

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

CHRISTY RANAY FIELDS, *

Petitioner, *

v. *

SECRETARY OF HEALTH
AND HUMAN SERVICES, *

Respondent. *

No. 02-311V
Special Master Christian J. Moran

Filed: May 14, 2008

Entitlement; hepatitis B; Wegener's
granulomatosis; lack of medical
records created contemporaneously

David L. Terzian, Esq., Rawls & McNelis, P.C., Richmond, VA., for petitioner;
Rebecca Trinrud, Esq., United States Department of Justice, Washington, D.C., for respondent.

AMENDED RULING FINDING ENTITLEMENT*

Christy Fields claims that a hepatitis B vaccination caused her to develop Wegener's granulomatosis, a disease that eventually necessitated a kidney transplant. Pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq. (2006), Ms. Fields seeks compensation for this condition. A preponderance of the evidence establishes that she is entitled to compensation.

* Because this published decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the website for the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

All decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, the person submitting the information has 14 days to identify and to move to delete such information before the document's disclosure. If the special master agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access. 42 U.S.C. § 300aa-12(d)(4)(B); Vaccine Rule 18(b).

I. Factual History

Ms. Fields was born on May 1, 1988. Exhibit 17 (affidavit of Mrs. Janet Fields, signed Feb.14, 2002) ¶ 3.¹ Her medical history before Ms. Fields received the first dose of the hepatitis B vaccine at age 12 appears not to be relevant. Respondent has not suggested her health before this vaccination affects the outcome of this case. Resp't Rep't, filed July 11, 2006, at 2.

Ms. Fields received the first dose of the hepatitis B vaccine on November 28, 2000. Exhibit 6 at 12. From this date until she saw her pediatrician, Dr. Alexander, on May 7, 2001, the parties dispute what symptoms Ms. Fields experienced. See Resp't Post Trial Br., filed Feb. 6, 2008, at 2-3, 15-17. The dispute arises from the absence of medical records created between December 2000 and April 2001.

Mrs. Fields explained that although her daughter was continually ill, she did not see a doctor for several months. The Fields lacked medical insurance. Therefore, they were reluctant to visit doctors unnecessarily. Tr. 17. Also, the Fieldses lived in Portales, New Mexico, a small town in a farming community without many doctors. Tr. 9, 21. This inconvenience combined with the lack of medical insurance explains why Ms. Fields did not receive medical attention in the months immediately following her vaccination. Consequently, no documents describing Ms. Fields's health were created between December 2000 and April 2001.² See Resp't Post Trial Br. at 2.

¹ To distinguish between mother and daughter, this opinion will refer to Janet Fields as "Mrs. Fields" and Christy Fields as "Ms. Fields."

² This case is not a case in which petitioner's delay in obtaining medical records caused the loss of records that otherwise would have been available.

Without contemporaneously created documents, the evidence about what happened to Ms. Fields in early 2001 consists of her affidavit, her mother's affidavit, and her mother's oral testimony. Compared to a document created contemporaneously, affidavits and oral testimony are weaker forms of evidence because they depend upon the historian's memory about events that occurred at least one year earlier. Specifically, Ms. Fields signed her affidavit in 2006, her mother signed her affidavit in 2002, and her mother testified orally in 2007. Ms. Fields, herself, chose not to testify at the hearing. Tr. 110.

Perhaps due to the fading of memories, the collective testimony is sometimes inconsistent and sometimes vague. Mrs. Fields's demeanor while testifying indicates that she attempted to testify as accurately as her memory would allow. Any inconsistencies appear to have been caused by the limits of her recollection, rather than an attempt to create a (deceptive) factual record more conducive to her daughter's case. In addition to some inconsistencies, the affidavits either omit facts or mention only vaguely facts that a doctor could find important. For example, Mrs. Fields's first affidavit describes her daughter's health from December 2000 to April 2001 in only three paragraphs.³ Exhibit 17 ¶¶ 5-7.

Despite these limitations, the two affidavits and Mrs. Fields's oral testimony are the most extensive evidence about Ms. Fields's condition from December 2000 to April 2001. If documents created around the time of the events being described existed, this documentary

³ This observation is not intended as a criticism of either Mrs. Fields or the attorney who presumably assisted (or at least reviewed) the affidavit. If the attorney participated too greatly in the preparation of the affidavit, the affidavit could appear staged and the attorney could be suspected of coaching the witness to present helpful testimony. This did not happen here.

On the other hand, attorneys may assist in the process of preserving recollections by eliciting relevant information as affidavits are being prepared. Appropriate questioning may prevent the loss of important details.

evidence would be preferred. Cucuras v. Sec’y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, in this case, there are no such documents. Thus, the collective testimony of Ms. Fields and her mother is the foundation for the following factual findings. See tr. 126 (testimony of Dr. Kaplan, stating that he usually believes what his patients tell him).

As mentioned, Ms. Fields received the first dose of the hepatitis B vaccine at the end of November 2000. After the first dose of the hepatitis B vaccine, Ms. Fields’s most prominent problem was having trouble with her eyes.⁴ Her eyes were red and sensitive to light. Exhibit 30 (affidavit of Ms. Christy Fields, signed October 19, 2006) at 2; see also exhibit 1 at 3 (report from Ms. Fields’s pediatrician, dated April 16, 2001, stating that Ms. Fields was having “chronic red eyes” for five months). The only information Ms. Fields and her mother provided about when the eye problem began was that it began after the first dose of the hepatitis B vaccine, which was November 28, 2000, and before the second dose, which was January 30, 2001.

In December, Ms. Fields also had a runny nose and a fever. The evidence about when Ms. Fields started having a runny nose and fever is an example of when the evidence is inconsistent. In Mrs. Fields’s first affidavit, she stated that her daughter said that she was not feeling well several days after the first dose. Exhibit 17 ¶ 5. In contrast, Mrs. Fields testified that Ms. Fields became ill on the same day as she was vaccinated. Tr. 11. Ms. Fields’s own affidavit provides no information about when her symptoms began. Exhibit 30. Because Mrs. Fields’s affidavit was created approximately five years before she testified, her affidavit is not subject to

⁴ Ms. Fields’s eye problems were “prominent” in the sense that the Fields family focused on them, and not other health issues. The long-term significance of the eye problems is not clear. Neither her expert, Dr. Gershwin, nor respondent’s expert, Dr. Kaplan, could explain whether the eye trouble was the first symptom of the process that was eventually diagnosed as Wegener’s granulomatosis. Tr. 68, 108-09, 154.

the same degree of fading. Therefore, a preponderance of the evidence establishes that Ms. Fields's runny nose, fever and fatigue began on approximately December 1, 2000.

Around Christmas, Ms. Fields slept much more than normal. Exhibit 17 ¶ 5; see also exhibit 1 at 3-4 (report of Ms. Fields's pediatrician stating that she has been increasingly fatigued since December); tr. 11.

In early January 2001, a teacher observed that Ms. Fields's eyes were red. Exhibit 12 (Mandy Hertel statement, signed Feb. 28, 2002). Ms. Fields tried taking over-the-counter eye drops, but these did not help. Exhibit 30 at 1.

The second dose of the hepatitis B vaccine was given to Ms. Fields on January 30, 2001. Exhibit 6 at 12. Ms. Fields was still having problems with her eyes. Exhibit 30 at 1.

After Ms. Fields received the second dose of the hepatitis B vaccine, she developed a cough. Both Mrs. Fields's affidavit and Ms. Fields's affidavit indicate that the cough began after the second dose. Exhibit 17 ¶ 7; exhibit 30 at 1. A preponderance of the evidence establishes that the cough began at the beginning of March. When Ms. Fields saw her pediatrician on April 16, 2001, she reported that she had a cough for six weeks. Exhibit 1 at 3. Consequently, Mrs. Fields's testimony that her daughter's cough began in December, tr. 37; is found inaccurate.

Although Mrs. Fields recalls that her daughter's health deteriorated after the second hepatitis B vaccination, she did not bring her daughter to a doctor for several months. Instead, because Mrs. Fields was primarily concerned about Ms. Fields's eyes, she consulted a local pharmacist who recommended over-the-counter eye drops. When this medicine did not help, the pharmacist recommended that Ms. Fields should see an "eye doctor." Tr. 12; see also exhibit 30 at 1.

On March 29, 2001, Ms. Fields saw Dr. Charles Brooks, an optometrist. An optometrist evaluates the health and visual ability of eyes. Dorland's Illustrated Medical Dictionary (30th ed. 2002) at 1319-20. Mrs. Fields reported that her daughter's eye trouble "had been going on for at least three months," (meaning since the end of December 2000). Dr. Brooks believed that Ms. Fields could have superior limbic keratoconjunctivitis. Dr. Brooks referred Ms. Fields to a pediatric ophthalmologist, Dr. Engstrom. Exhibit 2 at 5. An ophthalmologist is "a physician who specializes in the diagnosis and medical and surgical treatment of diseases and defects of the eye and related structures." Dorland's at 1317.

Dr. Engstrom saw Ms. Fields on April 9, 2001. Dr. Engstrom also believed that Ms. Fields had superior limbic keratoconjunctivitis. He also considered the possibility that Ms. Fields had a "vernal type reaction." Exhibit 2 at 6.

Ms. Fields went to her pediatrician's office April 16, 2001, and on May 7, 2001. On April 16, Ms. Fields saw a certified physician's assistant, Connie Lindsey. Ms. Lindsey recorded that Ms. Fields was having chronic red eyes for about five months and a cough for about six weeks that had worsened over the past two weeks. Ms. Lindsey's assessment was bronchitis. She ordered blood tests and requested that Ms. Fields follow up after the doctors received the results of the blood tests. Ms. Lindsey also provided an inhaler to address Ms. Fields's coughing. Exhibit 1 at 3; tr. 16-17.

During the May 7, 2001 visit, Ms. Fields complained about "generalized fatigue and not feeling well." In some respects, Dr. Alexander understates the severity of Ms. Fields's condition. Mrs. Fields was so worried about her daughter's health that they went to the pediatrician's office

and refused to leave until Dr. Alexander saw Ms. Fields. Tr. 17 -20; exhibit 1 at 3. Dr. Alexander ordered several tests to evaluate her condition. Exhibit 1 at 3.

The results came back two days later. These tests showed that Ms. Fields had an elevated level of blood urea nitrogen (“BUN”) and creatinine. Elevated levels of BUN and creatinine indicate that a person’s kidneys are not functioning well. Dr. Manzoor, a colleague of Dr. Alexander, diagnosed Ms. Fields as suffering from “renal failure, probably secondary to streptococcal infection.” Exhibit 1 at 4. These results prompted a referral to a nephrologist. (A nephrologist is a physician who specializes in the study of the kidney. Dorland’s at 1230.)

The nephrologist, Dr. Gusatavo Espino, saw Ms. Fields on May 9, 2001, in Clovis, New Mexico. Dr. Espino diagnosed Ms. Fields as suffering from “acute or subacute renal failure. . . . The cause of her renal failure is not clear right now.” Dr. Espino sent Ms. Fields to Presbyterian Hospital in Albuquerque, New Mexico, for a kidney biopsy and probable dialysis. Exhibit 25 at 89-90.

Ms. Fields entered the hospital on the next day. She underwent a renal ultrasound. This test showed Ms. Fields had a “renal disease.” She also had surgeries to place a catheter for use during dialysis. When she was discharged after 19 days in the hospital, her list of diagnoses included “Wegener’s granulomatosis . . . , rapidly progressive glomerulonephritis with renal failure.” Exhibit 22 at 4-8, 63.

Both the testifying experts agree with the diagnosis of Wegener’s granulomatosis. Exhibit 31 at 1; exhibit A at 2. Thus, events after Ms. Fields’s diagnosis have little, if any, relevance to deciding the pending question — whether the hepatitis B vaccinations caused the Wegener’s granulomatosis.

A summary of Ms. Fields's history after being diagnosed with Wegener's granulomatosis includes having dialysis care from a local facility. Exhibit 26 at 204-09. During this time, Ms. Fields was taking medication used for chemotherapy. The medication caused side effects, such as losing her hair, nausea and vomiting. Ms. Fields stopped attending school. Exhibit 30 at 1.

Eventually, the disease stabilized sufficiently that Ms. Fields could receive a kidney transplant. The donor was her mother. Exhibit 22 at 68-70.

Since the kidney transplant, Ms. Fields's health has been improved. Despite some hospitalizations in 2004, her health has been generally good. However, she must take medications every day. She also worries that, among other concerns, she will have a problem with her one functioning kidney and will be forced to return to dialysis. Exhibit 30 at 2-3.

II. Procedural History

The petition in this case was filed on April 12, 2002. At that time, the petitioners were Ms. Fields's parents, Philip and Janet Fields, because Ms. Fields had not reached the age of majority. (After Ms. Fields turned 18 years old, the case was recaptioned to reflect that she was the petitioner. Order, dated October 13, 2006. The identity of the petitioner does not affect the outcome in this case.) Ms. Fields filed her first set of medical records in December 2003. She filed several additional sets of exhibits in January and February 2004.

Although not reflected on the docket, this case did not progress for more than a year because the Office of Special Masters, counsel for several petitioners, and counsel for respondent attempted to develop a structure for resolving numerous cases in which petitioners alleged that they suffered harm from receiving the hepatitis B vaccination. Although everyone proceeded in

good faith, ultimately, this effort did not succeed. The case was reassigned to the present special master in 2006, and the case resumed.

Respondent filed his report and stated that the existing record failed to show that Ms. Fields was entitled to compensation. Respondent indicated that Ms. Fields was required to present a reliable medical opinion stating that the hepatitis B vaccination caused her Wegener's granulomatosis. Resp't Rep't, filed July 11, 2006, at 13.

Ms. Fields filed the report and curriculum vitae of her expert, Dr. Eric Gershwin, on January 5, 2007. Exhibits 31-32. She also filed several medical articles that Dr. Gershwin cited, including some that were written in French. Exhibit 33-48. Later, Ms. Fields filed English versions.

In response to Dr. Gershwin, respondent presented the report and curriculum vitae of his expert, Dr. Bernard Kaplan. Dr. Kaplan presented 15 articles.

On May 3, 2007, a status conference was held to schedule a hearing. Primarily because of Dr. Gershwin's schedule, the hearing was set for approximately five months later.

A hearing was held on September 26, 2007. Mrs. Fields testified. Dr. Gershwin appeared via videoconference. Dr. Kaplan testified in person. After the hearing concluded, Ms. Fields filed three articles that Dr. Gershwin said supported his opinion. See exhibits 55-57. In response, respondent filed a letter written by Dr. Kaplan addressing the three articles submitted by Dr. Gershwin. Exhibit C.

On April 9, 2008, this court issued a ruling finding that Ms. Fields was entitled to compensation because she had established, by a preponderance of the evidence, the three factors

identified in Althen v. Sec’y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). This ruling stated that respondent failed to respond to exhibits 55-57.

On April 21, 2008, respondent filed a motion for reconsideration of that ruling stating that the special master erred as a matter of law by not considering respondent’s exhibit C. On May 7, 2008, the parties participated in a status conference to discuss the pending motion for reconsideration. During the status conference, Ms. Fields did not object to granting the motion for reconsideration. Ms. Fields did, however, argue that for the reasons set forth in pages 15-19 of her post hearing brief, exhibit C should not change the result that she is entitled to compensation. Ms. Fields chose not to submit additional argument, but rather chose to rest on what she submitted previously.

On May 8, 2008, the court issued an order granting respondent’s motion for reconsideration. This order also vacated and withdrew from publication the April 9, 2008 ruling. After carefully considering respondent’s exhibit C, the record is complete and the case is ready for decision.

III. Analysis

Deciding this case is difficult because of the paucity of medical information from the date of Ms. Fields’s first vaccination, November 28, 2000, and the date Ms. Fields visited her pediatrician’s office, April 16, 2001. Because Ms. Fields did not see a doctor, no records were created during this time. Additionally, by the time Mrs. Fields and Ms. Fields provided information about Ms. Fields’s condition, the passage of time may have impaired their recollections. Nevertheless, section I, above, sets forth the pertinent findings of fact.

Even with the factual issues resolved, this case remains difficult because two well-qualified experts differ in their opinions as to whether the hepatitis B vaccine caused the Wegener's granulomatosis. To prove that the vaccine caused the Wegener's granulomatosis, the Federal Circuit has set forth what Ms. Fields must establish. The petitioner's

burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health and Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

An analysis of the evidence for these factors leads to the conclusion that Ms. Fields has met her burden. Consequently, she is entitled to compensation.

A. Medical Theory

To present a medical theory, Ms. Fields relies upon the testimony of Dr. Gershwin. Although his theory is somewhat difficult to summarize, a short synopsis is that he believes that immune complexes involving the hepatitis B surface antigen caused Ms. Fields's Wegener's granulomatosis. Respondent challenges the reliability of Dr. Gershwin's medical theory. Resp't Post Trial Br. at 12-15.

1. Dr. Gershwin's Theory

Dr. Gershwin believes that the hepatitis B vaccine can cause Wegener's granulomatosis and that it did, in fact, cause Wegener's granulomatosis for Ms. Fields. On the issue of "can

cause,” Dr. Gershwin reasons that Wegener’s granulomatosis is a form of vasculitis. According to Dr. Gershwin, although not according to Dr. Kaplan, “vasculitis is well known to be a complication of the hepatitis B vaccine.” Exhibit 31 at 3; see also exhibit A at 7. Dr. Gershwin compares Wegener’s granulomatosis to other forms of vasculitis, which some articles have associated with the hepatitis B vaccination.

In regards to Ms. Fields’s case specifically, Dr. Gershwin’s theory seemed to vary at least a little from the theory presented in his report. See Pet’r Post Trial Br. at 14 (describing the presentation of her own case as “a bit disjointed.”) Ultimately, Dr. Gershwin testified to a multi-step process. See Pet’r Post Trial Br. at 10, 13-14 (summarizing Dr. Gershwin’s theory); Resp’t Post Trial Br. at 13 (same). First, the initial dose of the hepatitis B vaccine caused the production of an antibody. (Producing an antibody is the normal response to a hepatitis B vaccination.) However, Ms. Fields’s production of an antibody was abnormal because the production caused her to become sick, to feel fatigued, and to suffer flu-like symptoms. Tr. 83.

Second, Ms. Fields received the next dose of the hepatitis B vaccine. The next dose of the hepatitis B vaccine boosted the response of Ms. Fields’s immune system and exacerbated her condition. This worsening was manifest as a sore throat, fatigue, aches and pains, and a cough. Tr. 59, 62. These symptoms, which are a consequence of Ms. Fields’s primary immune response, could appear at any time from 24 hours to several weeks after exposure to the antigen. Tr. 84.

Third, as part of the process of responding to the hepatitis B surface antigen, Ms. Fields developed immune complexes. Immune complexes are formed when a person’s antibodies bind with an antigen. The creation of an immune complex is part of the usual process for responding

to an invasion of a foreign substance, such as the hepatitis B surface antigen. Usually, the body eliminates (or clears) the immune complex. Tr. 94-95.

Dr. Gershwin theorizes about how Ms. Fields reacted when her body developed immune complexes. Unlike a typical person, Ms. Fields did not clear the immune complexes. Instead, the immune complexes lodged in the endothelial cells in her vessels. The persistence of this immune complex, which Dr. Gershwin describes as a “neo-antigen,” stimulated Ms. Fields to produce another immune response, including the production of anti-neutrophil cytoplasmic antibodies (ANCA). When Ms. Fields responded to the continuing presence of lodged immune complexes, inflammation developed in the endothelial cells of her kidneys. Tr. 61-62, 77, 80-83, 103. Finally, this response to the body’s own tissue constitutes an auto-immune disease, which in this case is Wegener’s granulomatosis. Tr. 97.

In regard to this third step, concerning the failure to clear the immune complexes, Dr. Gershwin does not provide a definite time. The third step must occur after the immune complexes are formed, which is probably a period of weeks. However, the auto-immune response to those immune complexes could occur months or years later according to Dr. Gershwin.

2. Legal Evaluation Of Dr. Gershwin’s Theory

The theory connecting the vaccine to the injury “must be supported by a sound and reliable medical or scientific explanation.” Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994); accord Pet’r Post Trial Br. at 2-3; Resp’t Post Trial Br. at 12.⁵

⁵ In Nussman v. Sec’y of Health & Human Servs., 2008 WL 449656 * 13 (Spec. Mstr. Jan. 31, 2008), mot. for review filed, Fed. Cl. 99-500V (Mar. 3, 2008), a theory proffered by petitioner’s expert was accepted without a discussion as to whether the theory was reliable.

Respondent argues that “Dr. Gershwin has offered an . . . unreliable medical theory.” Resp’t Post Trial Br. at 12. However, Dr. Gershwin’s medical theory is reliable. Therefore, Ms. Fields has met her burden of proving the first prong of Althen.

To determine whether an expert’s theory is reliable, a special master may use the factors set forth Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 594 (1993). Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (affirming special master’s use of Daubert in vaccine program cases). After Terran, decisions from judges of the Court of Federal Claims have consistently cited to Daubert. E.g. De Bazan v. Sec’y of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2000) (“A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness’s testimony regarding causation.”), appeal docketed, No. 08-2013 (Fed. Cir. Dec. 1, 2007); Campbell v. Sec’y of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006); Piscopo v. Sec’y of Health & Human Servs., 66 Fed. Cl. 49, 54 (2005).

Daubert lists several non-exhaustive factors that may be considered in assessing the reliability of the expert’s opinion. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 149 (1999). The factors include whether the expert’s opinion is well accepted in the relevant community. Daubert, 509 U.S. at 594; see also McDowell v. Brown, 392 F.3d 1283, 1299 (11th

Nussman differs from the present case.

In Nussman, respondent did not challenge the reliability of petitioner’s theory. Indeed, respondent’s expert actually agreed that the theory was possible (albeit unlikely). Therefore, there was no need to examine the theory’s reliability.

In contrast, in the present case, respondent actively challenges the reliability of Dr. Gershwin’s theory. The lack of reliability is one of respondent’s main arguments. See Resp’t Post Trial Br. at 12-15. Moreover, Ms. Fields agrees that Dr. Gershwin’s theory must be reliable. See Pet’r Post Trial Br. at 2-3. Under these circumstances, evaluating the reliability of the theory proposed by petitioner’s expert is appropriate.

Cir. 2004) (affirming district court's exclusion of expert whose theory lacked "testing, peer review, a potential error rate, and general acceptance."); Sullivan v. United States Dep't of Navy, 365 F.3d 827, 834 (9th Cir. 2004) (reversing exclusion of expert whose theory was generally accepted).

A closely related factor is how peer-reviewed articles have evaluated a theory. This point may also be considered in weighing the value of a medical opinion. Id.; see also Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364, 1374 (Fed. Cir. 2005); Libas v. United States, 193 F.3d 1361, 1366-67 (Fed. Cir. 1999); Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 354 (5th Cir. 2007) (stating a lack of textual support may "go to the weight, not the admissibility" of the expert's testimony); Waleryszak v. Sec'y of Health & Human Servs., 45 Fed. Cl. 573, 578-79 (1999), appeal dismissed, 250 F.3d 753 (Fed. Cir. 2000). These factors are useful in evaluating Dr. Gershwin's theory.

A critical step in Dr. Gershwin's logic is that the immune complexes are deposited in the endothelial cells of the vessels in Ms. Fields's kidneys. This step is important because if accurate, it constitutes part of the logical sequence between the vaccination, which prompts the creation of immune complexes, and the Wegener's granulomatosis. According to Dr. Gershwin after the deposit of immune complexes, Ms. Fields's immune system attacked these cells causing the inflammation that is a hallmark of Wegener's granulomatosis.

Most of the medical community believes that Wegener's granulomatosis is not causally connected to immune complexes. Medical articles describe Wegener's granulomatosis as an idiopathic disease, meaning science has not found what causes it. Exhibit A, tab 2 (Y.M Takwoingi & J.H. Dempster, Wegener's Granulomatosis: An Analysis of 33 Patients Seen Over

a Ten-Year Period, 28 Clin. Otolaryngol. 187, 187 (2003)) at 1; exhibit A, tab 4 (Wenche Koldingsnes & Hans Nossent, Epidemiology of Wegener's granulomatosis in Northern Norway, 43 Arthritis & Rheumatism 2481, 2481 (2000) at 1; exhibit A, tab 6 (Nabih I. Abdou et al., Wegener's Granulomatosis: Survey of 701 Patients in North America. Changes in Outcome in the 1990s, 29(2) J. Rheumatology 309, 309 (2002)) at 1; exhibit 57 (Menachem Rottem et al., Wegener's granulomatosis in children and adolescents: Clinical presentation and outcome, 122 J. of Pediatrics 26, 26 (1993). Dr. Kaplan stated that a cause for Wegener's granulomatosis has not been found. Tr. 117, 136.

Beyond the general description of Wegener's granulomatosis as idiopathic, one article specifically discussed and rejected a causal role for immune complexes. "[I]n many of the systemic vasculitis syndromes, there is little evidence that immune complexes are involved in pathogenesis. Specifically, elevated levels of circulating immune complexes, systemic complement depletion, and deposition of complement and immunoglobulin in vasculitic lesions are usually not found in Wegener's granulomatosis." Exhibit 44 at 8 (Michael C. Sneller & Anthony S. Fauci, Pathogenesis of Vasculitis Syndromes, 81 Med. Clinics of North America 222, 230 (1997)). Dr. Kaplan agrees with the Sneller and Fauci article. Tr. 125, 133.

Although the Sneller and Fauci article appears to contradict Dr. Gershwin's theory, Ms. Fields diminishes the weight of the Sneller and Fauci article with three points. First, the authors limit their statement by saying that there is "little evidence" and immune complexes "are usually not found." The authors did not say "no evidence" and "are never found." Tr. 148; see also Pet'r Post Trial Br. at 15-18. Second, Dr. Gershwin explained that Sneller and Fauci studied people who were already suffering from Wegener's granulomatosis. By the time the researchers looked

for an immune complex, they could not find one. Tr. 103-04. Dr. Kaplan agreed that the substance that causes a disease can be difficult to find. Tr. 128.

Third, and most important, Dr. Gershwin submitted, after the hearing, two additional articles that addressed whether immune deposits are found in people with Wegener's granulomatosis.⁶ (Dr. Gershwin also submitted a third article on another topic after the hearing.) These studies substantiate that Dr. Gershwin's theory is reliable.

In the first article, the authors recognize that "in most studies no immune deposits were found in biopsies from patients with WG." However, these researchers conducted a new investigation that "found immune deposits in skin but not in renal biopsies." "Thus [the authors] conclude that in contrast with current thinking, immune deposits can be found in, at least, a subset of patients with WG." Exhibit 55 (R H Brons et al., Detection of Immune Deposits in Skin Lesions of Patients with Wegener's Granulomatosis, 60 Ann. Rheum. Dis. 1097, 1101 (2001)).

The second article, which appears written for an audience with more specialized training, appears to confirm the study found in exhibit 55. Exhibit 56 (Mark Haas & Joseph A. Eustace, Immune complex deposits in ANCA-associated crescentic glomerulonephritis: A study of 126 cases, 65 Kidney Internat'l 2145 (2004)). Dr. Kaplan agreed that Haas and Eustace "did find relatively mild staining for glomerular immune deposits in cases of pauci-immune

⁶ Submitting these medical articles before the hearing would have been more efficient. Dr. Kaplan's report discusses the Sneller and Fauci article and questions whether the pathogenesis of Wegener's granulomatosis involves immune complexes. Exhibit A at 7. Thus, Ms. Fields and Dr. Gershwin were aware that the role of immune complexes was disputed and should have submitted literature before the hearing.

Nevertheless, the articles are part of the record, so they must be considered. 42 U.S.C. § 300aa-13.

glomerulonephritis.” Dr. Kaplan argued, however, that the article does not state that the clinical correlations cause the disease and that Ms. Fields, herself, had no immune deposits in her glomeruli. Exhibit C at 2.

Whether immune complexes cause Wegener’s granulomatosis is a point on which the assessment of the medical community may be evolving. The research by R H Brons et al. in 2001 is more recent than the work by Sneller and Fauci in 1997. The current assessment appears to be that immune complexes may play a causal role for the development of Wegener’s granulomatosis.

After evaluating exhibit 55 (Brons) and exhibit 56 (Haas & Eustace), Dr. Kaplan maintains his former position that “there is still no plausible evidence that links Hep B vaccine with WG as manifested in Ms. Fields.” Exhibit C at 2. However, Dr. Kaplan does not reject Dr. Gershwin’s theory absolutely. Dr. Kaplan acknowledges that “one cannot say there is absolutely **no** evidence supporting an immune complex pathogenesis of pauci-immune crescentic glomerulonephritis. However, it must be remembered that what evidence there is remains both weak and speculative.” Id. at 1 (emphasis in original).

Dr. Kaplan offers specific criticisms of exhibit 55 and exhibit 56. The essence of these criticisms is that the articles indicate that immune deposits in the kidneys are rarely found. Thus, Dr. Kaplan believes that the “evidence weighs **against** a role for immune complexes in the pathogenesis of pauci-immune crescentic glomerulonephritis.” Id. (emphasis in original).

Dr. Kaplan’s criticisms and observations are reasonable. As stated previously, the medical community is evaluating whether immune deposits cause Wegener’s granulomatosis.

The opinion of Dr. Gershwin reflects this state of flux. Dr. Gershwin admits that he does not hold his own opinion with 100 percent certainty. Tr. 76-77.

However, petitioners do not have to present opinions with certainty. A mere preponderance of the evidence is required. Bunting, 931 F.2d at 873. The dispute about the causal role of immune complexes in connection with Wegener's granulomatosis highlights the difference between, on the one hand, the amount of evidence that constitutes a preponderance of evidence in civil litigation and, on the other hand, the amount of evidence that scientists recognize as proof. See, e.g., Althen, 418 F.3d at 1280 (stating that the "Vaccine Act's preponderance [of the evidence] standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.") Some people in the medical community, such as Dr. Kaplan, may not accept Dr. Gershwin's theory that immune complexes play a role in causing Wegener's granulomatosis. See exhibit C. Nevertheless, literature indicates that this theory is accepted by some researchers. This acceptance makes Dr. Gershwin's theory sufficiently reliable that it can be considered in this Program in which medical certainty is not required.

Pursuant to the standard used in civil litigation, Ms. Fields has established the reliability of Dr. Gershwin's theory that immune complexes may cause Wegener's granulomatosis.⁷ Therefore, she has satisfied the first prong of Althen.

⁷ Although this ruling disagrees with Dr. Kaplan about the theoretical connection between immune deposits and Wegener's granulomatosis, Dr. Kaplan was a credible witness. He appeared interested in arriving at the correct answer even if the "answer" meant that Ms. Fields was entitled to compensation. See tr. 142.

B. A Logical Sequence of Cause and Effect Showing That the Vaccination Was the Reason for the Injury

Ms. Fields's case does not end with the production of a reliable theory. Instead, she is required to make the theory "persuasive" by demonstrating "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278, quoting Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Ms. Fields has established this prong as well.

The symptoms that Ms. Fields experienced, as found in section I, above, are consistent with Dr. Gershwin's theory and are consistent with the development of Wegener's granulomatosis. After receiving the first dose of the hepatitis B vaccine, Ms. Fields developed eye troubles, a fever, a runny nose, fatigue, and general flu-like symptoms. Ms. Fields experienced these relatively mild problems within approximately two weeks of the vaccination. Exhibit 17 ¶ 5-6. She was so tired in early January that she started to fall asleep during school. Tr. 14.

When people who are eventually diagnosed as having Wegener's granulomatosis first present themselves to a doctor, the clinical features vary. According to one study, which involved 700 patients, fatigue is the most common clinical feature at presentation, occurring in more than one-half of the cases. Sinusitis occurred in slightly less than one-half. Eye problems were relatively less common, appearing in only five percent of the cases. Exhibit A, Tab 6 (Abdou, Survey, at 311 (Figure 3)) at 3. Another study, which involved only 33 subjects, also lists malaise as a common clinical problem. In this study, ocular problems were more prevalent, occurring in 17 patients. Exhibit A, Tab 2 (Y.M. Takwoingi & J.H. Dempster, Wegener's

granulomatosis: an analysis of 33 patients seen over a 10-year period, 28 Otolaryngol. 187, 188 (Table 1) (2003)) at 2. Dr. Gershwin also testified that eye problems are common in children who suffer from Wegener's granulomatosis. Tr. 162, 170. Dr. Gershwin's last point was based upon an article, which he submitted after the hearing. (See footnote 6, above.) That article indicates that 87 percent of the 23 children or adolescents studied presented with problems involving their ears, nose or throat, with sinusitis being the most common clinical symptom. Exhibit 57 (Rottem, Children and Adolescents) at 27.

Ms. Fields's problems in December 2000 and January 2001 are consistent with an onset of Wegener's granulomatosis. Lacking any training in medicine, her parents did not bring Ms. Fields to a doctor. Thus, the problems went untreated.

At the end of January, Ms. Fields received the second dose of the hepatitis B vaccine. Exhibit 6 at 12. Although once again the record is sparse, a preponderance of the evidence establishes that she was still feeling sick. Mrs. Fields's first affidavit, which was signed February 14, 2002, states that she told her daughter's school nurse in January 2001 that "ever since Christy had received her first shot, she had not felt well." Exhibit 17 ¶ 6. When Ms. Fields eventually saw an optometrist, Mrs. Fields reported that Ms. Fields had been having eye trouble since December 2000. Exhibit 2 at 5.

Following the second dose of the hepatitis B vaccine, Ms. Fields "was feeling much worse." Exhibit 17 ¶ 7.⁸ Her eye problems continued. Exhibit 2 at 5.

⁸ Mrs. Fields's affidavit states that Ms. Fields's skin was yellowish, she had a rash, and her hair was falling out. Exhibit 17 ¶ 7. However, when Ms. Fields eventually sees an optometrist, an ophthalmologist, and a pediatrician, these symptoms are not reported. Exhibit 2 at 5-6, exhibit 1 at 3; see also tr. 40-47. Resolving whether Ms. Fields suffered from these other symptoms is not necessary because Dr. Gershwin does not base his opinion on them.

Later, Ms. Fields developed a severe cough and her mother described her lungs as “sound[ing] like they were full of fluid.” Exhibit 17 ¶ 7. Ms. Lindsey recorded that Ms. Fields was having chronic red eyes for about five months and a cough for about six weeks that had worsened over the past two weeks. Ms. Lindsey’s assessment was bronchitis. She ordered blood tests and requested that Ms. Fields follow up after the doctors received the results of the blood tests. Ms. Lindsey also provided an inhaler to address Ms. Fields’s coughing. Exhibit 1 at 3; tr. 16-17.

Respiratory problems are also a common manifestation of Wegener’s granulomatosis. According to an article co-written by Dr. Kaplan, about three-fourths of children with Wegener’s granulomatosis develop lung involvement over the course of the disease. Exhibit A, tab 12 (Madhura Pradhan et al., Wegener’s Granulomatosis – An Atypical Case, 14 *Pediatr. Nephrol.* 862, 866 (2000)) at 5. Other articles come to similar, albeit slightly less common, results. One survey showed that upper airway symptoms occurred in 60 percent of people with Wegener’s granulomatosis. Exhibit A, tab 4 (Koldingsnes & Nossent, Epidemiology) at 4. In another study, a cough was present in 39 percent of the cases. Exhibit A, Tab 6 (Abdou, Survey, at 311) at 3.

Respondent appears to contend that Ms. Fields cannot prevail on this factor because she was not tested for the presence of immune complexes, which are an essential part of Dr. Gershwin’s theory. Resp’t Post Trial Br. at 14, citing tr. 95-96; see also exhibit C (supplemental statement from Dr. Kaplan) at 2 (asserting that Ms. Fields did not have immune complexes). However, “to require . . . proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.” Knudsen, 35 F.3d at 549. Therefore, respondent’s argument is rejected as placing too high a burden on Ms. Fields.

In short, Ms. Fields's history of symptoms is consistent with a slowly developing form of Wegener's granulomatosis. Thus, she has established a "logical sequence of cause and effect showing that the vaccination was the reason for the injury."

C. Timing

The third part of Ms. Fields's burden is to establish "a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278; accord Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1358-59 (Fed. Cir. 2006). Ms. Fields has met her burden of proof on this factor as well.

Establishing the temporal relationship was challenging because establishing the onset of her Wegener's granulomatosis is difficult. People can have Wegener's granulomatosis for several months before it is detected. Tr. 163. In this regard, the onset of Wegener's granulomatosis must be distinguished from the onset of the glomerulonephritis because some people can have Wegener's granulomatosis without kidney disease. Tr. 168. For Ms. Fields, the challenge is even greater because of the dearth of medical records immediately following her vaccinations.

Dr. Gershwin's oral testimony provided information sufficient to allow Ms. Fields to meet her burden of proof.⁹ Although Dr. Gershwin's opinion with regard to the onset of the

⁹ As to timing, Dr. Gershwin's written report was vague because he does not say what sign or symptom marked the onset of the Wegener's granulomatosis. His report discusses the timing in two places. He states that "[t]here is a very strong temporal relationship of the vaccination to Christy Fields' WG." Exhibit 31 at 3. However, the remainder of this paragraph does not discuss Ms. Fields's history at all. Later, in the conclusion of his report, Dr. Gershwin states that "the temporal relationship is striking." Id. at 4. But, again, Dr. Gershwin does not set forth when he considers the Wegener's granulomatosis to have begun. It would be better for experts to set forth information about the onset of the disease in their written report explicitly.

Wegener's granulomatosis could have been presented more clearly, he has provided sufficient information to conclude that the beginning of the Wegener's granulomatosis matches what is expected for an adverse reaction to the hepatitis B vaccine.

During the hearing, Dr. Gershwin pointed to different signs and symptoms as the earliest manifestation of the Wegener's granulomatosis. Fortunately for Ms. Fields, these different signs and symptoms all occurred at approximately the same time. Dr. Gershwin said that her eye problems, aches and pains, fatigue, and flu-like symptoms were the beginning of her problem. Tr. 82, 84, 87; see also tr. 108 (Dr. Gershwin testifying that Ms. Fields's ocular problems "could have been one of the earlier manifestations of Wegener's."). Ms. Fields experienced all these conditions in December 2000. Tr. 11-14; exhibit 17 ¶ 5. Thus, Ms. Fields developed these problems within 30 days of her vaccination on November 28, 2000.

Other testimony from Dr. Gershwin about the onset of the Wegener's granulomatosis is rejected as not consistent with his earlier testimony. Near the end of the hearing, Dr. Gershwin testified that the Wegener's granulomatosis started with the cough and the sore throat and possibly the ocular problems. Tr. 168. Ms. Fields's cough began in mid-April, meaning that if this date were accepted as the onset of the Wegener's granulomatosis the time between the hepatitis B vaccine to the onset of the Wegener's granulomatosis would increase to approximately four and a half months. This single statement by Dr. Gershwin is inconsistent with his other testimony, including a portion of the same passage in which Dr. Gershwin noted that Ms. Fields's ocular problems, which began in December, possibly marked the onset of the Wegener's granulomatosis. Thus, the preponderance of the evidence establishes that Dr. Gershwin's opinion is that Ms. Fields's Wegener's granulomatosis began in December 2000.

It is important to repeat that finding that the Wegener's granulomatosis began in December is consistent with the later development of kidney disease. Dr. Kaplan persuasively explained that the results of Ms. Fields's kidney biopsy on approximately May 10, 2001, indicated that the glomerulonephritis (inflammation in part of the kidney) started relatively close in time to the biopsy. The biopsy showed inflammation but not any fibrosis (scarring) and fibrosis usually takes about three weeks to develop after inflammation. Exhibit 22 at 4; tr. 122-24.

Articles suggest that a person may have Wegener's granulomatosis for a period of time without involving the kidney. For example, one article reports that the median amount of time between presentation and diagnosis for 33 people was two months. Exhibit A, tab 2 (Takwoingi & Dempster, Analysis of 33 Patients) at 7. Another article indicates that the mean time from symptoms to diagnosis was six months. Exhibit A, tab 4 (Koldingsnes & Nossent, Epidemiology) at 4. As pointed out in a third article, the relatively long delay in diagnosing the Wegener's granulomatosis does not usually happen in cases with glomerulonephritis. Exhibit 57 (Rottem, Children and Adolescents) at 27. After the glomerulonephritis begins, the kidneys are impaired and the more overt and severe symptoms will lead to a diagnosis.

In addition to establishing that her Wegener's granulomatosis began within 30 days of her hepatitis B vaccination, Ms. Fields also established that this time is appropriate. On cross-examination, Dr. Gershwin testified that the formation of immune complexes can take as long as 18 days. Tr. 83, 87, citing exhibit 46 (Eric R. Lunn et al., Prolonged Hepatitis B Surface Antigenemia After Vaccination, 105 (No. 6) Pediatrics 81 (2000)). Given that the immune complexes must develop before Ms. Fields had an adverse reaction to them, the time for the

adverse reaction extends out several weeks. Tr. 83. Furthermore, respondent did not challenge Dr. Gershwin's opinion regarding the appropriate temporal relationship by presenting a contrary opinion through Dr. Kaplan. See tr. passim.

For these reasons, Ms. Fields has established the third prong from Althen. She is therefore entitled to compensation, as long as something else did not cause her Wegener's granulomatosis.

D. Alternative Cause

Respondent did not identify another cause of Ms. Fields's Wegener's granulomatosis in his report filed pursuant to Vaccine Rule 4. See Resp't Rep't, filed July 11, 2006. Similarly, Dr. Kaplan did not specify another cause in his report. See Exhibit A.

However, at the very end of the hearing, Dr. Kaplan stated that a viral infection in her respiratory system was the more likely cause of Ms. Fields's Wegener's granulomatosis. Tr. 169-70. This was the first time this assertion arose. Dr. Kaplan, in responding to the medical literature submitted by Ms. Fields after the hearing (Exhibits 54-57), stated that "it is more likely that [Ms. Fields's] disease was triggered by a respiratory viral infection than by Hep B vaccination." Exhibit C at 2.

Respondent's argument on this point is short, set forth in less than one page, and in only one line of Dr. Kaplan's post-hearing submission (exhibit C), a length that is consistent with the last-minute raising of this point. See Resp't Post Trial Br. at 18.

Respondent's argument is rejected as speculative. A fundamental proposition in this argument is that Ms. Fields's cough, which began in mid-April, was a manifestation of a viral infection. Although Ms. Fields could have suffered from a virus at this time, Ms. Fields had

other signs, such as eye trouble, that existed before the cough in April. Therefore, the virus, which allegedly caused the cough, could not have caused these problems. For the reasons explained above, Dr. Gershwin has presented a theory that connects all of the established facts. This more comprehensive theory is more persuasive than a last-minute, if not half-hearted, argument that the problem was caused by a virus.

IV. Conclusion

Ms. Fields is entitled to compensation for Wegener's granulomatosis because she established the elements of her case as set forth in Althen. The parties shall schedule a status conference to discuss the process for quantifying the amount of Ms. Fields's damages.

IT IS SO ORDERED.

Christian J. Moran
Special Master