OFFICE OF SPECIAL MASTERS

No. 98-426V

Filed: May 10, 2002

MATTIE LEMESHA WHITE,	*	
Petitioner,	*	
v.	*	To Be Published
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Donald P. Edwards, Atlanta, Georgia, for Petitioner.

Lisa Ann Watts, United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION

GOLKIEWICZ, Chief Special Master

Petitioner, Mattie Lemesha White, seeks an award under the National Vaccine Injury Compensation Program ("Vaccine Act" or the "Act").[1] After a complete review of the record and for the reasons stated below, the court finds that petitioner is entitled to an award.

[1] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-1 et seq. (West 1991 & Supp. 2001). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

I. PROCEDURAL BACKGROUND

On May 7, 1998, petitioner, Mattie Lemesha White, filed a claim under the Vaccine Act. Ms. White alleged that she contracted Guillian-Barré Syndrome ("GBS")[2] as a result of the measles, mumps, and rubella ("MMR") and adult tetanus vaccinations she received on May 11, 1995. See Petition for Compensation; Petitioner's Exhibit (hereinafter "P. Ex.") 1; P. Ex. 4 at 1, 17; P. Ex. 5 at 10. GBS is not a Table injury, and therefore is not entitled to a presumption of vaccine-causation. 42 U.S.C.A. § 300aa-14(a).

On August 21, 1998, the Secretary of Health and Human Services ("Secretary") filed a report in this matter contesting the sufficiency of the evidence and recommending compensation be denied. Respondent's Report ("R. Rpt."), filed Aug. 21, 1998. The Secretary contended that Ms. White failed to demonstrate that she suffered an injury listed on the Vaccine Injury Table and failed to show that the MMR or tetanus vaccinations actually caused her symptoms of weakness and poor sensation. R. Rpt. at 6-12.

In the Respondent's Report, the Secretary first addressed Ms. White's MMR vaccine. The Secretary asserted Ms. White did not produce any medical literature supporting a causal link between GBS and the MMR vaccine and, thus, Ms. White failed to establish that the MMR vaccine "can cause" and "did cause" her GBS. R. Rpt. at 9-10.

Regarding Ms. White's tetanus vaccine, the Secretary did note that the Institute of Medicine ("IOM") concluded that the evidence "favors a causal relation" between GBS and the tetanus vaccine. R. Rpt. at 10 (quoting Institute of Medicine, Adverse Events Associated with Childhood Vaccines–Evidence Bearing on Causality 86-90 (1994)). Further, the Secretary recognized that Ms. White's treating neurologist, Dr. Albert Cook, is of the opinion that a connection does exist between Ms. White's GBS and her vaccinations. R. Rpt. at 9. However, the Secretary emphasized that GBS is not a rare condition and argued that Ms. White had failed to provide sufficient evidence to demonstrate that the onset of her GBS was not coincidental to the tetanus vaccination. R. Rpt. at 11.

An evidentiary hearing was held in this matter on January 8, 1999. See Transcript of White v. Secretary of HHS, No. 98-426V (hereinafter "Tr."), filed Feb. 5, 1999. Ms. White presented expert testimony from Dr. Albert Cook.[3] Relying upon the timing, collection of symptoms, lack of apparent alternate causes, and "the experience of other clinicians," Dr. Cook

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[2] GBS is an acute febrile polyneuritis, which is a "rapidly progressive ascending motor neuron paralysis of unknown etiology." Dorland's Illustrated Medical Dictionary 1333 (27th ed. 1988).

[3] Dr. Cook's affidavit and curriculum vitae can be found at petitioner's exhibit 9. Ms. White was a patient under Dr. Cook's direct care in the neurology service of Grady Memorial Hospital from July 1995 to January 1998. P. Ex. 9 at 1.

opined that the vaccine was the cause of Ms. White's GBS. Tr. at 127-32. Dr. Cook did admit that he is unaware of any medical literature to support the proposition that the tetanus vaccine causes GBS, aside from the Pollard and Selby Study,[4] an example of recurring onset of GBS. Tr. at 159.

Dr. Neal Halsey[5] and Dr. Barry Arnason[6] testified on behalf of the Secretary. Dr. Halsey testified that given Ms. White's unilateral back pain, abdominal pain, fever, and her treating physician's diagnosis of an infection on her May 30, 1998 visit to Grady Hospital, he believes Ms. White had an infection. Tr. at 165-66. Dr. Halsey stated that Ms. White's infection could have been Campylobacter jejuni.[7] Tr. at 165. Dr. Halsey stressed that the possibility of a Campylobacter infection is important because Campylobacter is "one of the few organisms that there is very clear scientific evidence [indicating it] predisposes [an individual] to Guillain-Barré syndrome." Id.

Dr. Arnason echoed Dr. Halsey's testimony that Ms. White probably had an infection on her May 30, 1998 visit. Tr. at 209. Dr. Arnason opined that Ms. White's description of a hot feeling and her mother's description of the symptoms as fever are both indicative of an infectious process. Id. He stated that the most likely cause of fever is infection. Id. Dr. Arnason testified that an infectious antecedent seems likely, although he was not certain that the infection was Campylobacter. Tr. at 210.

Pursuant to the court's February 23, 1999 Order, the parties submitted their respective post-hearing briefs. One year later the court set forth the appropriate analytical framework for evaluating off-Table, or causation-in-fact, claims. Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001). On May 23, 2001, the court issued an Order directing the parties to present additional briefing addressing the five-prong framework for proving causation set forth in Stevens. Ms. White filed her status report applying Stevens to the

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[4] Petitioner's Supplemental Prehearing Submission, (J.D. Pollard and G. Selby, Relapsing Neuropathy Due to Tetanus Toxoid, 37 J. Neurological Sci. 113, 113-25 (1978)), filed Dec. 16, 1998.

[5] Dr. Halsey's expert report and curriculum vitae can be found at respondent's exhibit C and D. The court is very familiar with Dr. Halsey from previous cases. He is an extremely knowledgeable and a highly credible expert.

[6] Dr. Arnason's expert report and curriculum vitae can be found at respondent's exhibit A and B. The court is very familiar with Dr. Arnason from prior testimony, including that given in Watson v. Secretary of HHS, No. 96-639V, slip opinion at 14-15, 33, 39-40, 2001 WL 1682537, at *10-*11, *22, *27-*28 (Fed. Cl. Spec. Mstr. Dec. 18, 2001), discussed infra.

[7] Campylobacter jejuni is "a subspecies that is a common cause of acute bacterial gastroenteritis in humans." Dorland's Illustrated Medical Dictionary 257 (27th ed. 1988).

facts of her case on July 2, 2001. The Secretary filed his response to Ms. White's application of Stevens on July 25, 2001. On August 17, 2001, Ms. White filed a supplemental brief in response to the Secretary's post-Stevens reply. The Secretary then filed a brief response to Ms. White's supplemental brief on September 10, 2001. On September 27, 2001, Ms. White filed a second supplemental brief.

The case is now ripe for decision.[8] After considering the totality of the record, the court finds that Ms. White demonstrated by a preponderance of the evidence that the tetanus toxoid in-fact caused her GBS.[9] Furthermore, the Secretary has not established by a preponderance of the evidence that a factor unrelated to the vaccine caused Ms. White's GBS. Therefore, the court finds Ms. White is entitled to compensation.

II. FACTUAL BACKGROUND

Mattie Lemesha White was born on April 23, 1977, in Atlanta, Georgia, and was eighteen years old when she went to the Southside Health Clinic on May 11, 1995, to receive her MMR and adult tetanus vaccinations. Petition for Compensation; P. Ex. 4 at 1. Prior to her May 11, 1995, visit to the Southside Clinic, Ms. White was athletic and in good health. Petition for

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[8] The court encouraged the parties to settle the case, especially in light of this court's ruling in Watson v. Secretary of HHS, No. 96-639V, 2001 WL 1682537 (Fed. Cl. Spec. Mstr. Dec. 18, 2001), a tetanus/GBS case. Petitioner was willing; respondent adamantly declined. Respondent's position is confusing. One of the guiding principles of this Program is to treat similarly situated petitioners consistently. See H.R. Rep. No. 99-908, at 3 (1986) ("Part A of the system amends the Public Health Service Act to establish a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons *quickly, easily,* and with *certainty* and *generosity*." (emphases added)). Respondent is in the midst of settling the damages in Watson and has recently settled another tetanus/GBS case handled by my colleague. Absent a clear factor unrelated, one would be hard pressed to distinguish one tetanus/GBS case from another. See 60 Fed. Reg. 56,292 (Nov. 8, 1995) (Secretary's discussion of why GBS was not added to the Table **contrary** to recommendations by the National Vaccine Advisory Committee and the Advisory Commission of Childhood Vaccines). This court has seen similar inconsistent settlement efforts in at least two other types of cases – tetanus/Multiple Sclerosis and tuberous sclerosis cases – some cases settled while other similar cases were litigated to the fullest. Respondent should revisit their settlement policies to ensure conformity to the articulated goals of the Program. See Murakami v. United States, No. 99-55C, 2002 WL 519807, at *8 n. 7 (Fed. Cl. Apr. 4, 2002) (urging the government to reconsider counsel's approach which runs counter to the generosity Congress envisioned when it enacted the Civil Liberties Act of 1988 to redress the relocation and internment of United States citizens and permanent resident aliens of Japanese ancestry during World War II).

[9] At the hearing on January 8, 1999, Dr. Cook, petitioner's expert, did not contend that the MMR vaccine Ms. White received on May 11, 1995, was the cause of her GBS.

Compensation; P. Ex. 1; P. Ex. 4 at 1.

On May 30, 1995, Ms. White visited Grady Hospital complaining of back and abdominal pain. P. Ex. 15. She was treated for a urinary tract infection. Id. On June 12, 1995, Ms. White visited the Southside Health Clinic for a college physical. P. Ex. 4 at 2. During her physical exam, Ms. White indicated she had been experiencing low back pain on her left side. Id. Ms. White was diagnosed with a muscle strain. P. Ex. 4 at 5.

On June 27, 1995, Ms. White returned to Southside Health Clinic due to pain and spasms of the lumbar paraspinal muscles and weakness in her legs. P. Ex. 4 at 3. On June 30, 1995, she returned to Southside Health Clinic to consult with another physician. P. Ex. 4 at 4. She was then referred to Grady Hospital for evaluation. At the hospital Ms. White explained that she had experienced leg weakness during the previous month, in addition to difficulty walking and paresthesia down her left leg over the past two weeks. P. Ex. 5 at 3. She was admitted to the hospital for a presumptive diagnosis of GBS with elevated proteins and lymphocytes in the cerebrospinal fluid. P. Ex. 5 at 4. Electromyelogram and nerve connection studies showed lower extremity demylinating polyneuropathy with left perineal block. Id. Ms. White was discharged on July 6, 1995; she had regained some strength in her legs and was able to walk with the assistance of a cane. P. Ex. 5 at 5.

Although Ms. White initially improved, she subsequently relapsed and was readmitted to the hospital on July 24, 1995, due to some tingling and paresthesias in both feet. P. Ex. 5 at 10. Ms. White received plastmaphoresis treatment and physiotherapy. P. Ex. 5 at 11. She demonstrated improvement in both lower extremities. Id. However, she was unable to ambulate at the time of discharge, and the hospital arranged for home physical therapy on a daily basis. Id.

On September 6, 1995, Ms. White was admitted to Grady Hospital for intravenous therapy. P. Ex. 5 at 16. She was diagnosed with chronic inflammatory demyelinating polyneuropathy ("CIDP"). Id. She started a course in Prednisone and Axid. P. Ex. 5 at 18. She was discharged on September 13, 1995. Id. Ms. White continued physical therapy with the Grady Health System and her condition improved. P. Ex. 11 at 51-52. In January of 1996, Ms. White demonstrated steady improvement and could walk unassisted for short distances. Id. at 31.

In the fall of 1996, Ms. White began college. P. Ex. 3. On September 10, 1996, she had an acute onset of blurring vision and was admitted to Grady Hospital. P. Ex. 11 at 40. An MRI of her head and orbits showed multiple areas consistent with demyelination. Id. at 41.

In January of 1997, Ms. White began visits to a physical therapist closer to her college. P. Ex. 8 at 1. After noticeable improvement, she discontinued the visits in February 1997. Id. at 4. Ms. White suffered optic neuritis in April 1997 and again in May 1997. P. Ex. 11 at 8-9, 12, 42-50, 60, 64-66. Ms. White underwent neurological tests and was diagnosed with multiple sclerosis. Id. at 3-4, 57-59, 69.

III. THE VACCINE ACT AND THE *STEVENS'* CRITERIA

Causation in Vaccine Act cases can be established in one of two ways: (1) through the statutorily prescribed presumption of causation or (2) by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Vaccine Act.[10]

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. Once a Table injury has been established by a preponderance of the evidence, the presumption of vaccine-relatedness may be overcome by an affirmative showing that the injury was caused by a factor unrelated to the administration of the vaccine. 42 U.S.C.A. §13(a)(1)(B).

To demonstrate entitlement to compensation in an off-Table case, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See e.g., Grant v. Secretary of HHS, 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992); Hines v. Secretary of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991). To meet this preponderance of the evidence standard, a petitioner must "show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Secretary of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Secretary of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Secretary of HHS, 9 F.3d 958, 961 (Fed.Cir.1993); Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by a "reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960; see also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986) reprinted in 1986 U.S.C.C.A.N. 6344. While petitioner need not show that the vaccine was the sole or even predominant cause of the injury, petitioner bears the burden of establishing "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. A petitioner does not meet her affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1 at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Nor do petitioners satisfy this burden by merely showing a proximate temporal association between the

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[10] Petitioners must prove their case by a preponderance of the evidence, which requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before [the special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring) (quoting F. James, Civil Procedure 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

vaccination and the injury. Grant, 956 F.2d at 1148 (citing Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) ("inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation.")); Hodges, 9 F.3d at 960. Finally, a petitioner does not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

Ms. White seeks compensation for her GBS which she alleges was caused by the administration of the tetanus vaccine. GBS is not an injury listed in the Vaccine Injury Table. 42 C.F.R. §100.3(a). Therefore, Ms. White does not receive a presumption of causation; however, she is still entitled to compensation in an off-Table claim if she proves by a preponderance of the evidence, or more likely than not, that her condition was in-act caused by the tetanus vaccine. 42 U.S.C.A. §§11(c)(1)(C)(ii)(I) & (II); see also 60 Fed. Reg. 56,293 (Nov. 8, 1995) (Secretary's discussion of not including GBS on the Table but addressing it under the causation-in-fact standard).

In an off-Table or causation-in-fact claim, direct evidence – epidemiology – is the most desirable method for proving the vaccine more likely than not caused the injury. Epidemiologic evidence indicating a relative risk greater than two is sufficient to prove that the vaccine directly caused the alleged injury. Thus, when resolving a causation-in-fact case the court first determines if valid epidemiology exists. See Stevens, slip op. at 16-19, 2001 WL 387418, at *12-*14; see also Liable v. Secretary of HHS, No. 98-120V, 2000 WL 1517672 (Fed. Cl. Spec. Mstr. Sept. 7, 2000).[11] A petitioner successfully demonstrates actual causation through the submission of a relevant and reliable epidemiologic study showing a relative risk greater than two, if she establishes that she falls within the parameters of the study and the respondent fails to prove a factor unrelated. Likewise, if a valid epidemiological study establishes no heightened relative risk, a causal relationship is not proven and petitioner loses. In the absence of an available or valid epidemiologic study, petitioners typically rely on circumstantial evidence to establish a causative link between immunization and injury. Circumstantial evidence can include case reports, manufacturing disclosures, institutional findings, treating physician testimony, and epidemiology evidencing a relative risk less than two.[12]

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[11] Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that Daubert v. Merrell Dow Pharmaceuticals Inc., 43 F.3d 1311, 1320 (9th Cir. 1995), "is useful in providing a framework for evaluating the reliability of scientific evidence." Terran v. Secretary of HHS, 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999). In Daubert, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." Daubert, 509 U.S. at 590. Some application of the scientific method must have been employed to validate the expert's opinion. Id.

[12] Respondent concedes that to establish causation-in-fact epidemiological evidence is not required. Watson v. Secretary of HHS, No. 96-639V, slip opinion at 11, 2001 WL 1682537,

Based upon years of hearing and considering medical testimony from highly reputable experts, the undersigned established an analytical framework for evaluating such circumstantial evidence. Stevens v. Secretary of HHS, No. 99-594V, slip opinion at 36-45, 2001 WL 387418, at *23-*26 (Fed. Cl. Spec. Mstr. Mar. 30, 2001). Under Stevens, a petitioner successfully demonstrates causation-in-fact by a preponderance of the evidence by providing: (1) proof of medical plausibility; (2) proof of confirmation of medical plausibility from the medical community and literature; (3) proof of an injury recognized by the medical plausibility evidence and literature; (4) proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury; and (5) proof of the reasonable elimination of other causes. Stevens, slip opinion at 36-45, 2001 WL 387418, at *23-*26; see also Watson, slip opinion at 26-40, 2001 WL 1682537, at *18-*28 (applying Stevens to assess the strength of petitioner's case).

The court next addresses Ms. White's arguments under the legal standards governing this case.

IV. THE PARTIES' ARGUMENTS

A. Ms. White Argues She Has Satisfied All Five Prongs of Stevens

Ms. White argues that she has met each of the five prongs of the Stevens' evidentiary standard. With regard to proof of medical plausibility, prong one, Ms. White cites medical literature and vaccine jurisprudence to prove that the tetanus toxoid can cause GBS. Petitioner's Stevens Status Report ("P. Status Rpt.") at 2. Ms. White argues that she has also met prong two – proof of confirmation of medical plausibility from the medical community and literature; petitioner relies on IOM reports as demonstrating "the well-established nexus between the tetanus toxoid as a cause of GBS and other demyelinating diseases." Id. To meet her burden under prong three, proof of an injury recognized by the medical plausibility evidence and literature, Ms. White relies on the testimony of her treating physician, Dr. Cook, and the documentary evidence of her medical records. Id. With respect to prong four, proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, Ms. White cites that her first documented complaint of GBS symptoms falls within the time frame provided in the IOM report. Id. at 3. The IOM report indicates a latency period of five days to six weeks between the antecedent event and the first symptoms of GBS; Ms. White's first documented complaint of GBS symptoms nineteen days after the vaccination comfortably falls within these guidelines. Id.; Petitioner's Closing Argument ("P. Closing") at 2, 5; Tr. at 76. After presenting her proof for the initial four prongs of the Stevens' test, Ms. White addresses the more difficult fifth prong, proof of the reasonable elimination of other causes.

To satisfy the fifth prong, Ms. White relies on Dr. Cook's testimony and the medical records. Id. at 4. Ms. White argues reasonable efforts were made to rule out other causes. Petitioner cites Dr. Cook's testimony that HIV, the most highly suspected precipitant cause of

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at *8 (Fed. Cl. Spec. Mstr. Dec. 18, 2001).

GBS at Grady Hospital, was tested for and excluded as a possible cause of her GBS. Petitioner's Supplemental Response Brief at 2; Tr. at 88; P. Ex. 9 at 4. Further, according to Dr. Cook, Ms. White "had no other systemic signs that suggested the importantly definable infectious process, such as sore throat, fever, things that make you think of a diptheroid infection" and, therefore, she lacked the symptoms which would motivate consideration of other potential underpinnings for her illness. Tr. at 78; P. Closing at 5. Ms. White argues that, as required by Stevens, her treating physician took reasonable steps to consider and eliminate the more likely causative agents of her illness. P. Status Rpt. at 4.

Ms. White acknowledges that the fifth prong is central to the Secretary's position, but argues that the Secretary relies on a "nearly impossible standard" of requiring that she exclude a subclinical infection as the cause of her GBS. Id.

B. The Secretary Argues Ms. White Fails to Meet the Requirements of Prong Five

The Secretary argues that the fifth prong of the Stevens' test "does no more than prove that vaccine-causation is possible – not probable" and does not comport with existing evidentiary standards established by case law. Respondent's Response to Petitioner's Status Report ("R. Response to P. Status") at 2. The Secretary states several objections to the Stevens' approach and argues that the Stevens' analysis has the potential to create a Table injury for GBS. Id. at 7.[13]

Although the Secretary does not agree with the Stevens' approach, he argues that even if it is applied in this case Ms. White fails to meet all five prongs. The Secretary does not dispute that Ms. White has met the first four prongs of the Stevens' evidentiary standard. R. Response to P. Status at 8. The Secretary cites the IOM's conclusion that tetanus toxoid can cause GBS; thus, Ms. White meets prong one, medical plausibility, as well as prong two, confirmation of medical plausibility from the medical community and literature. Id. The Secretary also agrees that Ms. White has demonstrated that she suffered GBS, prong three, and that the time frame for the disease is consistent with causation, prong four. Id.

[13] Respondent paints the Stevens' decision as a judicially created Injury Table. Respondent's argument is off the mark. The Vaccine Injury Table was created by legislative fiat and refined through rulemaking. Both processes invoked policy considerations. See 60 Fed. Reg. 56,291 (Nov. 8, 1995) ("Making recommendations to change the Table invokes the difficult task of balancing scientific concerns and public policy concerns."). Stevens, on the other hand, represents an analytical framework utilized by countless highly credible experts testifying before the undersigned over the past fourteen years. This court accepts the fulfillment of that framework as sufficient to meet the preponderance standard. That the standard as articulated in Stevens runs counter to respondent's legal reasoning and is published in five steps to promote efficiency and consistency does not make it incorrect or judicial rulemaking, it makes Stevens informative and guiding.

However, with regards to prong five, the Secretary argues that Ms. White has failed to eliminate other known causes because she did not take all reasonable steps to rule out subclinical infections known to be causally associated with GBS. Id. The Secretary presents that medical literature accepts that some cases of GBS are preceded by subclinical infections. Id. at 9; R. Ex. G at 1440 (explaining the ways in which a viral infection could cause GBS). The Secretary argues that a reasonable means exist to exclude subclinical infections, yet the record fails to show that Ms. White was tested for subclinical infections strongly associated with GBS. Id.

V. REVIEW OF THE TESTIMONY

A. Mattie Lemesha White

At the hearing on January 8, 1999, the petitioner detailed her symptoms and the progression of her condition. Tr. at 10-34. She explained that on May 30, 1995, she began experiencing pain in her back, in her buttocks, and in her thigh on her left side. Tr. at 16. She visited Grady Hospital where she was diagnosed with a urinary tract infection. Tr. at 16-19. She was given Motrin, antibiotics, and told to drink plenty of water. Tr. at 19. Ms. White testified how her condition continued to regress. In late June she was walking in a stooped position, was falling down, and was unable to climb stairs. Tr. at 23. Ms. White stated that it was when she visited the Grady Hospital Emergency Room on June 30, 1995, that she was first diagnosed with GBS. Tr. at 24-25.

On cross-examination, she explained that her affidavit, P. Ex. 1, was prepared with the help of her mother; she wrote the affidavit and her mother typed it. Tr. at 36. Ms. White's mother, Rosa White, testified, "Some of it I wrote, some of it she [Mattie White] wrote and broke it down. I [Rosa White] typed it. That is how it was done." Tr. at 58. The affidavit is significant because on direct examination Ms. White testified that she did not have any fever, Tr. at 18; however, her affidavit indicates, "Within two weeks after the vaccine, I noticed my first reaction to the vaccine. My symptoms consisted of fatigue, *slight fever*, lower back pain, pain in my buttocks and thighs." P. Ex. 1 (emphasis added); Tr. at 37. Ms. White stated that she did not actually take her own temperature, but used the description of slight fever in her affidavit because she "felt hot." Tr. at 38.

During cross-examination, counsel for the Secretary questioned her about the medical history in three of her medical records. First, counsel for the Secretary asked Ms. White about a medical record from her May 30, 1995 visit to Grady Hospital that indicated upper quadrant abdominal pain for one month (preceding the vaccine). P. Ex. 15. Ms. White said she did not remember giving this history. Tr. at 41. Counsel for the Secretary then inquired about a June 12, 1995 record which indicated low back pain on the left side for one week. P. Ex. 4 at 2. Ms. White stated that she did remember giving that history either. Tr. at 42. Finally, the Secretary's counsel turned to a medical record prepared on July 31, 1995, which indicated the patient "had flu-like illness two weeks prior to beginning of leg weakness or the leg weakness onset associated with an MMR vaccine." R. Ex. N at 98. Ms. White did not recall making these

statements. Tr. at 43. Importantly, however, she conceded that she was the informant for each of these records. Tr. at 41.

B. Dr. Cook

Dr. Albert Cook, who is certified by the American Board of Psychiatry and Neurology with added qualifications in Clinical Neurophysiology and who has seen twenty to thirty cases of GBS, testified for Ms. White. Tr. at 61-163, 247-54.

Dr. Cook met Ms. White on July 1, 1995, shortly after she was admitted to Grady Memorial Hospital. Tr. at 62-63; P. Ex. 9 at 1. At that time, Dr. Cook was Director of the EMG Laboratory, as a faculty member of Emory University in the Department of Neurology. Tr. at 62; P. Ex. 9 at 5. Dr. Cook explained the factors which led to Ms. White's admitting diagnosis of GBS, including details of the electrodiagnostic clues which support her diagnosis. Tr. at 64-68. He also stated that fever is not noted in Ms. White's medical records. Tr. at 71-72. Dr. Cook testified that Ms. White "had no other systemic signs that suggested the importantly definable infectious process, such as sore throat, fever, things that make you think of a diptheroid infection and, again, it seemed unreasonable to consider occupational exposures to toxic substances." Tr. at 78.

When questioned about the medical record of May 30, 1995, documenting Ms. White's complaints of abdominal pains, Dr. Cook explained there were no abdominal films taken or antimedics prescribed (medicines that treat nausea, vomiting, and gastrointestinal symptoms). Tr. at 94. He said this suggests the "treating physician was more impressed by the degree of back pain that the patient had than by any abdominal symptoms that she may have had." Id. When questioned by the court why Ms. White was given an antibiotic, Dr. Cook indicated that it was a "relatively short course antibiotic" and was probably given "because of the bad urinalysis result that says leukoeterase is 1 plus." Tr. at 95. Dr. Cook also stated that there is no abdominal pain indicated at the June 12,1995 or June 27, 1995 Southside Health visits. Tr. at 96-97. When asked if statistically most people who present with GBS also have Campylobacter jejuni, Dr. Cook testified that for their facility "Campylobacter was not the most common cause of Guillain-Barré, HIV was the most common cause." Tr. at 107.

Dr. Cook was questioned about the process of differential diagnosis, the clinician's analytical process of determining the cause of a condition. He defined the process for the court:

> Given a patient that presents with a given set of symptoms, signs, findings, be they clinical or laboratory generated, you typically don't think of just a most likely potential etiology, you think of several possible etiologies that could land the patient in those dire straits and thereafter, you attempt to systematically eliminate one after the other to the best of your ability, again using clinical criteria, laboratory analyses, anything available to you, family history that may let you say this is not very likely, this is much more likely. After a given amount of

> deduction, you may arrive at a single overwhelmingly likely possibility, diagnosis if you want to explain someone's condition, or you may simply be left with two or three that will explain somebody's condition. From that point on, you decide whether it is worth treating any or all of those conditions, serially, simultaneously, what have you.

Tr. at 112. He continued by stating this process was done in Ms. White's case. Id.

During cross-examination, Dr. Cook agreed that he had not ruled out all clinical infections in this case. Tr. at 114. He stated that neither he nor anyone else could rule out clinical infections. Id. When asked if his opinion would change if the May 30, 1995 medical report was taken as factual, he answered yes. Tr. at 122-23. Dr. Cook stated that "if the pain had in fact been present at the time, or actually preceding the administration of the vaccine, [he] would not concur that the Guillain-Barré was in fact caused by the vaccine." Tr. at 123. Dr. Cook agreed that from time to time GBS cases will follow the tetanus vaccine by coincidence, but rejected coincidence in this case because of the "timing, collection of symptoms, [and] experience of other clinicians." Tr. at 131.

The court found Dr. Cook to be a highly credible witness. In addition to his experience with GBS, Dr. Cook, as the treating physician, was extremely knowledgeable about Ms. White's particular case, exhibited reasoned judgment, and expressed cogent arguments in advancing his opinions.

C. Dr. Halsey

Dr. Neal Halsey, a medical epidemiologist Board Certified in Infectious Disease, testified for the Secretary. Tr. at 163-201. Dr. Halsey believes Ms. White presented with symptoms of an infection: "Well, the treating physician diagnosed her as having an infection and I would have to say the presence of fever, abdominal pain, other things . . . that she presented with were consistent with an infection and would be more likely than not to have been an infection." Tr. at 166. He stated that "even if there were no other illness, you know, this [GBS] would be almost certainly a coincidental event." Tr. at 176. Dr. Halsey testified, "the medical record and the testimony we've heard today indicate that there was evidence of an illness." Tr. at 190. He stated that Ms. White:

> indicated that she felt hot, was flushed and her mother presumed it was a fever. I think that that also helps reinforce that there may have been an infectious disease at that time . . ., that is what the diagnosis was and so my opinion has not changed that there was evidence of having an infectious illness on the 30th of May.

Tr. at 192. He did admit, "No one can be one hundred percent certain it was not due to that, to the tetanus toxoid." Tr. at 194.

Dr. Halsey is a highly credentialed, extremely credible witness and this court has benefitted from his testimony in the past. However, his testimony was not critical to the court's resolution of the issue in this case.

D. Dr. Arnason

Dr. Barry Arnason is a renowned expert on GBS and neuroimmunologic disease. He testified:

> That [Ms. White] had an infectious process at some point in time I think is highly likely, given the fact that she describes this hot feeling and she and her mother wrote this description of it which they took to be evidence of a fever at that time and which I take to be evidence of a fever now. Now, the commonest cause of fever is infection. I think she had an infection in relation to this GBS but the precise timing of the hot feeling in relation to the upper quadrant pain is a blur at the moment and I can't sort out the precise chronology there. That there was an infectious antecedent though does seem likely to me, I wouldn't go so far as to invoke Campylobacter necessarily.

Tr. at 209-10. When questioned about the association demonstrated between infections and the subsequent onset of GBS, Dr. Arnason responded that the association is "Extremely strong." Tr. at 210.

Reflecting on the May 30, 1995 record from Grady Hospital which indicated abdominal pain and back pain, Dr. Arnason stated:

> [I]f that report on 5/30 is accurate that there was back pain for one month before, then the back pain goes back not to 5/30 but to 5/1, that is before she had the vaccine. If that is accurate, then I think we all have to agree that the back pain doesn't have anything to do with the vaccine and not only that, but if the back pain has been going on for weeks and weeks then it is really difficult to associate it with the GBS which developed subsequently and then you are left with, well, what was it and the answer is, I don't know.

Tr. at 216-17. On cross-examination, Dr. Arnason agreed that there is no reference by the physician to abdominal pain for the May 30, 1995 visit. Tr. at 221. Dr. Arnason also stated that he was not persuaded that Ms. White had a Campylobacter infection, but that he "was pretty sure she had an infectious illness." Tr. at 229.

The court has heard Dr. Arnason testify several times in the past. See e.g., Watson, slip opinion at 14-15, 33, 39-40, 2001 WL 1682537, at *10-*11, *22, *27-*28. His testimony cannot be easily dismissed or downplayed due to his vast experience with and studies of GBS. However, the court notes that Dr. Arnason clearly believes that one cannot prove a case of

tetanus toxoid caused GBS, except in a rechallenge situation. See Watson, slip opinion at 38-40, 2001 WL 1682537, at *27-*28. His testimony is seen as biased against petitioner due to his preconceived position.

VI. DISCUSSION

The epidemiological evidence filed in this case and relied upon by the parties here is the same submitted in Watson v. Secretary of HHS, No. 96-639V, 2001 WL 1682537 (Fed. Cl. Spec. Mstr. Dec. 18, 2001). In that case, the court examined an epidemiologic study published in the American Journal on Public Health titled "The Risk of Guillain-Barré Syndrome after Tetanus-Toxoid–Containing Vaccines in Adults and Children in the United States." Watson, slip opinion at 21-25, 2001 WL 1682537, at *14-*18; Respondent's Exhibit (hereinafter "R. Ex.") K at 2045-48. The study addressed whether vaccines containing tetanus-toxoid could cause GBS and concluded that if an association between tetanus-toxoid and GBS exists, "it must be extremely rare." R. Ex. K at 2045; Watson, slip opinion at 21-22, 2001 WL 1682537, at *14-*15. Following a hearing addressing the strength of the study where two highly qualified epidemiologists testified, the court found that based on their testimony this epidemiologic study was not dispositive on the issue of causation because it did not sufficiently pinpoint the relative risk. Watson, slip opinion at 20-24, 2001 WL 1682537, at *14-*17. The parties in this case made no convincing arguments to treat the epidemiologic study differently. Therefore, due to the absence of epidemiologic evidence sufficient to accept or reject a causal relationship between vaccines containing tetanus toxoid and GBS, the evidence presented in this case will be evaluated under the Stevens' construct. See Watson, slip opinion at 17-25, 2001 WL 1682537, at *12-*18 (Fed. Cl. Spec. Mstr. Dec. 18, 2001) (discussing inadequate epidemiological evidence regarding tetanus and GBS relationship).

As previously stated, in the absence of epidemiology, a petitioner must provide (1) proof of medical plausibility; (2) proof of confirmation of medical plausibility from the medical community and literature; (3) proof of an injury recognized by medical plausibility evidence and literature; (4) proof of a medically acceptable temporal relationship between the vaccination and onset of the alleged injury; and (5) proof of the reasonable elimination of other causes. Stevens, slip opinion at 36-45, 2001 WL 387418, at *23-*26; Watson, slip opinion at 20-24, 2001 WL 1682537, at *14-*17. Ms. White has indisputably met her burden with respect to the initial four prongs of the Stevens' test. However, Ms. White and the Secretary disagree as to whether she has satisfied her burden with regards to prong five of the Stevens' test.

Prong five requires a petitioner to "affirmatively demonstrate by a preponderance of the evidence that there is no **reasonable** evidence that an alternate etiology is the more probable cause of the alleged injury." Stevens, slip opinion at 43, 2001 WL 387418, at *26 (emphasis added). This does not mean petitioner must exclude "unapparent" or "spontaneous" factors, but does "require petitioner to eliminate *known* potential causes." Stevens, slip opinion at 29-31, 2001 WL 387418, at *20-*21 (emphasis in original). The court stressed that "*reasonable efforts* should be made to rule out *known* causes." Stevens, No. 99-594V, slip opinion at 43-44, 2001

WL 387418 at *26.

In Stevens, the court stated that in determining whether petitioner made reasonable efforts to eliminate known causes, the court values medical experts' opinions of causation based on differential diagnosis.[14] Differential diagnosis is defined as "the determination of which one of two or more diseases or conditions a patient is suffering from, by systematically comparing and contrasting their clinical findings." Dorland's Illustrated Medical Dictionary 461 (26th ed. 1988). Differential diagnosis reflects a critical part of the analytical process doctors engage in while rendering an opinion. Without eliminating to a reasonable degree other potential causes of the injury, in this court's experience, the experts would not give an opinion on a causal connection. Thus, this differential diagnosis, that is, the reasonable elimination of other possible causes, is a critical piece of circumstantial evidence relied upon by the experts. Differential diagnosis is critical to the fifth prong because such a process necessarily excludes a "more probable" cause for the injury other than the vaccine.[15] Medical expert testimony and contemporaneous medical

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[14] Courts have ruled that a differential diagnosis based on sound methodology is admissible under Daubert. See Watson, slip opinion at 29, 2001 WL 1682537, at *19 n.36 (citing Hardyman v. Norfolk & W. Ry.Co., 243 F.3d 255 (6th Cir. 2001) (holding that the trial judge's exclusion of a doctor's testimony based on differential diagnosis was reversible error); Glastetter v. Novartis Pharm. Corp., 252 F.3d 986 (8th Cir. 2001) (upholding district court's exclusion of medical expert testimony based on differential diagnosis when it found the diagnosis scientifically invalid); Cooper v. Smith & Nephew, Inc., 259 F.3d 194 (4th Cir. 2001) (recognizing that a medical expert opinion based upon differential diagnosis normally should not be excluded because "the opinion fails to rule out every possible alternative"); Turner v. Iowa Fire Equip. Co., 229 F.3d 1202 (8th Cir. 2000) (holding medical opinion of causation based upon proper differential diagnosis is sufficiently reliable to satisfy Daubert standard); Heller v. Shaw Indus., 167 F.3d 146 (3d Cir. 1999) (not addressing every possible alternative cause in a differential diagnosis did not render expert's opinion inadmissible); Westberry v. Gislaved Gummi AB, 178 F.3d 257 (4th Cir. 1999) ("a reliable differential diagnosis provides a valid foundation for an expert opinion")).

[15] See Almeida v. Secretary of HHS, No. 96-412V, 1999 WL 1277566, at *21 (Fed. Cl. Spec. Mstr. Dec. 20, 1999) ("The possibility of some other, unknown, unidentifiable [cause] exists in every vaccine case. Scientific certainty, however, is not required. The requisite standard requires a reasonable degree of medical certainty.") (footnote omitted). See also Lampe v. Secretary of HHS, 219 F.3d 1357, 1371, 1373 (Fed. Cir. 2000) (Plager, J., dissenting) (stating that the lack of an alternate cause is a necessary part of petitioner's proof of a logical sequence of cause and effect, not a separate showing in response to the Secretary's factor unrelated evidence, and petitioners' proof here of a "**total lack of evidence of alternative causation, as demonstrated by the negative results from the extensive tests for alternative causes . . . [was] very strong evidence in support of a well developed theory of causation such as the one presented here**." (emphasis added) (citations omitted)).

records, which demonstrate that alternative causes were considered and eliminated, are sufficient proof of completion of a differential diagnosis. Stevens, slip opinion at 43, 2001 WL 387418, at *26. In turn, proof of the differential diagnosis process in a case sufficiently meets the petitioner's burden under prong five to show that reasonable efforts to exclude alternate causes were undertaken. Watson, slip opinion at 35, 2001 WL 1682537, at *26.

The court recently applied these principles in Watson v. Secretary of HHS, No. 96-639V, 2001 WL 1682537 (Fed. Cl. Spec. Mstr. Dec. 18, 2001), a case whose outcome rested on the fifth prong. In that case, the petitioner alleged a vaccine-related injury, specifically GBS, following the administration of a tetanus vaccine. Watson, slip opinion at 1-2, 2001 WL 1682537, at *1. After this court concluded that the existing epidemiology was not dispositive on the issue of causation, the court assessed the strength of petitioner's circumstantial evidence under Stevens. Watson, slip opinion at 16-40, 2001 WL 1682537, at *12-*27. Likewise, in this case, the Secretary conceded that petitioner met the first four prongs under Stevens. Watson, slip opinion at 29, 2001 WL 1682537, at *19. To meet her burden as to prong five, petitioner filed contemporaneous medical records in connection with her injury which demonstrated that "her treating physicians effectively ruled out *apparent* alternative causes of petitioner's GBS by differential diagnosis." Watson, slip opinion at 30, 2001 WL 1682537, at *20 (emphasis in original). For example, the petitioner in Watson presented with symptoms which gave the "impression" she had an infection and she was in turn treated for a yeast infection. Watson, slip opinion at 2-3, 2001 WL 1682537, at *1. However, even with the treatment, petitioner's symptoms worsened. Watson, slip opinion at 3, 2001 WL 1682537, at *2. The petitioner underwent "'numerous tests ... to identify the causes'" of her condition, including routine stool culture laboratory tests which excluded the possibility of Campylobacter jejuni, a known alternative cause of GBS. Watson, slip opinion at 2, 2001 WL 1682537, at *2 (quoting Petitioner's Exhibit 9).

This court ruled that Ms. Watson met her burden as to prong five by demonstrating that her physicians ruled out apparent alternative causes through differential diagnosis. The undersigned rejected the Secretary's argument that the fifth prong precludes consideration of a "'pathological indistinct cause.'" Watson, slip opinion at 30, 2001 WL 1682537, at *20 (quoting Respondent's Response). This court reiterated the federal circuit courts' acceptance of differential diagnosis as a reliable method used to determine causation in an individual case, even when a physician does not rule out every potential cause of the patient's illness. Watson, slip opinion at 31, 2001 WL 1682537, at *20 (citing Cooper v. Smith & Nephew, Inc., 259 F.3d 194 (4th Cir. 2001) (recognizing that a medical expert opinion based on differential diagnosis normally should not be excluded because "the opinion fails to rule out every possible alternative cause of a plaintiff's illness"); Heller v. Shaw Indus., 167 F.3d 146 (3d Cir. 1999) (not addressing every possible alternative cause in a differential diagnosis did not render expert's opinion inadmissible); Westberry v. Gislaved Gummi AB, 178 F.3d 257 (4th Cir. 1999)); see also supra note 15. More importantly, the undersigned clarified the fifth prong of Stevens stating that: "Neither the Act nor caselaw requires petitioner to rule out unapparent infections – to do so would demand proof of causation beyond a reasonable doubt – a standard well beyond what is

required, by the Act or in traditional tort litigation." Watson, slip opinion at 38, 2001 WL 1682537, at *26.

As in Watson, prong five is the crucial issue in Ms. White's case. Here, the Secretary alleges Ms. White's condition is the result of an infection, a known cause of GBS, at the time of her treatment.[16] A high percentage of GBS cases are preceded by infection. See R. Ex. G at 1438 ("Two thirds of patients give a history of an antecedent acute infectious illness that has usually cleared by the time that neuropathic symptoms begin.") (citation omitted) and 1446 ("30 percent of patients recall no obvious antecedent event, although in some a subclinical infection has doubtlessly occurred"). Unless Ms. White can show either that the infection was not apparent or her treaters eliminated the infection as the cause of her illness, she cannot successfully demonstrate that the tetanus vaccine caused her GBS.

Therefore, two questions arise. First, did the petitioner exhibit symptoms of an apparent infection? And, if yes, was the infection effectively ruled out? If there was no clinically apparent infection, no testing was necessary, since there was nothing to reasonably test for. Again, Watson emphatically rejected respondent's argument that petitioners must test for asymptomatic infections to meet the fifth prong. Watson, slip opinion at 33, 2001 WL 1682537, at *20.

Thus, the court now turns to the first question: Did Ms. White exhibit symptoms of an apparent infection?

In this case, the Secretary argues two possible indicators of infection exist: abdominal pain and fever. After a review of the entire record, the court concludes Ms. White did **not** have symptoms suggestive of an infection. In arriving at this conclusion, the court first looked to the contemporaneous medical records. The court relies heavily on the reliability of contemporaneous medical records. See Cucuras v. Secretary of HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Medical records are not created in anticipation of litigation, but for the best care of the patient. The Federal Circuit has instructed:

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

Cucuras, 993 F.2d at 1528.

The medical records indicate that on May 11, 1995, Ms. White presented at Southside Health Clinic for her immunizations; she had a normal temperature and *did not voice any concerns*. P. Ex. 4 at 1 (emphasis added). On May 30, 1995, Ms. White went to the emergency

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[16] GBS is not an uncommon disease, see R. Ex. G at 1437-38, and can be expected to follow vaccinations strictly by chance. R. Ex. A at 3; R. Ex. K.

room. P. Ex. 15. The record from her visit to the emergency room notes left upper quadrant abdominal pain times one month, a normal temperature, and back pain. Id. She was diagnosed with a urinary tract infection, given a short course of Bactrium, and instructed to take Motrin. Id. Ms. White returned to the Southside Health Clinic on June 12, 1995; the medical record from that visit contains two notations of back pain. P. Ex. 4 at 2. The first states that Ms. White complains of low back pain times one week and that she was seen at Grady for the back pain. Id. The second reference reflects a several week history of "low back pain starting in posterior hip region & radiating down thighs posteriorly." Id. On June 27, 1995, Ms. White again returned to Southside. P. Ex. 4 at 3. Her temperature was normal. Id. At that visit, Ms. White stated she did not have any strength in her legs. Id.

The medical records present some conflicting evidence. On May 11, 1995, when Ms. White presented for her immunizations, she did not indicate any health problems or concerns. P. Ex. 4 at 1. However, the emergency room record for Ms. White's visit three weeks later, indicates she had abdominal pain for one month. P. Ex. 15. Thus, the abdominal pain commenced a week before the visit where she reported no health concerns.

When the medical records present a confusing understanding of the situation, the undersigned relies on factual or expert testimony to explain the situation. "As this court has stated previously, discrepancies between the testimony and records or gaps in the medical records are not in and of themselves decisive; clear, cogent, and consistent testimony can overcome such missing or contradictory medical records." Stevens v. Secretary of HHS, No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990) (citing 42 U.S.C.A. § 300aa-13(b)(1); Morris v. Secretary of HHS, No. 89-94V, slip op. at 8 (Cl. Ct. Spec. Mstr. Nov. 5, 1990)).

In this case, Drs. Cook and Arnason offered possible explanations for the apparent discrepancies in the records. Dr. Cook explained that the court can gain a more accurate picture of Ms. White's condition by reviewing where the physician concentrated his efforts according to the May 30, 1995, emergency room record. See Tr. at 252. Dr. Cook stated:

> There is nothing in here that makes me suspicious that that doctor was at all concerned with her abdomen. There are some features of her examination–in other words, if someone comes in with abdominal pain, you are not going to see very many notes recording that the deep end reflexes are 2 plus. People who are at risk for appendicitis, for instances [sic], their reflexes are not routinely checked. They look at the abdomen. Here you have a person who is, in theory, if the nurse's note is to be believed in it's entirety, has some problem with the left upper quadrant, there is nothing in here that shows the doctor was subsequently concerned with her left upper quadrant.

Tr. at 252.

Dr. Cook also noted the prescription for Motrin following the emergency room

examination is somewhat of an anomaly.

> Motrin, which is not a typically prescribed medication for the various gastrointetsinal disorders, is – in fact it is something that you would probably avoid for someone that had significant gastrointestinal problems, it is not the worse of the nuansorials of producing abdominal symptoms in the way of side effects but it is certainly one of the most likely of that class of drugs and providing the patient with Motrin suggests that the treating physician was more impressed by the degree of back pain that the patient had than by any abdominal pain that she may have had.

Tr. at 94.

Dr. Arnason, ultimately, concluded the May 30, 1995 record was unhelpful. Tr. at 209. Dr. Arnason testified:

> Then we obtained this record from the 30th of May and what it says is back pain, left side, left upper quadrant pain, the abdominal pain which we have been through endlessly, and then it says pain times one month and it doesn't specify whether the pain was the left upper quadrant pain or the back pain that has been present for a month but Ms. White said that she doesn't remember the left upper quadrant pain, if it had been present for a month, I am sure she would remember it and, therefore, what this is indicating is that the back pain, if the record is accurate began at the end of April or the beginning of May prior to the vaccination.
>
> . . . .
>
> In any case, if it antedates the onset, the vaccination, then it can have nothing to do with anything else and even if it began in proximity to that visit at the end of May, it would require a month interval between the back pain and the overt onset of the weakness and so on, which is outside of my experience and I don't know of it.

Tr. at 207-09.

Based on the testimony of Drs. Cook and Arnason, as well as the court's review of the emergency room record and other records, the notation of abdominal pain is not helpful in determining the cause of the GBS. Dr. Cook testified that if the abdominal pain existed it was insignificant in relation to the back pain, as evidenced by the examination and medicine prescribed. Dr. Arnason indicated that if the abdominal or back pain[17] predated the vaccine it could not have been caused by the vaccine nor does the pain fit the time frame to be related to her GBS. See Tr. at 208 (Testimony of Dr. Arnason) ("[Back pain] can be a symptom of GBS as I

[17] Dr. Arnason noted the record was unclear as to whether the one month time frame was referring to the back or abdomen. Tr. at 207.

have said, though I am unaware of a back pain that preceded GBS by four weeks let alone eight weeks in the medical literature."). Further, Ms. White's earlier May 11, 1995 medical record makes no mention of persistent abdominal pain. P. Ex. 4 at 1. Her July 6, 1995 Discharge Summary from Grady Memorial recounts that she was seen May 30, 1995 for "low back pain"; there is no reference to abdominal pain. P. Ex. 5 at 3. In a September 26, 1995 record Ms. White related that she went to Southside Clinic in May 1995 for her adult tetanus shot and "two weeks later she started having lower back pains in the flanks and thigh pains which were occurring simultaneously"; there is no suggestion that she also suffered abdominal pains at that time. P. Ex. 6 at 2. Thus, after a careful review of the contemporaneous medical records and the help of the medical experts in interpreting any possible contradictions included therein, the court finds the abdominal pain was not an apparent symptom of an infection when Ms. White presented for treatment.[18]

The second potential symptom of an apparent infection that was heavily relied on by the Secretary's experts was the possibility of fever. In her affidavit, Ms. White described her symptoms to include "slight fever." P. Ex. 1. However, Ms. White testified that she did not have fever when she visited Grady on May 30, 1995. Tr. at 18. She also testified, "From what I remember I didn't have a fever. ... I didn't take my temperature or anything and so I can't possibly say that there was a fever or not." Tr. at 38. Her *medical records, including the visit to the emergency room, do not indicate the presence of fever; in fact, the medical records evidence that she was afrebrile* (without fever). P. Ex. 15. Dr. Cook testified that there was no record of fever in the Grady Hospital records, Tr. at 71-72, or in the June 27, 1995 Southside record, Tr. at 97, and that she had no signs of fever or an infectious process. Tr. at 78. In his testimony, Dr. Arnason also noted, "In the medical record, no fever was recorded." Tr. at 228. With regards to the May 30, 1995 record, Dr. Arnason, testified that "She is not febrile here." Tr. at 222. Hence, the only mention of fever in the record is Ms. White's affidavit prepared on May 1, 1996, nearly a year after the events, indicating her symptoms included "slight fever." P. Ex. 1.

The court finds the contemporaneous medical records, which document Ms. White's actual temperature, more reliable on whether she experienced a fever at the relevant time as compared to Ms. White's affidavit prepared at a much later date, in anticipation of litigation.[19]

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[18] The determination of whether abdominal pain was present is a critical one. Dr. Cook stated that if in fact Ms. White had abdominal pain preceding the vaccine he would not opine that the vaccine caused her injury.

[19] The court notes the Secretary does not argue that petitioner demonstrated signs of a specific infection. The Secretary's general claim of infection relies heavily on Ms. White's description of slight fever in her affidavit. Both Drs. Arnason and Halsey indicated that fever is a strong indication of the presence of infection. See Tr. at 165-66, 209. However, the medical records document Ms. White's temperature at numerous appointments; according to those records, there is no indication that Ms. White was ever febrile.

Therefore, based on the court's review of the abdominal pain and fever evidence from the record and testimony, Ms. White did not demonstrate symptoms of an apparent infection. The evidence presented does not support a finding of the presence of fever or persistent abdominal pain. Ms. White was treated at the emergency room for a urinary tract infection ("UTI"), but the Secretary offered no evidence to suggest that her UTI was in any way related to her subsequent diagnosis of GBS. See also Tr. at 96 (Dr. Cook testified, "I am not aware of any common urinary tract infection causing Guillain-Barre and have not seen it referred to as a potential predisposition in the literature that I've read."). Since the court finds Ms. White did not exhibit symptoms of an apparent infection which could have caused her GBS, it is unnecessary to resolve the second issue of whether an infection was effectively ruled out.

Further, the record shows that steps were taken by the treating physician, Dr. Cook, to rule out HIV, the most common precipitant cause of GBS in patients presenting at Grady Hospital. Tr. at 88. Based on the records and testimony, Ms. White satisfies Stevens' requirement that she demonstrate reasonable efforts were taken to rule out known alternative causes of her illness. Stevens, slip opinion at 43, 2001 WL 387418, at *26.

In so finding, the court reiterates that Stevens states "Reasonable efforts to rule out alternate causes is sufficient to meet the preponderance standard. The reasonableness of the efforts is usually apparent from the medical records." Id. The court does not require exhaustive medical tests to rule out all potential causes when the patient is asymptomatic (having no symptoms of illness or disease). Although numerous medical tests can provide reliable evidence in a court proceeding, exhaustive testing is not always in the best interest of the patient or the best use of medical resources. Doctors consider symptoms to rule out etiologies, to diagnose the patient, and ultimately to render the best treatment and care given the patient's condition and circumstances. A treating doctor's priority is treatment, not necessarily causality. It is unreasonable for courts to establish a test contrary to medical practice. This court will not retrospectively criticize medical treatment which did not definitively rule out all possible precipitants of a condition when the patient does not present with symptoms of the precipitant. The court views the treatment and testing in light of the symptoms present when the patient sought medical care.

By meeting Stevens' five prongs, Ms. White has established her prima facie case as required by the statute. 42 U.S.C.A. §13(a)(1)(A). Before awarding compensation, however, the court must also determine that the injury alleged is not due to factors unrelated to the administration of the vaccine. 42 U.S.C.A. §13(a)(1)(B). Although differential diagnosis – prong five – and the investigation of factors unrelated are two distinct inquiries, they are in reality closely related in that the same medical facts and tests are considered. However, it is important to remember that differential diagnosis is one piece of an analytical framework used by medical experts to opine to a reasonable degree of medical probability that causation exists under the Vaccine Program, see 42 U.S.C.A. §13(a)(1)(A), whereas demonstration of factors unrelated is a legal inquiry mandated by the statute and imposed as a burden upon respondent by case law. See 42 U.S.C.A. §13(a)(1)(B); see O'Connor v. Secretary of HHS, 24 Cl. Ct. 428, 429-30 n. 2

(1991), aff'd, 975 F.2d 868 (Fed. Cir. 1992) (respondent has the burden under 42 U.S.C.A. § 13(a)(1)(B) to show "an actual alternative cause"); McClendon v. Secretary of HHS, 24 Cl. Ct. 329, 333 (1991), aff'd, 41 F.3d 1521 (1994) (the Vaccine Act "implicitly places the onus of proving the existence of an alleged alternative cause squarely on the shoulders of the respondent." (citation omitted)).

As discussed supra, the court found that through the analytical process of differential diagnosis, Dr. Cook eliminated other potential causes of Ms. White's GBS. Likewise, the court finds that the Secretary was unable to establish by a preponderance of the evidence that Ms. White's GBS was caused by an infection or any other factors unrelated to the administration of the vaccine.

VII. CONCLUSION

Based on the foregoing, the court finds, after considering the entire record in this case, that Ms. White is ENTITLED to compensation under the Vaccine Act. Ms. White met her burden on all five prongs of Stevens by a preponderance of the evidence. Furthermore, the Secretary has not established by a preponderance of the evidence that a factor unrelated to the vaccine caused Ms. White's GBS. Damages shall be awarded accordingly at a later time. The court issued a scheduling Order to quickly resolve the issue of the amount of damages to be awarded. The parties are encouraged to work cooperatively toward this end.

IT IS SO ORDERED.

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Gary J. Golkiewicz
Chief Special Master