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

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PAUL A. VISCONTINI,	*	No. 98-619V
	*	Special Master Christian J. Moran
	*	
Petitioner,	*	
	*	Filed: October 21, 2011
v.	*	
	*	
SECRETARY OF HEALTH	*	Entitlement, hepatitis B vaccine,
AND HUMAN SERVICES,	*	Crohn's disease, reliability of expert's
	*	theory, challenge-rechallenge
Respondent.	*	
	*	
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Clifford J. Shoemaker, Shoemaker and Associates, Vienna, VA., assisted by Daniel Gerken and Steven Meyers, student attorneys, for petitioner;
Lisa Watts, United States Dep't of Justice, Washington, D.C., for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

[1] 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 United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

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

Paul Viscontini filed a petition seeking compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 et seq. (2006). Mr. Viscontini alleged that the hepatitis B vaccine caused him to develop Crohn's disease. Mr. Viscontini relies upon the opinion of two doctors retained for this litigation, Joseph Bellanti (an immunologist) and Meyer Solny (a gastroenterologist).

The Secretary opposed Mr. Viscontini's claim for compensation. She relies upon the opinion of Dr. Andrew Warner, who specializes in treating irritable bowel diseases, including Crohn's disease.

Mr. Viscontini's case shares some similarities with another case presenting the claim that the hepatitis B vaccine caused Crohn's disease, Locane v. Sec'y of Health & Human Servs., No. 99-589V, 2011 WL 3855486 (Fed. Cl. Spec. Mstr. Feb. 17, 2011), motion for review denied, ___ Fed. Cl. ___, 2011 WL 3252807 (July 15, 2011), appeal docketed, No. 2011-5131 (Fed. Cir. Sept. 15, 2011).[2] The experts overlapped --- Dr. Bellanti has testified for the petitioner in both cases, Dr. Solny offered a report in Locane and testified in the present case, and Dr. Warner testified for the respondent in both cases. The same attorney represents both petitioners. The overlap between the two cases influenced the procedural history in Mr. Viscontini's case, especially with regard to evolutions in the opinions offered by Mr. Viscontini's experts.

The resemblance of the two cases, however, has not affected the outcome of Mr. Viscontini's case. Mr. Viscontini's case has been adjudicated based upon the evidence (medical records, reports, and testimony) in his case alone. See Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274,1278 (Fed. Cir. 2005)(stating "[t]he special master's role is to assist the courts by judging the merits of individual claims on a case-by-case basis."). The uncontroverted evidence in Mr. Viscontini's case demonstrates that he experienced symptoms that are consistent with Crohn's disease after he received the second dose of the hepatitis B vaccine and he experienced additional symptoms after the third dose. Mr. Viscontini was diagnosed with Crohn's disease approximately four months after the third dose and there is no dispute about the accuracy of this diagnosis.

[2] There is a third case in which the petitioner claimed the hepatitis B vaccine caused Crohn's disease. Neither the decision of the special master nor the order upon a motion for review by the Court of Federal Claims in that case has been made available to the public due to a pending motion for redaction.

Mr. Viscontini's claim that his Crohn's disease was caused by the hepatitis B vaccine lacks persuasive value in two respects. The primary problem is that he failed to present a reliable theory explaining how the hepatitis B vaccine can cause Crohn's disease. Although Mr. Viscontini retained a doctor specializing in immunology (Dr. Bellanti), he did not ever explain why the hepatitis B vaccine is capable of setting in motion a series of events that lead to Crohn's disease. The theory presented by Dr. Bellanti is far removed from what the medical community understands about Crohn's disease. The improbability of this theory means that Mr. Viscontini is not entitled to compensation.

The second obstacle to awarding Mr. Viscontini compensation, although not as stark as the first problem, concerns what happened to him. Through testimony, Mr. Viscontini claims that he developed certain ailments within days of receiving doses of the hepatitis B vaccine. Mr. Viscontini's experts base their opinions, at least in part, on these assertions. However, a preponderance of evidence shows that the chronology offered by Mr. Viscontini is not accurate. Persuasive evidence indicates that the relevant abdominal problems followed the second dose of the hepatitis B vaccine by approximately one month. This finding means that there is a discrepancy between the facts as found in the litigation and the assertions assumed to be accurate by the experts. This difference constitutes a separate basis for denying Mr. Viscontini compensation.

I. Facts

There is (mostly) little dispute about the facts. Statements contained in the medical records describing Mr. Viscontini's health have been accepted as accurate. The disagreement stems from testimonial assertions that Mr. Viscontini experienced various health problems that are not memorialized in a medical record created around the time in which Mr. Viscontini is alleged to have suffered the problem. Although the inconsistency pertains to a relatively limited span of time, December 1995 to July 1996, this particular time is crucially important because it was during this time that Mr. Viscontini received doses of the hepatitis B vaccination. Consequently, the standards used for finding facts are given in section A. Section B contains the findings of fact.

A. Standard for Finding Facts

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence

standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa–11(c)(2). Medical records that are created contemporaneously with the events that they describe are presumed to be accurate. Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Not only are medical records presumed to be accurate, they are also presumed to be complete, in the sense that the medical records present all the problems of the patient. Completeness is presumed due to a series of propositions. First, when people are ill, they see a medical professional. Second, when ill people see a doctor, they report all of their problems to the doctor. Third, having heard about the symptoms, the doctor records what he (or she) was told.

Appellate authorities have accepted the reasoning supporting a presumption that medical records created contemporaneously with the events being described are accurate and complete. A notable example is Cucuras in which petitioners asserted that their daughter, Nicole, began to have seizures within one day of receiving a vaccination, although medical records created around that time suggested that the seizures began at least one week after the vaccination. Cucuras, 993 F.3d at 1527. A judge reviewing the special master's decision stated that "In light of [the parents'] concern for Nicole's treatment . . . it strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred." Cucuras v. Sec'y of Health & Human Servs., 26 Cl. Ct. 537, 543 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993).

Decisions by judges of the Court of Federal Claims have followed Cucuras in affirming findings by special masters that the lack of contemporaneously created medical records can contradict a testimonial assertion that symptoms appeared on a certain date. E.g. Doe/70 v. Sec'y of Health & Human Servs., 95 Fed. Cl. 598 (2010); Doe/17 v. Sec'y of Health & Human Servs., 84 Fed. Cl. 691, 711 (2008); Ryman v. Sec'y of Health & Human Servs., 65 Fed. Cl. 35, 41-42 (2005); Snyder

v. Sec'y of Health & Human Servs., 36 Fed. Cl. 461, 465 (1996) (stating "The special master apparently reasoned that, if Frank suffered such [developmental] losses immediately following the vaccination, it was more likely than not that this traumatic event, or his parents' mention of it, would have been noted by at least one of the medical record professionals who evaluated Frank during his life to date. Finding Frank's medical history silent on his loss of developmental milestones, the special master questioned petitioner's memory of the events, not her sincerity."), aff'd, 117 F.3d 545, 547-48 (Fed. Cir. 1997).

The presumption that contemporaneously created medical records are accurate and complete, however, is rebuttable. For cases alleging a condition found in the Vaccine Injury Table, special masters may find when a first symptom appeared, despite the lack of a notation in a contemporaneous medical record. 42 U.S.C. § 300aa-13(b)(2). By extension, special masters may engage in similar fact-finding for cases alleging an off-Table injury. In such cases, special masters are expected to consider whether medical records are accurate and complete.

In weighing divergent pieces of evidence, contemporaneously written medical records are usually more significant than oral testimony. Cucuras, 993 F.2d at 1528. However, compelling oral testimony may be more persuasive than written records. Campbell ex rel. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); Camery v. Sec'y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998) (this rule "should not be applied inflexibly, because medical records may be incomplete or inaccurate"); Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir. 1992).

The relative strength or weakness of the testimony of a fact witness affects whether this testimony is more probative than medical records. An assessment of a fact witness's credibility usually involves consideration of the person's demeanor while testifying. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The facts of Mr. Viscontini's case will be found in accord with the criteria set forth above. The record includes the medical records and the testimony from a hearing. The testimony from the experts was helpful in explaining the significance of Mr. Viscontini's signs and symptoms.

B. Findings of Fact

Mr. Viscontini was born in 1982, and was periodically checked by a pediatrician during his childhood. Mr. Viscontini did not have any significant medical issues for his first 13 years and respondent has not asserted that any problem from this time caused Mr. Viscontini's Crohn's disease. See exhibit 2; tr. 9-10; Resp't Rep't, filed Feb. 28, 2007.

In his childhood, Mr. Viscontini participated in soccer, baseball, and basketball. He was a particularly strong swimmer, placing second in a regional competition for his age group in a butterfly event. According to Mr. Viscontini's description, his coaches believed that he had great promise. Tr. 10-11.

Mr. Viscontini received from his pediatrician, Marcelino DeSantos, the first dose of the hepatitis B vaccine on December 7, 1995. The doctor's record for this visit notes a problem with "sinusitis," but otherwise does not describe any health concerns. Mr. Viscontini was 62.5 inches tall and weighed 108.5 pounds. Exhibit 2 at 1, 10.

According to the testimony of Mr. Viscontini and Ms. Viscontini, after the December 7, 1995 vaccination, Mr. Viscontini suffered an illness. Ms. Viscontini said that her son had "flu-like symptoms." Exhibit 1 (affidavit, dated July 14, 1998). Mr. Viscontini stated that he had "a slight cold." Exhibit 40 (affidavit, dated Dec. 7, 2007) ¶ 6. Mr. Viscontini did not recall either having nausea or vomiting. Tr. 36. No medical record was created around this time to confirm any illness shortly after December 7, 1995.

Here, the lack of a medical record is not very troubling. In December 1995, Mr. Viscontini was 13 years old. It seems unlikely that a typical 13 year old would seek medical attention for a "slight cold." See tr. 102. Thus, the testimonial assertions of Mr. Viscontini and Ms. Viscontini are accepted.

Mr. Viscontini received the second dose of the hepatitis B vaccine on January 11, 1996. Exhibit 2 at 1, 4. As with the previous vaccination, Mr. Viscontini and his mother assert that he had health problems after this vaccination. Their assertions are contained in their affidavits and their oral testimony.

In Ms. Viscontini's affidavit, which was written in 1998, she stated "Following his second vaccination with the hepatitis B vaccine, Paul became ill. His symptoms included muscle and joint aching, frequent vomiting, and extreme

loss of appetite. He began to recover in June of 1996." Exhibit 1 ¶ 4. Mr. Viscontini's 2006 affidavit asserted that "Shortly after this vaccination my cold intensified and I started to suffer [from] new ailments. I was back and forth to the doctor with symptoms of abdominal pain, vomiting and constant nausea." Exhibit 40 ¶ 6.

Mr. Viscontini's and Ms. Viscontini's oral testimony was basically consistent with their affidavits. However, they provided more specific information about the onset of the abdominal problems. According to them, Mr. Viscontini experienced abdominal problems within four days of the vaccination. Tr. 15; tr. 53-54. Again, there is no medical record created around January 15, 1996, that indicates that Mr. Viscontini had abdominal pain, vomiting, or nausea on that date.

A medical record from Dr. DeSantos shows that Mr. Viscontini complained about abdominal pain on January 27, 1996. Mr. Viscontini also complained about pain in both ears and a headache. Although the record is not entirely clear, the context suggests that all problems started two days earlier. More information about the nature of the abdominal pain is not available because Dr. DeSantos's notes do not reflect any information about the abdominal pain gained via a physical examination of Mr. Viscontini. Exhibit 2 at 4.

On March 4, 1996, Mr. Viscontini told Dr. DeSantos that since March 1, 1996, he was having a sore throat, intermittent cough, and chest pain. Dr. DeSantos's examination suggested a mild infection in his throat and revealed pectoral and abdominal discomfort. Dr. DeSantos diagnosed Mr. Viscontini as suffering from a viral syndrome and possible overuse syndrome. Exhibit 2 at 4. In an addendum to these office notes, Dr. DeSantos stated that Mr. Viscontini was swimming two miles per day and had recently started weight training. Dr. DeSantos recommended that Mr. Viscontini and his mother meet with his school's athletic trainer to coordinate Mr. Viscontini's training sensibly. Id. at 5.

On March 7, 1996, Ms. Viscontini wrote to a person at her son's school, stating that he should not participate in weight training. Ms. Viscontini stated that "Up until 3 weeks ago, he was practicing [on the Spirit Swim Team] 4 or 5 times a week, often swimming 2 1/2 miles a practice. He has missed most practices in the last 2 weeks and was only able to complete 2 practices the week before that all due to chest and abdominal pain." Exhibit 4 at 35. This letter means that until three weeks before March 7, 1996 (February 15, 1996), Mr. Viscontini was swimming long distances consistently.

Mr. Viscontini returned to Dr. DeSantos on March 26, 1996. Mr. Viscontini reported that his upper respiratory problems had resolved. Mr. Viscontini was having fatigue, abdominal pain, a low-grade fever, and he vomited once over the weekend. Exhibit 2 at 6. Mr. Viscontini informed Dr. DeSantos that he was having abdominal pain twice more, on April 2, 1996, and May 10, 1996. Id. at 6-7.

The sequence of records created in March through May 1996 suggests that the significant abdominal pain started in mid-February 1996. Ms. Viscontini's March 7, 1996 letter describes her son's abilities and health accurately. In that letter, she states that abdominal pain started to interfere with her son's vigorous swimming during the week of February 15, 1996. Once Mr. Viscontini started having abdominal pain of such intensity that it interfered with his activities, he saw his pediatrician fairly regularly.

The two doctors with expertise in gastroenterology interpreted the written records as indicating that Mr. Viscontini's Crohn's disease began around this time. Dr. Solny placed the onset as between February and May 1996. Dr. Solny cited Ms. Viscontini's July 14, 1998 affidavit and Mr. Viscontini's December 7, 2007 affidavit in support of this opinion. Exhibit 43 (supplemental report) at 1.[3] Dr. Warner opined that Mr. Viscontini's Crohn's disease began sometime "in early 1996." Dr. Warner based his opinion on Mr. Viscontini's report of abdominal pain and laboratory tests showing anemia, an elevated sedimentation rate, and a low amount of albumin. Tr. 304-05.

On July 31, 1996, Dr. DeSantos's office administered a third dose of the hepatitis B vaccine. This vaccination appears to be the only reason for that visit because Dr. DeSantos's file does not include any other records pertaining to a visit on this date. Exhibit 2 at 7.

Mr. Viscontini had another instance of abdominal pain, stomach ache, and cramps on August 4, 1996. He saw Dr. DeSantos on August 9, 1996, and during this appointment, Dr. DeSantos requested additional tests. Exhibit 2 at 7. Following this episode, Ms. Viscontini began to think that the hepatitis B vaccine caused Mr. Viscontini's problem. Tr. 60-63.

[3] This supplemental report was ordered because Dr. Solny's initial report omitted any discussion of when Mr. Viscontini's Crohn's disease began. Order, filed Nov. 19, 2009.

Mr. Viscontini saw a pediatric gastroenterologist, Kevin Kelly, on September 10, 1996. Mr. Viscontini told Dr. Kelly that he was having daily intermittent abdominal pain. Mr. Viscontini's mother stated that "this constellation of symptoms began abruptly after Paul was given his second Hepatitis B vaccine injection in February of 1996."[4] Dr. Kelly considered that Mr. Viscontini may have an inflammatory bowel disease and requested an upper GI series. The radiologist stated that "There is no radiographic evidence of Crohn's disease." Exhibit 15.

It appears that in September 1996, Mr. Viscontini was 62.5 inches tall and weighed 99 pounds. Exhibit 2 at 11. Another set of measurements (using the metric system) appear in Dr. Kelly's record. Exhibit 15 at 2. These measurements show that Mr. Viscontini had lost approximately nine pounds since December 1995. See exhibit 2 at 10.

From November 9 to November 10, 1996, Mr. Viscontini was hospitalized because he was having severe epigastric pain with vomiting. At discharge, he was encouraged to see a pediatric gastroenterologist. Exhibit 24 at 10-11; see also tr. 39-40.

Mr. Viscontini consulted Kenneth Breslin, a pediatric gastroenterologist, on November 12, 1996. Dr. Breslin requested an endoscopy, which was done on November 14, 1996. Biopsies showed results that were consistent with Crohn's disease. Exhibit 4 at 8-10.

After this diagnosis, Mr. Viscontini was treated for Crohn's disease by various doctors. See tr. 25-31; tr. 75-90. The details of these visits are not particularly helpful in determining whether the hepatitis B vaccine caused Mr. Viscontini's Crohn's disease. After many years of fluctuations in the severity of his symptoms, Mr. Viscontini underwent an operation. Exhibit 31. Following this operation, Mr. Viscontini's Crohn's disease has been much improved. Tr. 31-34; tr. 93-96.

Crohn's disease is chronic inflammation in the intestinal tract. Tr. 289. The gastrointestinal tract is part of the immune system and contains bacteria that are both helpful and harmful. Tr. 115; tr. 228. (The medical term for helpful bacteria

[4] Ms. Viscontini's affidavit contains an error in that her son actually received the second dose of the hepatitis B vaccine in January 1996. However, Ms. Viscontini's affidavit appears correct in dating the onset of Mr. Viscontini's symptoms to February 1996.

is "commensal bacteria." Dorland's Illustrated Medical Dictionary (31st ed. 2007) at 397.) The intestinal tract is approximately 23 feet long and within this pathway, small segments that are a few inches long become inflamed. Tr. 291. (For Mr. Viscontini, his esophagus, stomach, and duodenum were affected. Tr. 291; accord exhibit 4 at 4 (biopsy results).)

Crohn's disease typically begins when the person is a teenager. Tr. 151; tr. 289. Affected people have pain in their abdomen, especially after eating. Laboratory tests usually show iron deficiency anemia and low amount of albumin. Crohn's disease causes teenagers to fall off their growth curve. Tr. 289-90. Approximately 1 to 1.5 million people in the United States suffer from Crohn's disease. Tr. 289.[5]

The cause of Crohn's disease is not known. Tr. 291; tr. 309. Some scientists advance the "hygiene hypothesis." In this theory, the environment of the modern urban and suburban lifestyle, which is cleaner than environments found in traditional rural settings, prevents people from encountering certain helpful bacteria. Without the stimulation from these helpful bacteria residing in people's gastrointestinal tract, modern people's immune system do not develop properly and disorders of the immune system, such as Crohn's disease, result. Tr. 115-22; tr. 151. The hygiene hypothesis, however, cannot explain why the allegedly harmful bacteria are present in people who are not suffering from Crohn's disease. Tr. 291. A variation of the hygiene hypothesis is that the problem is a lack of parasites, not a lack of bacteria. Tr. 310.

Crohn's disease may also have a genetic basis. People with Crohn's disease have an increased incidence of certain genes. Exhibit 83 (Lloyd Mayer, Evolving paradigms in the pathogenesis of IBD, 45 J. Gastroenterol 9, 10-11 (2010)) at 10-11; tr. 148; tr. 234-36.

If Crohn's disease has a genetic component, then it appears likely that a factor from the environment also contributes. Scientists have evaluated the role of genetics by looking at twins who have the same genes. (These twins are known as identical twins or monozygotic twins. Dorland's at 1198.) The incidence in which identical twins develop the same disease is known as the concordance rate. For Crohn's disease, the concordance rate is 50 percent. This rate suggests that a

[5] The testimony did not indicate whether this is the total number of cases or the number of new cases per year.

factor from the environment contributes to the cause of Crohn's disease. Tr. 149-50; tr. 213; tr. 339.

In this litigation, Mr. Viscontini asserts that an environmental factor that can cause Crohn's disease is the hepatitis B vaccine and that the hepatitis B vaccine actually did cause his Crohn's disease.

II. Procedural History

The petition and one affidavit were filed on July 29, 1998.[6] The affidavit, which was about one page in length, was from Mr. Viscontini's mother. Exhibit 1. No medical records were filed with the petition, although the statute requires those records to be filed. See 42 U.S.C. §300aa-11(c).

After three years passed with no meaningful activity, Mr. Viscontini was ordered, in August 2001, to file a single medical record. Mr. Viscontini filed exhibits 2 and 3 in October 2001. Again, time went by without progress and the case was formally stayed in February 2003. In 2006, the case was reassigned and the stay was lifted. Mr. Viscontini periodically filed medical records throughout 2006.

Respondent assessed these records in her report filed pursuant to Vaccine Rule 4 on February 28, 2007. Respondent recommended that compensation was not appropriate. Respondent noted that Mr. Viscontini's treating doctors had not determined the cause of his condition and that Mr. Viscontini had not submitted a report from an expert to support his claim.

On November 9, 2007, Mr. Viscontini filed the report of Joseph Bellanti, an immunologist. Dr. Bellanti is a professor of pediatrics and microbiology-immunology at Georgetown University's School of Medicine. He has extensive experience in immunology. He served as the president of the American College of Allergy and Immunology and on the editorial boards of various journals. He has written more than four hundred articles in journals and has edited or authored textbooks in immunology. Exhibit 38 (curriculum vitae).

[6] From July 1998 until April 2006, Mr. Viscontini's mother, Joan Viscontini, acted as the petitioner because Mr. Viscontini had not reached the age of majority to prosecute a case on his own behalf. For simplicity, Mr. Viscontini is treated as the petitioner throughout this decision.

Dr. Bellanti's report summarizes Mr. Viscontini's medical history through 2005. Dr. Bellanti discusses Crohn's disease and notes that antibodies against saccharomyces cerevisiae are markers for Crohn's disease.[7] Saccharomyces cerevisiae are a type of yeast, which is used in the manufacture of the hepatitis B vaccine. Dr. Bellanti stated that "[i]njection of a yeast antigen into someone with ASCA triggers an immediate immunologic response. This would seem to be a very logical mechanism to explain the onset and progression of disease in [Mr. Viscontini's] case." Exhibit 37 (report) at 9.[8] Dr. Bellanti cited no articles in his report.

Following Dr. Bellanti's report, respondent filed a report from Andrew Warner, a specialist in gastroenterology. Dr. Warner is the Chairman of the Gastroenterology Department in the Lahey Clinic. He is board-certified in gastroenterology and is a fellow in the American College of Gastroenterology. Dr. Warner is a member of the Crohn's and Colitis Foundation of America. For four years, Dr. Warner served on the editorial board of Inflammatory Bowel Diseases. He has authored 19 publications, including a book entitled 100 Questions and Answers and Crohn's Disease and Ulcerative Colitis: The Lahey Clinic Guide. Exhibit B (curriculum vitae).

Dr. Warner's report condenses Mr. Viscontini's medical history to about one page and does not dispute the summary provided by Dr. Bellanti. Dr. Warner, however, challenges Dr. Bellanti's opinion that the hepatitis B vaccine caused Mr. Viscontini's Crohn's disease. Dr. Warner states that "there is no medical or scientific evidence suggesting that the hepatitis B vaccine can cause or significantly aggravate Crohn's disease." Exhibit B (report) at 3.

Given the divergent opinions from Dr. Bellanti and Dr. Warner, the special master scheduled the case for hearing to be held December 11, 2008. Order, filed July 15, 2008. However, the case was then transferred to the undersigned special master.

Once this case was assigned to the undersigned, a status conference was held on October 31, 2008. At this point, the parties discussed holding a hearing in Mr.

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[7] The abbreviation for anti-saccharomyces cerevisiae antibodies is "ASCA."

[8] Dr. Bellanti's discussion of ASCA in Mr. Viscontini's case essentially repeats the report that he submitted in Locane.

Viscontini's case with a supplemental hearing in Locane.[9] In that status conference, Mr. Viscontini indicated a plan to replace Dr. Bellanti with a different expert. Consequently, Mr. Viscontini was given 45 days to file a status report indicating whether he would file a report from another expert.

After receiving five enlargements of time, Mr. Viscontini filed a report from Meyer Solny on October 27, 2009. Dr. Solny is board-certified in gastroenterology and is a fellow in the division of gastroenterology at the New York Hospital-Cornell Medical Center. He has written three publications and operates a private practice in internal medicine and gastroenterology. In a year, Dr. Solny diagnoses about 8-12 cases of Crohn's disease. Exhibit 42 (curriculum vitae); see also tr. 112-14; tr. 142.

Dr. Solny expressed the opinion that the hepatitis B vaccine caused Mr. Viscontini's Crohn's disease. Dr. Solny supported this conclusion with several reasons. First, the hepatitis B virus has been linked to a disease called polyareritis nodosa (PAN) through immune complexes. Second, Crohn's disease is understood to be mediated through the immune system and that vaccinations can alter the body's "gut bacterial flora in a manner sufficient to disrupt normal immune homeostasis and cause inflammation." Third, the Bacille Calmette-Guerin vaccination appears to increase the risk of developing Crohn's disease. Fourth, there is "clear temporal association" between Mr. Viscontini's receipt of the hepatitis B vaccines and a progression of Crohn's disease. Exhibit 41 (report).

Dr. Solny's report was discussed at a status conference held on November 19, 2009. See Vaccine Rule 5. Respondent asked for more information on four topics mentioned in Dr. Solny's report. Another problem was that Dr. Solny's report omitted any discussion of the appropriate temporal relationship, which is an element on which a petitioner must present preponderant evidence. See Althen, 418 F.3d at 1278. Consequently, Mr. Viscontini was ordered to file a supplemental report from Dr. Solny. Dr. Solny's supplemental report was filed on March 19, 2010, as exhibit 43. Mr. Viscontini also filed medical articles on which Dr. Solny relied.

Respondent was ordered to obtain a supplemental report from Dr. Warner to address the opinions presented by Dr. Solny. Dr. Warner's supplemental report

[9] Locane was more advanced procedurally in that a hearing was held on April 17, 2008, during which Dr. Bellanti and Dr. Warner testified.

was filed on May 24, 2010, as exhibit C. Dr. Warner disagreed with the first three points raised by Dr. Solny.

Also on May 24, 2010, an order was issued to schedule events leading to a hearing on October 5, 2010. The May 24, 2010 order provided that the parties should file briefs before the hearing and should be certain that they had submitted the articles which their experts intended to discuss by certain dates. For Mr. Viscontini, the date for filing articles was August 31, 2010.

On August 31, 2010, Mr. Viscontini submitted articles as exhibits 52-82. Mr. Viscontini filed his pre-hearing brief in which Mr. Viscontini stated that he intended to call Dr. Bellanti as a witness to testify about the opinions expressed in his expert report, exhibit 37. Respondent filed her brief. These submissions were discussed during the pre-trial conference on September 21, 2010, in anticipation of the hearing starting on October 5, 2010. However, during the hearing, Mr. Viscontini elicited no specific testimony about any of these articles. See tr. 138 (Dr. Solny); tr. 229 (Dr. Bellanti).

On October 4, 2010, Mr. Viscontini filed two additional articles, exhibits 83-84. Information from the Court's electronic case filing system indicates that these two exhibits were uploaded at 9:51 P.M.[10] On October 5, 2010, the hearing was held. Mr. Viscontini and his mother testified about Mr. Viscontini's medical history. Their testimony has been discussed in the findings of fact. To present the medical aspects of his case, Mr. Viscontini called Dr. Solny and Dr. Bellanti. Respondent called Dr. Warner.

Following the testimony from the percipient witnesses, Dr. Solny presented his opinion. His testimony was consistent with what he had disclosed in his two reports before the hearing. Dr. Solny provided helpful information about Crohn's disease. Dr. Solny, however, did not give any persuasive reason for finding that the hepatitis B vaccine caused Mr. Viscontini's Crohn's disease, which, of course, is the precise question being litigated.[11] After Dr. Solny completed his testimony,

[10] Counsel explained that exhibit 84 was published within the last few days and that exhibit 84 led counsel to discover exhibit 83, which was published online in 2009. See Pet'r Notice of Filing Documents, filed Oct. 4, 2010, and tr. 138.

[11] Mr. Viscontini's reliance on Dr. Solny's testimony is limited. Mr. Viscontini's initial brief relies upon Dr. Solny's testimony for proof relating to the appropriate temporal relationship, Pet'r Br., filed Dec. 19, 2010, at 20. Mr.

Mr. Viscontini's counsel – without consulting the special master – excused Dr. Solny. Tr. 229-30.

Dr. Bellanti testified next. He orally presented a theory that was quite different from the theory in his report. His written report had hypothesized that giving a vaccine developed in yeast to a person who has anti saccharomyces cerevisiae antibodies (ASCA) "triggers an immediate immunologic response." Exhibit 37 at 9. However, during his direct testimony, Dr. Bellanti was not questioned about ASCA at all. See tr. 188-230. On cross-examination, Dr. Bellanti was asked whether ASCA was still involved in his opinion and Dr. Bellanti answered that "I don't think it's involved in the pathogenesis." Tr. 250.[12]

Instead of the theory based on ASCA, Dr. Bellanti set forth new ideas.[13] During his testimony, Dr. Bellanti explained the difference between autoimmune diseases, which arise because of a deficiency in the adaptive part of the immune system, and autoinflammatory diseases, which arise because of a deficiency in the other part of the immune system, the innate portion. Tr. 192-212, especially tr. 206. Dr. Bellanti based his presentation on a lecture that he presented in May 2010. Tr. 192.[14]

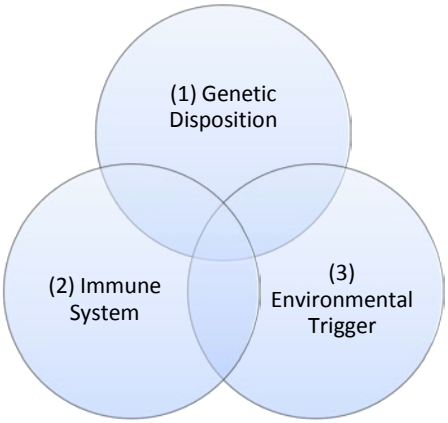
Eventually, Dr. Bellanti explained that Crohn's disease occurs when three factors coincide. The three factors are a genetic predisposition to developing Crohn's disease, a deficient immune system, and a trigger from the environment. Tr. 217. Dr. Bellanti drew a Venn diagram to illustrate his idea:

Viscontini's reply brief cites Dr. Solny's testimony in support of finding rechallenge. Pet'r Reply, filed March 29, 2011, at 7.

[12] Dr. Solny did not rely on a theory based on ASCA. Tr. 155.

[13] Dr. Bellanti's trial testimony was "new" in two senses. It had not been disclosed in any report filed in this case. It also summarized concepts that had been discussed during one conference but had not been incorporated into any textbooks published at the time of the hearing. Dr. Bellanti expected that the new edition of his textbook on immunology would incorporate the ideas that he expressed during his testimony. Tr. 232-33.

[14] Although Dr. Bellanti made this presentation five months before his testimony, Dr. Bellanti did not submit a supplemental expert report disclosing his theory.



Dr. Bellanti stated that the hepatitis B vaccine could be an environmental trigger that leads to Crohn's disease. In his briefs, Mr. Viscontini advances the "environmental trigger theory." Pet'r Br. at 11-15; Pet'r Reply at 11-15.[15]

When Dr. Warner testified, Dr. Warner disagreed with Dr. Bellanti's assertion that the hepatitis B vaccine caused Mr. Viscontini's Crohn's disease. In direct response to Dr. Bellanti's theory that an environmental trigger is needed to cause Crohn's disease, Dr. Warner explained that the theory made sense in a general sense but he did not know whether a trigger was needed. Dr. Warner emphasized that even if a trigger was needed, no evidence shows that the hepatitis B vaccine is a trigger. Tr. 300-01.

After the hearing, the parties were instructed to file briefs. Mr. Viscontini filed a primary brief, respondent filed one brief, and Mr. Viscontini filed a reply brief. The case is ready for adjudication.

III. Standards for Adjudication

There are at least three distinct parts to evaluating whether a petitioner is entitled to compensation. One part is to articulate the elements of the petitioner's case. These elements are "what" petitioner must establish. A separate part of the analysis is the quantum of evidence that a petitioner must introduce, which is the burden of proof. A final aspect is the process of weighing or evaluating the evidence that is submitted. These three portions are discussed separately.

[15] Mr. Viscontini's initial brief devotes a single paragraph to ASCA. Pet'r Br. at 14, citing Dr. Bellanti's report. Mr. Viscontini's reply does not discuss ASCA at all.

A. Elements of Petitioner's Case

To receive compensation under the Program, Mr. Viscontini must prove either: (1) that he suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding to the hepatitis B vaccination, or (2) that he suffered an injury that was actually caused by the hepatitis B vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, Crohn's disease is not associated with the hepatitis B vaccine on the Vaccine Injury Table. Thus, Mr. Viscontini must prove causation in fact.

When a petitioner proceeds on a causation-in-fact theory, a petitioner must establish three elements. 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, 418 F.3d at 1278.

B. Burden of Proof

For the elements that petitioners are required to prove, their burden of proof is a preponderance of the evidence. 42 U.S.C. § 300aa–13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. Moberly, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu, 569 F.3d at 1379-80 (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health

& Human Servs., 219 F.3d 1357 (2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty). In this regard, "close calls regarding causation are resolved in favor of injured claimants." Althen, 418 F.3d at 1280.

C. How to Weigh Evidence

The preceding sections explain what a petitioner is required to establish and what level of proof satisfies the petitioner's obligation. The remaining issue is how to evaluate evidence submitted to meet the standard of proof on those elements. Three authorities generally instruct special masters in how to evaluate evidence. They are Congress, the United States Court of Federal Claims, and the United States Court of Appeals for the Federal Circuit.

Congress is the first authority for instructions about how to weigh evidence. In enacting the National Vaccine Injury Compensation Act, specifically section 13, Congress provided some instructions about how special masters should analyze the evidence. Among other provisions, section 13 dictates that the special master should consider "the record as a whole." Section 13 also provides that the special master shall consider "any diagnosis, conclusion, medical judgment or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition or death." Nevertheless, "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court."

The second authority is the United States Court of Federal Claims, in its capacity as rule maker. Congress authorized the Court of Federal Claims to promulgate rules of procedure for cases in the Vaccine Program. 42 U.S.C. § 300aa−12(d)(2). Collectively, the judges of the Court of Federal Claims have issued the Vaccine Rules. The Vaccine Rules, in turn, provide that the special master "must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties." Vaccine Rule 8(b)(1).

The third authority is the United States Court of Appeals for the Federal Circuit. Decisions by the Federal Circuit are binding precedent. 42 U.S.C. § 300aa−12(e). Within the Vaccine Program, the Federal Circuit expected that special masters would "consider[] the relevant evidence of record, draw[]

plausible inferences and articulate[] a rational basis for the decision." Hines, 940 F.2d at 1528.

A particular topic on which the Federal Circuit has guided special masters is the process for evaluating the testimony of expert witnesses. The leading case on this topic is Terran. In Terran, the special master "examined" the expert's opinion "in light of the four guideposts enumerated in Daubert," and "conclude[d] that petitioner's theory of causation is not based on reliable scientific evidence." Terran v. Sec'y of Health & Human Servs., No. 95-451V, 1998 WL 55290, at *11 (Fed. Cl. Spec. Mstr. Jan. 23, 1998). When Ms. Terran's appeal reached the Federal Circuit, she argued that "the Special Master improperly applied the Daubert factors to the expert's testimony." The Federal Circuit rejected this argument and indicated that the special master reasonably used "Daubert's questions as a tool or framework for conducting the inquiring into the reliability of the evidence." Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999). As recognized in Terran, the Daubert factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and, (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2, citing Daubert, 509 U.S. at 592-95.

After Terran, decisions from judges of the Court of Federal Claims have consistently cited to the Daubert criteria as useful in assessing an opinion that a vaccine can cause an injury. E.g. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 742-45 (2009); Cedillo v. Sec'y of Health & Human Servs., 89 Fed. Cl. 158, 182 (2009), aff'd, 617 F.3d 1328, 1347 (Fed. Cir. 2010); De Bazan v. Sec'y of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2006) ("A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness's testimony regarding causation."), rev'd on other grounds, 539 F.3d 1347 (Fed. Cir. 2008); 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).

The reliability of the expert's theory is not presumed. A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly, 592 F.3d at 1324 (citing Terran). Furthermore, the reliability of an expert's theory affects the persuasiveness of the evidence. Special masters may "inquir[e] into the reliability of testimony from expert witnesses. Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases." Id. at 1325 (citing Terran).

A petitioner's proffer of any theory does not satisfy his (or her) burden on this prong. If the special master finds that the expert's theory is supported by only an "ipse dixit", then the Special Master may reject this opinion. Snyder, 88 Fed. Cl. at 745, n.66 (2009) (quoting Gen. Elec. Co. v. Joiner, 522, U.S. 136, 146 (1997)); see also Cedillo, 617 F.3d at 1339 (also quoting Joiner).

In evaluating expert testimony and scientific literature, special masters should analyze scientific literature "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." Andreu, 569 F.3d at 1379. "In other words, a finding of causation in the medical community may require a much higher level of certainty than that required by the Vaccine Act to establish a prima facie case. The special master must take these differences into account when reviewing the scientific evidence." Broekelschen v. Sec'y of Health & Human Servs., 89 Fed. Cl. 336, 343 (2009), aff'd, 618 F.3d 1339 (Fed. Cir. 2010).

Generally, the Federal Circuit expects that a special master will present a reasonable basis for rejecting the opinion of an expert. Lampe, 219 F.3d 1361; Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

These standards will be used to determine whether Mr. Viscontini has established that he is entitled to compensation. For reasons explained in the following section, Mr. Viscontini has not met his burden of proof. Therefore, he is not entitled to compensation.

IV. Analysis

A. Prong One from *Althen*

The starting point for analysis is the theory proposed by the expert that "causally connect[s] the vaccination and the injury." Althen, 418 F.2d at 1278. This element of petitioner's case is sometimes referred to as answering the "can it" question. Pafford v. Sec'y of Health & Human Servs., No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), aff'd, 64 Fed. Cl. 19 (2005), aff'd, 451 F.3d 1352 (Fed. Cir. 2006).

Here, Mr. Viscontini advances the theory that the hepatitis B vaccine can be an environmental trigger for Crohn's disease. This theory, as reflected in the Venn diagram, is based upon the three assertions (1) that there is a genetic predisposition to developing Crohn's disease, (2) that some people have an immune system that is deficient in some way, and (3) that the exposure to some agent from the environment will trigger the onset of Crohn's disease. It is important to recognize that this case is about the third assertion – the environmental trigger. Mr. Viscontini is entitled to compensation from the Vaccine Program only if he establishes by a preponderance of the evidence that he "sustained . . . any illness . . . which was caused by a vaccine [listed on the Vaccine Injury Table]." 42 U.S.C. § 300aa—11(c)(1)(C)(ii)(I); accord Cedillo, 617 F.3d at 1349 (discussing special master's focus on MMR vaccine). Thus, this decision focuses on evidence relating to (that is, both for and against) the proposition that the hepatitis B vaccine can cause Crohn's disease.

Here, Dr. Bellanti proposes a theory that the hepatitis B vaccine can cause Crohn's disease. Pursuant to Terran, 1998 WL 55290, at *11, aff'd, 195 F.3d at 1316, this theory will be assessed using the Daubert factors.

- whether a theory or technique can be (and has been) tested

The evidence on this point is relatively weak. Dr. Solny stated that the theory could be tested but he was not aware of any testing. Tr. 157-58. Dr. Bellanti indicated that his theory could be tested using animal models, but Dr. Bellanti was not certain that animal models have been developed for Crohn's disease. Tr. 279. Dr. Warner stated that there are animal models for Crohn's disease. Tr. 305. This point does not weigh in favor of accepting or rejecting the theory that hepatitis B vaccine can cause Crohn's disease.

- whether the theory or technique has been subjected to peer review and publication

The evidence on this point strongly favors rejecting the theory that the hepatitis B vaccine can cause Crohn's disease. According to Dr. Warner, the theory that the hepatitis B vaccine can cause Crohn's disease has not been subject to peer review. Tr. 294-95. Dr. Bellanti has not published any peer-reviewed articles discussing a causal association between the hepatitis B vaccine and Crohn's disease. Tr. 231-32. Dr. Bellanti did not assert that the theory that the hepatitis B vaccine can trigger Crohn's disease had been subjected to peer review. Thus, Mr. Viscontini cannot rely upon the peer review process to support the reliability of the theory he espouses.

Additionally, published articles do not support a finding that the hepatitis B vaccine can cause Crohn's disease. As noted previously, Mr. Viscontini filed approximately 30 articles that ostensibly were advanced to support the proposition that hepatitis B vaccine can cause Crohn's disease. However, Mr. Viscontini did not solicit any testimony about these articles. Tr. 138 (Dr. Solny); tr. 229 (Dr. Bellanti). Similarly, Mr. Viscontini's briefs do not cite to any of these articles. Without any testimony from Mr. Viscontini's experts about these articles and without any argument from Mr. Viscontini's attorney about these articles, it is difficult to understand how the articles advance the expert's opinions. The undersigned has reviewed the articles independently and does not find those articles support the claim that the hepatitis B vaccine can cause Crohn's disease. See Moberly v. Sec'y of Health & Human Servs., 85 Fed. Cl. 571, 598 (2009) (noting that a special master is not required to conclude that a medical article may be interpreted without the assistance of a medical expert), aff'd, 592 F.3d 1315.

Mr. Viscontini's briefs actually cite to only the articles filed the evening before the hearing, exhibits 83 and 84. See Pet'r Br. at 10-15; Pet'r Reply at 10. These articles do not advance Mr. Viscontini's proof with regard to establishing a causal connection with the hepatitis B vaccine.

Exhibit 83 supports the idea, captured in Dr. Bellanti's Venn diagram, that Crohn's disease "reflects the contributions of host genetics, an environmental trigger, and the consequent immune response." Exhibit 83 (Mayer) at 9. When it comes to defining what environmental factors serve as the trigger, exhibit 83 states "Several triggers have been identified and there is strong evidence that no single

factor or agent is responsible for development of disease." Id. at 11. The Mayer article does not identify any vaccine as a possible trigger. Tr. 251.

Exhibit 84 describes how the gut's immune system interacts with bacteria that live in the immune system. Exhibit 84 (Nadine Cerf-Bensussan and Valerie Gaboriau-Routhiau, The immune system and the gut microbiota: friends or foes?, 10 Nat. Rev. Immunol. 735 (2010)). It supports the second portion of Dr. Bellanti's Venn diagram, that a deficiency in the immune system contributes to Crohn's disease, see tr. 271-73, and this is the context in which Mr. Viscontini cites to this article. See, e.g., Pet'r Br. at 11. When exhibit 84 refers to vaccines, the discussion relates to "lifestyle changes or medical practices," exhibit 84 at 740 (figure 4), corresponding to the hygiene hypothesis discussed above. See tr. 139; tr. 252. Exhibit 84 does not discuss vaccines as an environmental trigger.

Although these articles do not assert that the hepatitis B vaccine triggers Crohn's disease, a different article investigated the connection between hepatitis B vaccine and Crohn's disease. That article, which was filed by Mr. Viscontini, reported a study from France. The researchers based their study on 222 people with Crohn's disease compared to matched control subjects. The researchers analyzed 140 variables, including receipt of the hepatitis B vaccine, to see if any increased the risk of developing Crohn's disease. The researchers did not find any increased incidence. Exhibit 45 at 359 (noting article reports "only positive findings"), at 360 (noting positive reports for other vaccines), and at 361 (noting no increased incidence for hepatitis B vaccine and ulcerative colitis). Dr. Solny, who cited this article in his report, stated that "there is a lack of association in this study between hepatitis B vaccination and Crohn's disease." Tr. 160.[16]

Consequently, the evidence relating to peer review and publication provides no support for the theory that the hepatitis B vaccine can cause Crohn's disease.

- whether there is a known or potential rate of error and whether there are standards for controlling the error

[16] Mr. Viscontini objected to the question leading to the answer on the ground that petitioners are not required to present epidemiology. However, when epidemiological studies have been presented, the special master may consider them. Andreu, 569 F.3d at 1379 .

No evidence was introduced on this topic. It appears that the theory proposed by Dr. Bellanti is not susceptible to having an error rate calculated. Thus, this factor does not constitute affirmative or negative evidence.

- whether the theory or technique enjoys general acceptance within a relevant scientific community

The last criterion given by the Supreme Court concerned the "general acceptance" of a theory. Here, the theory that the hepatitis B vaccine can cause Crohn's disease falls dramatically short of being generally accepted.

Dr. Warner is qualified to express an opinion as to whether people in his field accept the theory that the hepatitis B vaccine can cause Crohn's disease.[17] Dr. Warner has specialized in gastroenterology for nearly 20 years. His more specific specialty is the study of inflammatory bowel diseases, including Crohn's disease. He has served on advisory boards of organizations related to Crohn's disease. He has written a book about Crohn's disease. He has served as a peer-reviewer and an editor for medical journals focused on inflammatory bowel diseases. Tr. 282-286; tr. 335; exhibit B (curriculum vitae) at 4-6.

Dr. Warner stated that outside of litigation in the Vaccine Program, he has not heard of the idea that the hepatitis B vaccine can cause Crohn's disease. Tr. 293. Dr. Warner asserted that although Crohn's disease has been researched for 50 years, no one has suggested that a vaccine causes it. Tr. 306. He has not encountered any proposed articles linking the hepatitis B vaccine and Crohn's disease. Tr. 335. Dr. Warner's assessment is similar to Dr. Solny's. Dr. Solny, who is a general gastroenterologist, stated that he has not heard people at professional meetings discuss the idea that hepatitis B vaccine can cause Crohn's disease. Tr. 168.[18] So, too, Dr. Bellanti could not estimate the percentage of

[17] When special masters evaluate petitioner's evidence, they may consider contrary evidence presented by the Secretary. Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (stating "The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case in chief.").

[18] Dr. Solny added that this theory "is in the medical literature in multiple places." Mr. Viscontini was instructed to submit any articles on this point, order, filed Nov. 19, 2009, but did not submit any articles to confirm what Dr. Solny stated.

immunologists who think that one of the environmental triggers for Crohn's disease is the hepatitis B vaccine. Tr. 276-78.

The practice of gastroenterologists is to recommend that their patients with Crohn's disease receive the hepatitis B vaccine. Tr. 293; tr. 347. This approach seems to reflect the idea that the gastroenterologists believe that any risk of harm from receiving the vaccine is less than the risk of foregoing the vaccine and possibly developing a hepatitis B infection.

Thus, the evidence regarding the general acceptance in the relevant scientific community does not favor accepting the theory that the hepatitis B vaccine can cause Crohn's disease. A possible rejoinder to this finding is an argument that the theory is so new that it has not had time to become known and generally accepted. The Supreme Court, in Daubert, cautioned against finding a theory did not satisfy the minimal standards for admissibility / reliability solely because the theory was new. "Publication (which is but one element of peer review) is not a sine qua non of admissibility; it does not necessarily correlate with reliability." Daubert, 509 U.S. at 593.

The novelty of the theory that the hepatitis B vaccine can cause Crohn's disease is just one factor that is considered. The fact that for decades, researchers have been investigating Crohn's disease and have not proposed that any vaccine functions as an environmental trigger suggests that the theory that the hepatitis B vaccine causes Crohn's disease does not fall within the mainstream. It is conceivable that mainstream scientific researchers have overlooked the role played by vaccines in causing Crohn's disease. It is imaginable that Dr. Bellanti may have discovered something that other researchers have missed. A theory that breaks new ground could rest on reliable foundations yet still not be generally accepted in the relevant scientific community.

Mr. Viscontini has not presented any persuasive evidence that this scenario occurred. Dr. Bellanti does not regularly treat people with Crohn's disease. Tr. 231 (estimating that he has seen 30-40 cases of Crohn's disease in his 47-year career). He has not studied the hepatitis B vaccine, although he has studied other vaccines. If there were to be an innovation in understanding how Crohn's disease is caused, Dr. Bellanti would be unlikely to be the person to make it.[19]

[19] This refers specifically to the theory that the hepatitis B vaccine can trigger Crohn's disease. It does not refer to the way that Dr. Bellanti distinguished autoinflammatory diseases from autoimmune diseases.

- additional considerations

In defining how district court judges should determine whether expert opinion is admissible, the Supreme Court has emphasized that the approach should be "flexible." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 151 (1999) (citing Daubert, 509 U.S. at 594). Thus, the analysis of whether the theory that the hepatitis B vaccine can cause Crohn's disease may consider more than just the four factors explicitly listed in Daubert.

One consideration is the origins of the expert's opinion. On remand from the Supreme Court, the Ninth Circuit stated:

> One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying. That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture. But in determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1317 (9th Cir. 1995).

Here, Dr. Bellanti's opinion that the hepatitis B vaccine caused Crohn's disease appears to be an opinion developed for this litigation.[20] Although Dr. Bellanti has occasionally seen a patient with Crohn's disease, Dr. Bellanti has not been involved with studies involving the hepatitis B vaccine. Tr. 230.

Another pertinent factor is why the expert offering the opinion thinks that the opinion is reliable. During Mr. Viscontini's examination of Dr. Bellanti, no questions that invited a defense of his theory were posed to him. On cross-

[20] On the other hand, Dr. Bellanti stated that he donates any money he receives for his participation in litigation to "research and education, a not-for-profit foundation." Tr. 259.

examination, the Secretary's counsel probed the basis for his theory. For example, Dr. Bellanti was asked to explain whether the hepatitis B vaccine was different from other vaccines or whether any substance that causes the immune system to react could function as the trigger in his theory. Dr. Bellanti stated:

> [The] Hepatitis B vaccine would work like any other vaccine.
>
> * * *
>
> What is different about this one, and that's what we don't know, it acts as a trigger for this underlying innate [genetic] defect [that] is present in the innate [immune] system.
>
> So there's something in that vaccine that we don't know. Whether it's the Hepatitis surface antigen, whether it's the aluminum adjuvant, or whether it's an excipient in the material, I honestly don't know and I don't think anybody knows.

Tr. 241-42. The Secretary's counsel continued and asked the basis for the conclusion that something in the hepatitis B vaccine affects the genetics. Dr. Bellanti answered:

> Well, the observation is that we established that there is a temporal and a causative relationship. Obviously we have a difference of opinion. I think there is. You [respondent's counsel] may not.
>
> But assuming that there is, then, we have to assume there's something in the vaccine that's causative, either the Hepatitis surface antigen . . . or something that's been added to it.

Tr. 242-43.

This passage suggests that Dr. Bellanti starts with a result (the vaccine can cause a problem) and reasons to get to that result. Dr. Bellanti observes a temporal relationship, tr. 242:23, but a temporal sequence is not a sufficient basis for finding causation. Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Dr. Bellanti also asserts that "we established . . . a causative relationship." Tr. 242:22-23. But, this is circular. Dr. Bellanti is being asked to explain why there is a causative relationship. It does not advance the proof to say,

as Dr. Bellanti essentially does, that the evidence supporting that causative relationship is that we have established a causative relationship. See Doe /70, 2011 WL 539133, at *18 (Fed. Cl. Spec. Mstr. May 26, 2010), aff'd, 95 Fed. Cl. 598 (Fed. Cl. 2010).

Because Dr. Bellanti may not have appreciated the import of his responses, the undersigned returned to this topic. The undersigned requested that Dr. Bellanti provide an additional response to the Secretary's question. With regard to the idea that the hepatitis B vaccine can trigger an underlying genetic defect, Dr. Bellanti said:

> [T]his is a plausible theory. It's a medical theory based on immunologic – it's a logical sequence of cause and effect, and there's a temporal relationship between the vaccine and what's going on.

Tr. 275-76.

Again, Dr. Bellanti missed a chance to provide the basis for his opinion. The undersigned inquired further as to why Dr. Bellanti thinks that the theory that the hepatitis B vaccine can cause Crohn's disease is plausible. Dr. Bellanti answered:

> What makes it plausible is that it's one of the modifying events that can participate in the, you know, the basis – pathogenetic mechanism we're talking about. You know, an innate immune system defect, an environmental stimulus trigger, and a dis-regulated immune system, the three parts of the Venn circle.
>
> Now, why this vaccine does it and why another one doesn't do it, I honestly don't know, but it's more likely than not that there is a causal relationship at least in my opinion.

Tr. 276. This response does not help. Dr. Bellanti's answer essentially repeats what the theory is (the Venn diagram with three circles). Dr. Bellanti's answer does not provide any explanation for why the hepatitis B vaccine would function as the environmental trigger.

These passages show that Dr. Bellanti could not provide any basis for linking the hepatitis B vaccine to the onset of Crohn's disease. Dr. Bellanti's recitation that "it's more likely than not that there is a causal relationship," tr. 276:15-16, is based upon nothing more than Dr. Bellanti's own words. As such, his opinion is not reliable.

During the hearing, Mr. Viscontini objected to the Secretary's questioning Dr. Bellanti about how the hepatitis B vaccine affects an underlying genetic condition. Tr. 245-46. This objection was probably based upon Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994), in which the Federal Circuit stated that causation may be established "without detailed medical and scientific exposition on the biological mechanism."

There is a difference between requiring a petitioner to present an exact pathogenic model of causation – which Knudsen prohibits – and requiring a petitioner to present reliable evidence – as stated in Vaccine Rule 8. In regard to the hepatitis B vaccine specifically, Dr. Bellanti presented no basis for concluding that the hepatitis B vaccine triggers a process leading to Crohn's disease. Dr. Bellanti stated "Hepatitis B has got nothing to do with Crohn's in terms of its causation but indirectly it is by producing the inflammatory milieu." Tr. 216. Despite many opportunities, Dr. Bellanti did not provide any basis for focusing on the hepatitis B vaccine. Thus, even if Dr. Bellanti's testimony were the only opinion offered in this case, there would still be no persuasive reason for finding the theory that the hepatitis B vaccine can trigger Crohn's disease to be reliable. "Mere conclusory opinions – or ones that are nearly so as unaccompanied by elaboration of critical premises will not suffice as proof of causation, no matter how vaunted or sincere the offeror." Doyle v. Sec'y of Health & Human Servs., 92 Fed. Cl. 1, 8 (2010) (denying motion for review and finding that the chief special master did not err legally or factually in rejecting testimony from petitioner's expert).

Although Dr. Bellanti could not support the theory he advances, Mr. Viscontini argues that the Secretary's expert (Dr. Warner) supports much of what Dr. Bellanti offered. See Pet'r Reply at 11-14. Mr. Viscontini is correct that Dr. Warner found some parts of the theory advanced by Dr. Bellanti to be reasonable. For example, Dr. Warner agreed with depicting the factors contributing to the onset of Crohn's disease in a Venn diagram and Dr. Warner also agreed that the theory that there is an environmental component to Crohn's disease is generally accepted. Tr. 300; tr. 318; cf. tr. 167 (Dr. Solny briefly discussing the need for an environmental trigger).

However, as Mr. Viscontini recognizes, Pet'r Reply at 14-15, Dr. Warner did not agree that the hepatitis B vaccine can act as the environmental trigger. Tr. 293. Needless to say, in the Vaccine Program, whether the vaccine plays a role in causing an illness is the key question. Dr. Warner's cautious acceptance of parts of the theory preliminary to the step involving the hepatitis B vaccine does not mean that Dr. Warner agreed with that step. Dr. Warner did not support the theory that the hepatitis B vaccine triggers Crohn's disease because "[t]here's simply no proof" for this assertion. Tr. 317.

- **Synopsis**

In sum, Mr. Viscontini advances through Dr. Bellanti's testimony the theory that the hepatitis B vaccine can trigger Crohn's disease in an individual who happens to have a genetic disposition to developing Crohn's disease and whose gut-immune system is defective. This testimony may be credited only when it is based upon reliable evidence, Vaccine Rule 8(b)(1), and one method useful in determining the reliability of an expert's opinion is to use the Daubert factors, Terran, 195 F.3d at 1316.

Mr. Viscontini has offered no persuasive reason for finding that Dr. Bellanti's opinion that the hepatitis B vaccine can trigger Crohn's disease is reliable. His opinion passes none of the Daubert factors.[21]

The lack of support for Dr. Bellanti's theory is so stark that had Mr. Viscontini disclosed the theory before the hearing, the undersigned would not have proceeded to a hearing on this theory as presented. As permitted by the statute, 42 U.S.C. § 300aa—12(d)(3)(B), the undersigned would have required Mr. Viscontini to submit some evidence supporting the reliability of this theory. See Moberly, 592 F.3d at 1324. Mr. Viscontini proceeded to a hearing on the basis of a theory

[21] Mr. Viscontini is not being required to present an expert's theory that passes all of the Daubert factors because special masters may not condition an award of compensation upon a petitioner introducing a theory that is generally accepted in the medical community or supported by medical literature. Althen, 418 F.3d at 1280. Rather, Mr. Viscontini is being held to submit "some indicia of reliability to support the assertion of the expert witness." Moberly, 592 F.3d at 1324.

that was not disclosed and failed to elicit evidence demonstrating that this theory is reliable. Mr. Viscontini has not established the first prong of Althen.

B. Prong Two of *Althen*

The second element in a petitioner's case is to submit preponderant evidence establishing "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." This prong has been interpreted to mean an inquiry into whether the vaccine "did cause" the injury to the vaccine. Pafford, 451 F.3d at 1354. Under this prong, the relevant evidence tends to be evidence specific for the petitioner, as opposed to evidence about causation in general. The types of evidence that may be probative on second prong include the statements of treating doctors and evidence of challenge-rechallenge. Capizzano, 440 F.3d at 1326.

As a matter of logic, the first and second prongs relate to each other. See Capizzano, 440 F.3d at 1327 ("We see no reason why evidence used to satisfy one of the Althen III prongs cannot overlap to satisfy another prong."). If it is found that the vaccine "did cause" an injury, then the vaccine must be capable of causing the injury. Conversely, if there has not been a showing that the vaccine "can cause" an injury, then the vaccine cannot be said to have caused the injury for a specific petitioner. See Caves v. Sec'y of Health & Human Servs., __ Fed. Cl. ___, No. 07-443V, 2011 WL 2523438, at *23 (June 24, 2011), appeal docketed, No. 2011-5108 (Fed. Cir. July 13, 2011).

Mr. Viscontini's case falls into the latter category. For the reasons set forth in section A, he has failed to establish that the hepatitis B vaccine can cause Crohn's disease. Nevertheless, the evidence that pertains to prong two (some of which happens to overlap with prong one) is considered below.

1. Statements of Treating Doctors

Mr. Viscontini's brief does not advance the statement of any treating doctor as evidence supporting his proof of prong two. See Pet'r Br. at 15-19. The record, however, contains one piece of evidence that a treating doctor connected Mr. Viscontini's condition to the hepatitis B vaccination. In light of the special master's obligation to decide cases based upon the "record as a whole," 42 U.S.C. § 300aa—13(a), this evidence is considered.

Mr. Viscontini's mother testified that Dr. Safer linked the hepatitis B vaccine to his gastrointestinal problems. Dr. Safer treated Mr. Viscontini in Middletown, Connecticut, when he went to the emergency room in November 1996. Dr. Safer believed that Mr. Viscontini had pancreatitis. According to Ms. Viscontini, Dr. Safer told her that her son was one of the three percent of people who react adversely to the hepatitis B vaccination. Tr. 69-71.[22]

Dr. Safer's admission report states that Dr. Safer initially held the impression that Mr. Viscontini suffered from an ulcer. This report does not mention the hepatitis B vaccine. Exhibit 24 at 17-18. The handwritten notes mention the possibility of pancreatitis. Id. at 19. The discharge report indicates that the diagnosis included pancreatitis and gastrointestinal hemorrhage. The discharge report does not mention the hepatitis B vaccine at all. The discharge report recommends that Mr. Viscontini seek treatment from a pediatric gastroenterologist. Exhibit 24 at 10-11.[23]

In light of all the material, the undersigned declines to assign much probative weight to Ms. Viscontini's testimony about Dr. Safer's opinion. As a matter of law, special masters may not award compensation "on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa—13(a). Additionally, even if Dr. Safer had clearly written that Mr. Viscontini had an adverse reaction to the hepatitis B vaccination, this statement is not binding on the special master. 42 U.S.C. § 300aa—13(b)(1). Finally, the understandable uncertainty about the disease afflicting Mr. Viscontini before a complete work up by a pediatric gastroenterologist could affect Dr. Safer's opinion regarding causation.

2. Challenge-Rechallenge

Challenge-rechallenge is a paradigm for exploring whether one substance caused an adverse reaction. "Under this model, an individual who has had an adverse reaction to the initial vaccine dose (the 'challenge event') suffers a worsening of symptoms after a second or third injection (the 'rechallenge event')."

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[22] Mr. Viscontini provided similar testimony in response to leading questions on direct examination. Tr. 20-23.

[23] The pediatric gastroenterologist ordered the biopsy that led to the diagnosis of Crohn's disease.

Doe/70 v. Sec'y of Health & Human Servs., 95 Fed. Cl. 598, 603 (2010) (brackets and quotation marks omitted); accord tr. 322.

Mr. Viscontini emphasizes the argument that his case illustrates an instance of challenge-rechallenge. Pet'r Br. at 16-19. This argument rests upon the following sequence of events:

(a) on December 7, 1995, Mr. Viscontini received the first dose of the hepatitis B vaccine, Exhibit 2 at 10

(b) within one week, Mr. Viscontini experienced a loss of appetite, "flu-like symptoms," and general malaise. Tr. 12; tr. 52; tr. 101-02.

(c) on January 11, 1996, Mr. Viscontini received the second dose of the hepatitis B vaccine,

(d) within about four days of the vaccination, Mr. Viscontini started vomiting and experienced abdominal cramping. Exhibit 12 (records of Dr. Marcelino DeSantos) at 2; tr. 15; tr. 53-54.

(e) on July 31, 1996, Mr. Viscontini received the third dose of the hepatitis B vaccine.

(f) within three days of the third dose, Mr. Viscontini had "extreme[ly] excruciating" abdominal pain. Tr. 63.

Both Dr. Solny and Dr. Bellanti stated that Mr. Viscontini's case presented a case of challenge-rechallenge. Tr. 136 (Dr. Solny); tr. 145-46 (same); tr. 176 (same); tr. 215 (Dr. Bellanti); tr. 226 (same).

Some of Mr. Viscontini's assertions are not supported by medical records created when those events allegedly happened. For example, the "flu-like symptoms" that Mr. Viscontini allegedly had within one week of the December 7, 1995 vaccination did not prompt Mr. Viscontini to see his doctor. See exhibit 2 at 4. Similarly, although Mr. Viscontini testified that he had abdominal cramping within four days of the January 11, 1996 vaccination, the next medical record was created on January 27, 1996. This record notes that Mr. Viscontini has been having a stomach ache in his mid-abdominal area and, although no specific time was given for when this problem began, the context suggests that it was within two days. Id. When the factual assertions underlying a challenge-rechallenge argument are not supported, a special master may reasonably reject the challenge-rechallenge argument. Doe/70, 95 Fed. Cl. at 609-10.

The more significant problem in Mr. Viscontini's use of the challenge-rechallenge model is that the symptoms invoked as demonstrating the development

of Crohn's disease as a reaction to the hepatitis B vaccine are very common. In December 1995, Mr. Viscontini did not "feel[] like eating," felt a "little feverish," and had a "runny nose." Tr. 52. These symptoms could possibly represent the onset of Crohn's disease, but, according to Dr. Warner, they were not the beginning of Mr. Viscontini's Crohn's disease. Tr. 325-28. As previously discussed, Mr. Viscontini's Crohn's disease began in mid-February 1996. See section I.B, above; cf. Locane, 2011 WL 3252807 at *11 (finding that the special master did not err in crediting Dr. Warner's opinion about when a case of Crohn's disease began).

This finding effectively modifies the challenge-rechallenge model. Instead of a model of challenge (first dose) – rechallenge (second dose) – further rechallenge (third dose), the challenge event is the second dose and the rechallenge event is the third dose. See Doe, 95 Fed. Cl. at 609-10 (discussing how special master's factual findings affected Dr. Bellanti's use of challenge-rechallenge). The second dose was on January 11, 1996. Then, Mr. Viscontini had an episode of abdominal pain on approximately January 25, 1996. Mr. Viscontini had consistent abdominal pain for which he sought medical treatment, starting on May 4, 1996. Mr. Viscontini's abdominal pain abated. He received the third dose of the hepatitis B vaccine on July 31, 1996. Then, he had more intense abdominal pain. This sequence supports the challenge-rechallenge model.

Mr. Viscontini argues that "if an individual experiences a rechallenge event, or can demonstrate the presence of pathological markers indicated that the vaccine caused the injury, a petitioner has established causation-in-fact." Pet'r Reply at 6, quoting Capizzano v. Sec'y of Health & Human Servs., No. 00-759V, 2004 WL 1399178, at *10 (Fed. Cl. Spec. Mstr. June 8, 2004) (emphasis added in petitioner's brief).[24] This argument is significantly overstated for two reasons.

First, to the extent that Mr. Viscontini is presenting an absolute argument that "if petitioner establishes challenge-rechallenge, then causation is always established," then this argument is not tenable. The Federal Circuit has explained that "[c]ausation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules." Knudsen, 35 F.3d at 548.

[24] Petitioner's brief cites to the Capizzano decision that was issued in August 2003, but the source of the quotation is actually the June 2004 decision.

Second, Mr. Viscontini takes the statement from Capizzano out of context. Rose Capizzano's case was one case in a consolidated set of cases exploring whether the hepatitis B vaccine caused the petitioner's rheumatoid arthritis. In an earlier decision, the special master found that the evidence established that it is biologically plausible for the hepatitis B vaccine to cause rheumatoid arthritis. The basis for this finding included an article from a medical journal reporting four cases of rheumatoid disorders that developed after the hepatitis B vaccination. Capizzano v. Sec'y of Health & Human Servs., No. 00-759V, 2003WL 2242500 (Fed. Cl. Spec. Mstr. Aug. 5, 2003).[25] Thus, the special master's statement quoted by Mr. Viscontini is based upon a previous finding that the vaccine "can cause" an injury. Under this circumstance, the evidence of rechallenge fulfills petitioner's burden to present preponderant evidence that the vaccine "did cause" his (or her) particular injury.

Here, in contrast, the evidence does not support a finding that the hepatitis B vaccine can cause Crohn's disease. As discussed in section IV.A., the only evidence supporting such a causal connection is the testimony of Dr. Bellanti and Dr. Solny, neither of whom was persuasive. Thus, the evidence makes Mr. Viscontini's case different from Capizzano. See Doe/70 v. Sec'y of Health & Human Servs., No. [redacted], 2011 WL 539133, at *13 n.22 (Fed. Cl. Spec. Mstr. May 26, 2010) (discussing the use of rechallenge in Capizzano and distinguishing Capizzano from the case at bar), motion for review denied, 95 Fed. Cl. 598, 612-13 (2010) (finding that the special master did not err in rejecting Dr. Bellanti's reliance on challenge-rechallenge).

The attractiveness of the challenge-rechallenge model is that the perceived pattern of exposure followed by an adverse event appears to increase the likelihood that the exposure caused the adverse event. Without the repetition, the argument that the hepatitis B vaccine must have caused the Crohn's disease because the hepatitis B vaccine preceded the Crohn's disease could be rejected as based upon unsound logic. Grant, 956 F.2d at 1148; Dixon v. Sec'y of Health & Human Servs., 61 Fed. Cl. 1, 12 (2004). Yet, even with repetition, there is still a possibility that the perceived pattern is nothing more than a coincidence as Dr. Bellanti recognized. Tr. 226.

[25] This analysis referenced prong one of the Stevens test. After this decision the Federal Circuit held that some aspects of the Stevens test were not in accord with law in Althen, 418 F.3d at 1281.

C. **Prong Three from *Althen***

The final element of petitioner's case is to establish a "showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278. When petitioners fail to establish this element, they are not entitled to compensation. Pafford, 64 Fed. Cl. at 29-30 (2005), aff'd, 451 F.3d at 1358-59. The Federal Circuit has elaborated that the third prong of the Althen test requires "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." Bazan, 539 F.3d at 1352. Thus, the two components of this prong are the timeframe for which it is "medically acceptable to infer causation," and the onset of the condition for which petitioner seeks compensation.

Here, Dr. Warner, the person with the most extensive knowledge of Crohn's disease in this case, refrained from providing a time in which the medical community would recognize as appropriate to infer causation. Dr. Warner could not provide this time because what causes Crohn's disease is not known. Without some understanding of the etiology of Crohn's disease, it is not possible to explain how much time should pass between the exposure to an antigen (the vaccination) to the onset of Crohn's disease. Tr. 312; see also tr. 350-51. Dr. Warner's approach is logical. If science does not understand how a disease progresses, how can anyone provide any helpful information about how long the process should take?

Nevertheless, the Federal Circuit has stated that one element of a petitioner's case is to establish the appropriate temporal relationship. Thus, the undersigned will evaluate the evidence presented by Mr. Viscontini, which is the testimony of Dr. Solny and Dr. Bellanti.

Dr. Solny provided muddled testimony regarding the appropriate temporal relationship. Dr. Solny was not asked any questions about the timeframe in which it is acceptable to infer causation as part of direct examination. Dr. Solny did touch upon the interval between the vaccination and the perceived course of Mr. Viscontini's Crohn's disease when Dr. Solny asserted that Mr. Viscontini's case was an example of challenge-rechallenge. Tr. 136. When the undersigned asked Dr. Solny to give his opinion regarding the appropriate temporal relationship, Dr. Solny responded that an immunologist would give a better answer. Dr. Solny suggested that the appropriate temporal relationship would be set in a paper by Dr. Schonberger. Tr. 161-62. Then, in response to leading questions on redirect, Dr.

Solny agreed that the onset of symptoms within seven days following the first exposure would be an appropriate amount of time for which to infer causation. Tr. 181-82. Finally, as part of recross examination, Dr. Solny stated that the Schonberger paper examined the relationship between flu vaccination and Guillain-Barré syndrome. Dr. Solny stated that the differences did not prevent him from using the Schonberger study as a "rough guide to the reactivity of vaccinations in general." Tr. 184-86.

The remaining witness was Dr. Bellanti. Dr. Bellanti testified that symptoms seven days after the first dose, symptoms four-to-five days after the second dose, and symptoms three days after the third dose are consistent with "immunologic dogma." Tr. 218. This testimony draws upon his earlier testimony in which he explained how the immune system develops a memory (or anamnestic) response. Tr. 214.

Consequently, solely for the purposes of this case, the undersigned accepts, without critical evaluation, the testimony that symptoms between three days and seven days after a vaccination would be an appropriate interval for which it is medically appropriate to infer that the hepatitis B vaccine caused Mr. Viscontini's symptoms. If the evidence were analyzed, the testimony might have been found to be lacking persuasive value because much of the testimony was conclusory. For example, because Dr. Bellanti did not propose a theory explaining why the hepatitis B vaccine can act as a trigger in a genetically susceptible individual, he did not explain why the appropriate amount of time for the initial response is seven days. See Doe/70, 2011 WL 539133, at *17.

Even after the accuracy of the interval of three, four, or seven days is accepted, Mr. Viscontini's evidence regarding Althen prong three still has problems. Both Dr. Solny and Dr. Bellanti assume that Mr. Viscontini had abdominal problems, which were symptoms of his Crohn's disease, within four-to-five days of his January 11, 1996 vaccination.

This assumption is not based upon the medical records. Dr. DeSantos's records mention an incident of abdominal pain at the end of January 1996. Consistent notations of abdominal problems start toward the end of March 1996. Exhibit 2 at 4-7. As discussed in the section on fact-finding, a preponderance of evidence supports a finding that Mr. Viscontini's Crohn's disease began in mid-February 1996. Mid-February 1996 is more than seven days after the January 11, 1996 vaccination. Consequently, the onset of problems did not occur within the time discussed by Dr. Solny and Dr. Bellanti.

V. Conclusion

Mr. Viscontini received three doses of the hepatitis B vaccine between December 1995 and July 1996. During this time, he experienced abdominal problems and, in November 1996, he was diagnosed as having Crohn's disease. Mr. Viscontini contends that the hepatitis B vaccine caused his Crohn's disease.

Mr. Viscontini's evidence was not persuasive. Despite the requirement found in Vaccine Rule 8(b)(1) that special masters consider evidence that is "reliable," Mr. Viscontini failed to demonstrate the reliability of a theory that causally connects the hepatitis B vaccine to Crohn's disease. The evidence was resoundingly poor. Dr. Bellanti disclaimed the ASCA-based theory that he had presented in his report and instead presented a novel theory that the hepatitis B vaccine is a trigger for Crohn's disease. Mr. Viscontini presented no evidence, other than Dr. Bellanti's testimony, that suggests that the hepatitis B vaccine is a trigger for Crohn's disease. The medical articles that were filed into the record approximately 60 days before the hearing in ostensible support for the expert's opinions were largely ignored. In short, the reasonableness of Mr. Viscontini's approach to litigation is questionable.

The finding that Mr. Viscontini did not present persuasive evidence of a theory causally connecting the hepatitis B vaccine to Crohn's disease means that Mr. Viscontini is not entitled to compensation. Mr. Viscontini's evidence on the other two prongs from Althen was also lacking.

Mr. Viscontini has not met his burden of establishing that he is entitled to compensation. The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

IT IS SO ORDERED.

S/Christian J. Moran
Christian J. Moran
Special Master