in the first two weeks after vaccination: chest pain, serologic evidence of inflammatory reaction, and EKG changes showing ST signal elevation. Tr. at 141. In many cases of myocarditis, no causal agent is identified. Tr. at 151. Dr. Charash indicated that if a vaccine were causal, particularly vaccination for a disease to which the patient had been previously exposed, he would expect a reaction within days. The myocarditis would then progress rapidly over the next four to six weeks after exposure to the inciting agent and he would expect the disease to then be in “full gallop.” Tr. at 96-98. Even in a primary exposure to the causal agent, Dr. Charash would expect to see symptoms after four weeks. *Id.* at 98.

### 3. Mrs. Walton’s Diagnosis: Onset and Timing.

Although for purposes of the Vaccine Act, the label for the illness is not crucial in an off-Table case (*see, e.g., Kelley v. Sec’y, HHS*, 68 Fed. Cl. 84, 100 (2005)), the diagnosis in this case is significant in terms of the expert opinions on the mechanisms of causation and the temporal relationship between the vaccination and onset of relevant symptoms, as well as the eventual diagnosis.

Mrs. Walton was first diagnosed with myocarditis in late September 2001, some five to six months after her MMR vaccination. Doctor Charash testified that “she probably did have myocarditis.” Tr. at 80. His report cited abdominal rash, racing heart, lightheadedness, and dizziness, followed by a diagnosis of arrhythmias two or three months later.<sup>72</sup> Pet. Ex. 20, pp. 1-2. He testified that, given all the facts of the case, myocarditis was “the most likely diagnosis.” Tr. at 80-81. Her June 2001 symptoms of palpitations, rapid heart beat, shortness of breath, and diaphoresis were also consistent with myocarditis, in his opinion. Tr. at 100-04.

He acknowledged, however, that she had symptoms consistent with myocarditis (dizziness, shortness of breath, and nausea) in January 2001, nearly three months prior to her MMR vaccination. *Id.* at 84-85, 103-04. He also agreed that her April symptoms of dizziness and syncope could be caused by conditions other than myocarditis, such as low blood glucose levels. Tr. at 99-100. When pressed to find all the symptoms recorded in his report in the contemporaneous medical records, he admitted that symptoms of generalized weakness, chest pain, pruritic eruption, and fever were not present in any of the medical treatment records in January-June 2001, calling his failure

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<sup>72</sup> He also testified that a rash within a few days of vaccination would be symptomatic of myocarditis. Tr. at 97. Because I do not accept some of the factual underpinnings of this opinion, I do not find his opinion on onset of the myocarditis in April to be persuasive.

to note that “sloppiness” on his part. Tr. at 105-07. He agreed that heart palpitations were not recorded as a symptom until June 2001, although he questioned whether the medical records from Pro Med and Seton Hospital in April 2001 reflected an adequate evaluation of cardiac symptoms because they did not reflect any specific inquiry into such symptoms. Tr. at 107.

In contrast, Dr. Brinker based his analysis of Mrs. Walton’s condition primarily on the contemporaneous medical records. Based on those records, he concluded that she did not display any symptoms suggestive of myocarditis in April 2001. Tr. at 133. Doctor Brinker further opined that, with two EKGs showing heart rates in the normal range, even considering Mrs. Walton’s self-reports of heart palpitations during March through August to be correct, he would consider myocarditis to be an unlikely diagnosis. Despite the Holter monitor<sup>73</sup> on September 11, 2001 showing some abnormalities, Dr. Brinker remained hesitant to attribute Mrs. Walton’s supraventricular tachycardia to myocarditis, because the ECG results during September 2001 were normal, an unusual presentation in viral myocarditis. Tr. at 139-40.

He also noted that the blood tests done in early September 2001 (referring to test results found at Pet. Ex. 8, pp. 8-9) showed a normal C-reactive protein level and normal white blood cell counts, indicating no ongoing inflammatory or immune response. *Id.* Commenting on the titer for coxsackie virus taken at the same time, Dr. Brinker agreed with Dr. Charash’s testimony that two titers would ordinarily be necessary to diagnose an acute disease, but felt the interpretation of the complement fixation test should be left to a virologist, deferring to Dr. Glezen’s opinion. Tr. at 138.

Doctor Glezen was the most qualified of these three experts to comment on the significance of the test results. While he agreed in general with the principle that two titers were a better indication of the timing of the exposure, he asserted that the complement fixation test performed was indicative of a recent infection because the antibodies present were not persistent ones. Tr. at 118-19. He also noted that the laboratory performing the test considered it evidence of an acute or recent infection, and that such a test would indicate exposure during the prior three months. *Id.*

While his report questioned whether Mrs. Walton actually had myocarditis (Res. Ex. C , 4<sup>th</sup> page), Dr. Brinker’s testimony reflected that this was more due to a lack of information in the records, rather than a disagreement with the treating doctor. Tr. at 145-46. Given Mrs. Walton’s cardiac arrhythmia and serologic evidence of coxsackie virus, he thought that a diagnosis of myocarditis was a relatively easy one to make. He would, however, have ordered a more intense work up. He commented that myocarditis

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<sup>73</sup> A Holter monitor records heart rate and rhythm for a period of time up to seventy-two hours. It is used to identify cardiac rhythm disturbances and to correlate them with the patient’s subjective symptoms through a diary completed by the patient. Event recording or monitoring and ambulatory monitoring are other terms used to describe Holter monitoring. MOSBY’S LABS at 587-88. The Holter monitor results appear at Pet. Ex. 8, pp. 11-13.



was “not rare” and that most physicians would default to that diagnosis, in the absence of any other cause. Tr. at 145-46.

#### 4. Medical Theories, Logical Sequence of Cause and Effect and Proximate Temporal Relationship.

Doctor Charash opined that there were three mechanisms by which the vaccine could have “gotten in,” but that only a cardiac biopsy could determine which of the mechanisms was actually responsible. While he could not state with certainty which of them actually caused her to develop myocarditis, he testified that it was more probable than not that the MMR vaccine caused the myocarditis. Tr. at 79-80.

The first mechanism Dr. Charash discussed was inflammation of the heart by a vaccine component. He considered this the least likely of the three mechanisms that he discussed. Tr. at 78. Doctor Glezen criticized this theory, testifying, “if it was possible [for the MMR vaccine to cause myocarditis], we would have seen it by now because millions of doses of the vaccine have been given and this has not been reported.” Tr. at 124.

The second mechanism was the vaccine causing a hypersensitivity reaction or hyper immune reaction, leading to myocarditis. *Id.* at 78-79. Doctor Charash later amplified on this theory, indicating that Mrs. Walton’s prior exposure to the MMR vaccine made a hyper immune response more likely. *Id.* at 86. He explained this in terms of an allergic response: the first exposure creates antibodies; the second exposure triggers the allergic reaction. *Id.* He opined that vaccination of those already immune can lead to immune complex disease in a small number of susceptible people. Tr. at 87. Doctor Glezen again disagreed. He testified that studies show that someone is more likely to react to the first dose of the MMR vaccine than the second dose. Tr. at 123. He was unaware of any risk of developing immune complex disease, even if an MMR vaccination were given during an illness. Tr. at 127. His position is supported by the medical literature accompanying his report. The Morbidity and Mortality Weekly Report, appearing at Res. Ex. A, indicates that side effects of vaccination tend to occur among persons receiving an initial vaccination and are very rare after revaccination. Res Ex. A, Tab 2, MMWR, No. 47, pp. 26, 31. Hypersensitivity or allergic reactions are likewise rare. *Id.*, pp. 27, 34-35. Doctor Charash offered no literature in support of his opinion that MMR revaccination can lead to immune complex disease and his testimony regarding a hyper immune response to vaccination is arguably outside his area of specialization. He offered no testimony or any other evidence associating cardiac disease (an area clearly within his speciality) to hyper immune response and proffered no evidence that his specialty, cardiology, confers any degree of expertise in immune response. A cardiologist’s testimony about the causes of cardiac disease is likely to be reliable evidence. Here, however, Dr. Charash’s opinions did not concern cardiac disease *per se*, but rather the underlying process that could, he posited, lead to cardiac disease. He offered no support for his theories among cardiologists, the medical literature, or medical research. He did not comment on the medical literature filed with

Dr. Glezen's report that contradicted his theory about hyper immune response when someone is vaccinated against a disease to which they have immunity.

The third mechanism Dr. Charash discussed was an immune deficiency, generated by a protein within the vaccine or by illness at the time of the vaccination. Under this mechanism, exposure to a vaccine component leaves the immune system weakened and unable to fight an opportunistic infection caused by another virus. Thus, he theorized, it is likely that Mrs. Walton's myocarditis was the result of a coxsackie viral infection to which she was rendered susceptible by vaccination alone or by vaccination while already ill. Tr. at 79-80, 87. Doctor Glezen acknowledged that the wild measles virus can be immunosuppressive, but opined that immune deficiency was unlikely to occur with the attenuated virus in the vaccine. Tr. at 124. He noted that reactivation of tuberculosis has been observed during a measles infection, but Mrs. Walton, with a history of tuberculosis, showed no reactivation of that disease on the CT scan after her vaccination. Tr. at 124-25.

Doctor Glezen offered the May 29, 1998, Morbidity and Mortality Weekly Report, (filed as Res. Ex. A, Tab 2) as support for his testimony that minor illness is not a contraindication for vaccination (*id.*, p. 33) and that even those with immune system diseases such as HIV who are not severely immunosuppressed may be safely vaccinated. *Id.*, pp. 21-22, 36.

Doctor Charash acknowledged that he could find no medical literature directly supporting his theories of causation. Tr. at 89-90. He explained that the absence of literature did not affect his opinion on causation, either because the occurrence of myocarditis caused by the mumps vaccine<sup>74</sup> was too rare to be reported or that such cases reflected immune system alteration by the vaccine, rendering the system vulnerable to another infectious agent. He was apparently asserting that the other infectious agent would be blamed, rather than the vaccine. He also commented that there was considerable literature regarding cardiac response to injected proteins, but that he considered a reaction to proteins in the vaccine the least likely causal mechanism in Mrs. Walton's myocarditis. *Id.* at 91.

Doctor Glezen opined that it was unlikely that Mrs. Walton's post vaccination symptoms were related to the MMR vaccine based on her natural immunity to measles

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<sup>74</sup> He focused on the mumps component of the MMR vaccine because the wild mumps virus can cause myocarditis directly. Tr. at 92. Doctor Charash pointed to Mrs. Walton's high titer for antibodies to the mumps virus as evidence that she had exposure to mumps prior to her vaccination, because a titer that high would not be based on vaccination alone. Tr. at 93. I note that the MMWR filed as Res. Ex. A, Tab 2, addressed the issue of immune response after one vaccination. The second dose of MMR vaccination is not considered a booster dose because the first dose normally provides immunity. Res. Ex. A, Tab 2, MMWR at 9. More than 97% of susceptible vaccinees developed measurable antibodies to mumps after only one vaccination. *Id.*, at 8. Res. Ex. A, Tab 1, indicates that one dose of MMR vaccine "should be adequate" to protect against mumps in those born after 1957. Res. Ex. A, Tab 1, MMWR, Vol. 54, No. 40, at q2, dated Oct. 14, 2005.

and rubella. The immune response to vaccination in such cases is to stop multiplication of the viruses. Tr. at 114. There is no data linking MMR vaccinations to myocarditis. Tr. at 119. He testified that the more than two month delay between vaccination and the first cardiac symptoms in June made any connection biologically implausible. Tr. at 115, 119.

##### 5. Conclusions Regarding Causation.

In weighing and evaluating the testimony and documentary evidence in this case, I found Dr. Brinker's testimony about cardiac disease, signs and symptoms of myocarditis, and manifestation of cardiac illness in Mrs. Walton to be the most cogent and persuasive. His testimony was grounded in the objective medical records and supported by medical literature. The general acceptance of a theory within the scientific community may affect an assessment of the theory's reliability. *Daubert*, 509 U.S. 594.

While she had some cardiac symptoms (palpitations, shortness of breath, dizziness, and diaphoresis) earlier, there was no clinical evidence consistent with myocarditis before September 2001. I placed great reliance on Dr. Brinker's evaluations of the EKGs performed in June and August 2001 as well as his assessments of the ECG and serological tests. As for evidence of coxsackie viral infection in September 2001, I found Dr. Glezen most qualified to opine on the significance of the test results in light of the type of testing performed. While all three doctors agreed that two titers would be necessary to provide conclusive evidence of how recently Mrs. Walton had been infected, Dr. Glezen's explanation was clear, supported by the opinion of the testing laboratory, and the test was relied upon by the treating physicians for a diagnosis of coxsackie-induced myocarditis.

A medical or scientific theory must be "more than subjective belief." *Daubert*, 509 U.S. at 593. It must be grounded in the methods and procedures of medicine. *Id.* at 590. Well-grounded, but innovative theories may not yet have achieved scientific consensus. Thus, publication in peer reviewed journals is relevant, but not dispositive, in assessing scientific validity. *Id.* at 593-94.

In weighing the medical opinions in this case against *Daubert* and *Althen*, I found Dr. Charash to be far less persuasive than Dr. Glezen or Dr. Brinker. Doctor Charash relied upon assertions of fact not supported by contemporaneous medical records, failed to address the significance of negative cardiac testing, relied upon a temporal relationship between vaccination and onset of symptoms not established by the evidence, failed to demonstrate any support for his theories in research, and failed to address the contrary research evidence submitted by respondent's experts.

Even if I were to accept either Dr. Charash's theory of hyper immune response or his theory of immune suppression, I would still have difficulty in finding a logical connection between the MMR vaccination and Mrs. Walton's cardiac disease. Doctor Charash testified that Mrs. Walton's symptoms in December 2000 (shortly after she

received three vaccinations in Germany) were consistent with early myocarditis. These symptoms preceded her MMR vaccination. Mrs. Walton was ill enough to seek medical treatment in January 2001, whereas after the first MMR vaccination, she did not seek medical attention until the day of her appointment for the second MMR vaccination. Doctor Charash did not explain why the MMR vaccination, rather than the German vaccinations, triggered the hyper immune or immune suppressive response in Mrs. Walton. There was no evidence adduced to suggest that the MMR vaccination aggravated a pre-existing myocarditis.

Perhaps the most significant problem with Dr. Charash's theories of causation is the lack of temporal connection between the MMR vaccination and evidence of a cardiac illness. Both Dr. Brinker and Dr. Charash testified that an acute reaction from a vaccine-caused myocarditis would be expected to manifest within days to two weeks of infection. Both testified that the disease would rapidly progress over the next four to six weeks, at which time the disease would be, in Dr. Charash's words, in "full gallop. Doctor Glezen thought two to three weeks would be needed, and any reaction would be severe enough to cause someone to seek medical treatment. Yet, Mrs. Walton's April 2001 symptoms occurred well over three weeks after her vaccination, and the manifestation of cardiac symptoms (palpitations and borderline tachycardia) did not occur until early June, ten weeks after the MMR vaccination. Even then, her EKG was normal. By her own testimony, Mrs. Walton saw several doctors in Germany between the end of June and August, 2001 and all their testing failed to disclose any cardiac illness. The first objective medical test showing cardiac problems was the September 11, 2001 test, and it showed only a rapid heartbeat over a one hour period out of the 19 hours she was monitored. The diagnosis of PSVT, left upper gastric pain, and possible coxsackie viral infection with myocardial involvement and possible myocarditis came in late September 2001, six months after her vaccination.

## VI. CONCLUSION

Petitioner must present adequate evidence on each of *Althen's* three causation factors. 418 F.3d at 1278. Evidence that the MMR vaccination could, theoretically, cause myocarditis is insufficient. Petitioner must demonstrate, either directly or through circumstantial evidence, that the vaccination caused her myocarditis. In meeting her burden to demonstrate "but for" causation, petitioner must do more than show that the vaccination was "an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford*, 451 F.3d at 1355. She has failed to do so.

Petitioner has not demonstrated by a preponderance of the evidence that her condition was either caused or significantly aggravated by the MMR vaccination she received on March 31, 2001. She has thus failed to establish a *prima facie* case for compensation and the petition for compensation is therefore DENIED.

Because I have concluded that petitioner has failed to demonstrate by preponderant evidence that the MMR vaccination in question caused her myocarditis, it is unnecessary to address whether respondent has provided sufficient evidence of causation by a factor unrelated to this vaccine. *Bradley*, 991 F.2d at 1575. Assuming, *arguendo*, that it is necessary to reach the issue of a factor unrelated, I find by preponderant evidence that Mrs. Walton's cardiac condition was caused by a coxsackie viral infection and that such infection was, more likely than not, unrelated to the MMR vaccination.

In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.

**IT IS SO ORDERED.**

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**Denise K. Vowell**  
Special Master