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

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JENNIFER LOCANE,	*	
	*	No. 99-589V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	Filed: February 17, 2011
	*	Released: August 11, 2011
SECRETARY OF HEALTH	*	Entitlement, hepatitis B vaccine,
AND HUMAN SERVICES,	*	Crohn's disease, onset, significant
	*	aggravation
Respondent.	*	
* *		

Clifford J. Shoemaker, Shoemaker and Associates, Vienna, VA, for petitioner; Melonie J. McCall, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Ms. Locane alleged that the hepatitis B vaccine given to her in 1997 caused her to suffer Crohn's disease. Ms. Locane seeks compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10 et seq. (2006).

[1] When this decision was originally filed, the parties were notified of their opportunity to seek redaction pursuant to 42 U.S.C. § 300aa–12(d)(4) and Vaccine Rule 18(b). Ms. Locane filed a motion for redaction. However, this motion was denied in an order issued on August 11, 2011, because the Court's July 15, 2011 opinion is available to the public. The February 17, 2011 decision is now being made available to the public through 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). Other than this footnote, no other changes have been made.

Ms. Locane has not established that she is entitled to compensation because a preponderance of the evidence shows that she had Crohn's disease before she received the hepatitis B vaccinations. Therefore, the hepatitis B vaccines did not cause her Crohn's disease. Furthermore, there is not preponderant evidence that the hepatitis B vaccinations significantly aggravated the Crohn's disease.

I. Procedural History

Ms. Locane filed her petition on August 4, 1999, which was near the last day petitions alleging that the hepatitis B vaccine caused an injury before August 6, 1997, could be filed. See 42 U.S.C. § 300aa-16(b); 63 Fed. Reg. 25777, 25778 (clarifying the date on which the hepatitis B vaccine was added to the vaccine injury compensation table). Ms. Locane did not file any medical records with her petition, although the statute requires those records to be filed. See U.S.C. § 300aa-11(c).

For approximately six years, Ms. Locane's case did not advance. During this time, counsel for petitioners, who alleged that the hepatitis B vaccine caused them an injury, and counsel for respondent attempted to establish a mechanism for resolving cases involving the hepatitis B vaccine. These efforts, although undertaken in good faith, did not succeed.

After the need for individual adjudication of cases became apparent, development of Ms. Locane's case started in 2006. Ms. Locane filed her first set of medical records in 2006. Ms. Locane filed her affidavit, which is exhibit 17, in October 2006. By January 2007, Ms. Locane had produced enough factual material about her claim that she was ordered to obtain a report of an expert. Order, filed January 23, 2007.

Ms. Locane filed the report of Dr. Joseph Bellanti in June 2007. 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 22 (curriculum vitae); tr. 33-38.

In his report, approximately nine pages are devoted to recounting Ms. Locane's medical history. Exhibit 22. One page (three paragraphs) contains Dr.

Bellanti's analysis. Dr. Bellanti stated that "[t]his record clearly shows a temporal relationship between the hepatitis B vaccination and the development of Crohn's disease." Dr. Bellanti also stated that "[t]he evidence for vaccination causing Crohn's disease in the literature is sparse at best." After quoting from Cecil's Textbook of Medicine, Dr. Bellanti stated that "it seems clear that any antigen could set off an inflammatory cascade like an infection or a vaccination could cause Crohn's disease." Dr. Bellanti also suggested exploring whether Ms. Locane had anti-Saccharomyces cerevesiae antibodies (ASCA). Exhibit 22 at 10. Saccharomyces cerevesiae is a species of yeast used in baking and brewing. Dorland's Illustrated Medical Dictionary (30th ed. 2002) at 1649. These antibodies were of interest to Dr. Bellanti because many patients with Crohn's disease have ASCA and the hepatitis B vaccine is cultured in yeast. Exhibit 22 at 10.

On August 6, 2007, respondent filed her report pursuant to Vaccine Rule 4. Respondent maintained that Ms. Locane was not entitled to compensation. Respondent supported her position by submitting a report from Dr. Andrew S. Warner. Dr. Warner is the Chairman of the Gastroenterology Department in the Lahey Clinic. He is board-certified in gastroenterology and also 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); tr. 100-04.

Dr. Warner presented the opinion that "the temporal relationship [between Crohn's disease] to Ms. Locane receiving the hepatitis B vaccine is probably coincidental. In addition, there is evidence in [Ms. Locane's] case history indicating that she had Crohn's disease prior to receiving the hepatitis B vaccine." To support this assertion, Dr. Warner relied upon a graph charting Ms. Locane's growth in both height and weight. Exhibit A at 3.

Dr. Warner also addressed the connection between the hepatitis B vaccine and Crohn's disease as posited by Dr. Bellanti. Dr. Warner stated that "There is actually no evidence in the literature linking hepatitis B vaccination to Crohn's disease." Regarding Dr. Bellanti's discussion of ASCA, Dr. Warner stated "This is nonsense." Exhibit A at 2.

After both sides had presented reports from an expert, the process of scheduling a hearing began. In November 2007, a hearing was scheduled for April 17, 2008. In the pre-trial process, both parties were ordered to file literature relied upon by their experts. Order, filed April 4, 2008. The hearing took place on April 17, 2008, in Washington, D.C. At this hearing, Ms. Locane and Dr. Bellanti testified for the petitioner and Dr. Warner testified for respondent.

After the hearing, Ms. Locane was ordered to file a brief by June 19, 2008. She actually filed this brief on August 25, 2008. In this brief, Ms. Locane argued that the hepatitis B vaccine "can cause Crohn's disease." Pet'r Br. at 10-11. She also alternatively contended that the "Hepatitis B vaccines clearly caused a significant aggravation of her condition." Id. at 11.

Because Ms. Locane's argument regarding significant aggravation was not developed well, she was ordered to file a supplemental brief on this topic. Order, filed Aug. 28, 2008. Instead of filing a supplemental brief discussing evidence that was already in the record, Ms. Locane responded to the August 28, 2008 order by filing a motion to allow additional evidence, including an additional hearing. Respondent opposed this motion.

Despite respondent's opposition, Ms. Locane's motion was granted. Ms. Locane was permitted to file a supplemental expert report addressing whether the hepatitis B vaccine significantly aggravated a pre-existing Crohn's disease. Ms. Locane was ordered to file a status report by December 11, 2008, stating her progress in obtaining a supplemental report. Order, filed Oct. 29, 2008.

Ms. Locane did not file this status report. After Ms. Locane missed this deadline, she was ordered to file a supplemental expert report by April 17, 2009. Order, filed Feb. 20, 2009. Ms. Locane filed three timely motions for enlargement of time and filed a supplemental report from Dr. Bellanti on August 28, 2009. Exhibit 42. Ms. Locane also filed a report from a different doctor, Meyer Solny, on October 27, 2009. Exhibit 43.

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. Exhibit 44 (curriculum vitae).

Dr. Solny's first report did not address whether the hepatitis B vaccine significantly aggravated a pre-existing Crohn's disease which was the pending

question. Therefore, Ms. Locane was ordered to file a supplemental report from Dr. Solny by January 19, 2010. Order, filed Nov. 19, 2009. Ms. Locane filed two timely motions for enlargement of time and filed a supplemental report and associated literature from Dr. Solny on March 19, 2010. Exhibits 45-54.

Because Ms. Locane filed evidence after the hearing, respondent was given an opportunity to respond. Respondent filed a supplemental report from Dr. Warner on June 8, 2010. Exhibit D. Respondent also filed, on June 29, 2010, a brief in response to Ms. Locane's original post-hearing brief, which had been filed on August 25, 2008.

Ms. Locane had an opportunity to file a reply brief. After filing six timely motions for enlargement of time, Ms. Locane filed her reply brief on August 31, 2010. With the filing of that brief, the case is ready for adjudication.

II. Facts

Ms. Locane was born in July 1983. She was adopted and knows no information about the medical history of her biological family. Tr. 9. Medical records from her pediatrician show that Ms. Locane had injuries and illnesses that are typical for childhood. See exhibit 10 and exhibit 12.

At various times, Ms. Locane's doctors recorded her height and weight and plotted these values on standard charts. Throughout much of Ms. Locane's childhood, her height and weight was at approximately 50 percent. Exhibit 6 at 15-16. At age 10 (1993), for example Ms. Locane was slightly more than 54 inches in height, which placed her at the 50 percentile. Ms. Locane weighed approximately 72.5 pounds.[2] Exhibit 6 at 15 and exhibit 6 at 19.

Ms. Locane did not stay on this curve. The chart from her pediatrician's office shows that at age 13 (1996), Ms. Locane's height (59 and one-half inches)

[2] This decision presents Ms. Locane's weight in pounds. When her weight was measured in kilograms, the number of kilograms was converted to pounds based upon the formula 1 kg = 2.2 pounds. See Dorland's Illustrated Medical Dictionary (31st ed. 2007) at 2162.

Similarly, Ms. Locane's height is presented in inches. Information recorded in centimeters is translated to inches based upon the formula 1 cm = 0.39 inches. Id. at 2163.

had fallen to the 25th percentile. The drop in her weight was even more significant. She was at only the 10th percentile. Exhibit 6 at 15; exhibit 12 at 26.

Additional information about Ms. Locane's weight comes from her visit to a pediatrician for various illnesses. At these visits, Ms. Locane's weight was recorded but not her height. The available information shows the following changes in Ms. Locane's growth:

Weight and Height Percentages for Ms. Locane[3]						
Date	Age	Weight in pounds	Wt. Percent	Height in inches	Ht. Percent.	Source
7/13/93	10	72.5	50	54.25	50	Exhibit 6 at 19
10/0/94?	11.25	83	45-50			Exhibit 12 at 23
5/0/95?	11.75	83	35-40			Exhibit 12 at 23
11/20/95	12.25	82.5	25			Exhibit 12 at 24
3/7/96	12.5	80	18			Exhibit 12 at 25
7/9/96	13	82	15	60.25	25	Exhibit 12 at 26
3/0/97?	13.75	88.25	12			Exhibit 12 at 27
8/29/97	**14**	**88**	**10**	**61**	**25**	**Exhibit 12 at 28**
11/18/97	14	84	5			Exhibit 12 at 30
11/28/97	14	82	<5	61.25	5-10	Exhibit 3 at 12
11/28/97	14	76	<5			Exhibit 12 at 30
11/28/97	14	77	<5			Exhibit 10 at 15 (hospital)

On August 29, 1997, Ms. Locane saw her pediatrician, Dr. Arnold Tanis, for a physical examination to qualify her to participate in sports in high school. Exhibit 12 at 28; tr. 11. During this visit, Ms. Locane's height and weight were

[3] The medical records do not always clearly indicate the day of a month in which Ms. Locane saw a doctor. So, some entries have a zero for the day of the month. Additionally, for some entries, the weight percentage was estimated. See tr. 142-43.

recorded and these entries are bolded in the chart above. Ms. Locane also received a dose of the hepatitis B vaccine. Exhibit 14 at 11; exhibit 12 at 14.[4]

Within a week or two after the vaccination, Ms. Locane started having stomach cramps, some loose stools, and a decreased appetite. She was also feeling nauseated. Tr. 12.

On November 18, 1997, Ms. Locane returned to her pediatrician. The chief complaint was that Ms. Locane's mother "was concerned about [weight] loss." At this visit, Ms. Locane weighed 84 pounds, which was four pounds less than she weighed approximately three months earlier. Ms. Locane's pediatrician assessed her as having a viral illness. Exhibit 14 at 27; tr. 12 (Ms. Locane's testimony about this visit).

Over the Thanksgiving holiday, Ms. Locane developed blood in her stool. She was also having diarrhea. Ms. Locane returned to the pediatrician on November 28, 1997. The doctor noted that she weighed 76 pounds, which was a decrease of eight pounds in 10 days. The pediatrician assessed Ms. Locane as having either Crohn's disease or ulcerative colitis. The pediatrician referred Ms. Locane to a pediatric gastroenterologist, Dr. Mario Tano. Exhibit 14 at 30; tr. 14-15.

Dr. Tano saw Ms. Locane the same day. Dr. Tano obtained a history that is consistent with the facts recited above, although Dr. Tano did not mention the hepatitis B vaccination. Dr. Tano recorded Ms. Locane's weight (82 pounds) and noted that this placed her below the fifth percentile. Dr. Tano also reported Ms. Locane's height and noted that it was between the fifth and tenth percentiles. Dr. Tano's impressions included inflammatory bowel disease. He recommended that Ms. Locane be admitted to a hospital for laboratory studies. Exhibit 3 at 11-13.

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[4] A preponderance of the evidence establishes that the August 29, 1997 vaccination was the first dose of the hepatitis B vaccine given to Ms. Locane. A record mentions a hepatitis B vaccination on March 24, 1994. Exhibit 14 at 51. However, the March 24, 1994 vaccination is not reflected in the "Vaccine Administration Record" created by Ms. Locane's pediatrician. See exhibit 14 at 11; exhibit 12 at 14. Ms. Locane stated that she does not remember receiving the hepatitis B vaccine in March 1994. Tr. 10. Further, Ms. Locane is not relying upon a vaccination on March 24, 1994. Tr. 5 (statement of Ms. Locane's attorney). Ms. Locane asserted that on August 29, 1997, "she received her first hepatitis B vaccination." Pet'r Br., filed Aug. 25, 2008, at 1.

Ms. Locane was admitted to Joe DiMaggio Memorial Regional Hospital on the same day, November 28, 1997. Her weight at admission was 77 pounds. Exhibit 10 at 167 (nursing assessment at admission), at 266. Tests for various pathogens in her stool were negative. Exhibit 10 at 4-5. Ms. Locane had a colonoscopy with biopsy on December 4, 1997, and this test showed lesions, ulcers, and perianal fistula suggestive of Crohn's disease. Exhibit 10 at 93-95. The next day, Ms. Locane had an upper GI and small bowel radiographs that revealed a 15-20 centimeter nodular and irregular area in the terminal ileum. This also was consistent with Crohn's disease. Exhibit 10 at 28. Ms. Locane was discharged on December 9, 1997. Her medications included prednisone. Exhibit 10 at 3.

Two days after discharge, Ms. Locane saw her pediatrician. As no specific complaint is described, this appointment appears to be a follow-up to Ms. Locane's hospitalization. Ms. Locane was given a second dose of the hepatitis B vaccine. She also received an influenza vaccine and a pneumococcal vaccine. Exhibit 14 at 26. Ms. Locane did not recall having any adverse effects after receiving these vaccinations. Tr. 17.

On December 16, 1997, Ms. Locane saw Dr. Tano, her pediatric gastroenterologist, again. Dr. Tano recorded that Ms. Locane was doing better, continued the prednisone, and recommended that Ms. Locane return in six weeks. Exhibit 3 at 9-10. On December 31, 1997, Dr. Tano reduced the amount of prednisone that Ms. Locane was taking. Id. at 7.

The return visit to Dr. Tano took place on February 5, 1998. Ms. Locane was improved and Dr. Tano's impression was "Crohn's disease, in signs of remission." Dr. Tano recommended weaning the amount of prednisone. Exhibit 3 at 3-4; see also tr. 18 (Ms. Locane's testimony about this visit).

The next day, Ms. Locane saw her pediatrician. The purpose of the appointment was to receive the third dose of the hepatitis B vaccine. Exhibit 14 at 26; exhibit 12 at 14 (vaccination record).

On March 16, 1998, Ms. Locane saw Dr. Tano on an "urgent basis" because she was having blood in her stool and had a temperature of 103 degrees. Dr. Tano's impression included "Crohn's disease with exacerbation of symptoms." Dr. Tano recommended a change in Ms. Locane's medication, including an increase in the amount of prednisone. Exhibit 3 at 1-2.

Over the next decade, Ms. Locane periodically had problems with her Crohn's disease. Ms. Locane described these problems in her affidavit (exhibit 17) and in her testimony (tr. 20-26). They are also described in various medical records, although these records are not summarized in this decision because the details of Ms. Locane's Crohn's disease after March 1998 do not affect whether she is entitled to compensation. See Pet'r Br. at 4 (summarizing Ms. Locane's history after March 1998).

III. Analysis

Ms. Locane is presenting alternative theories, which differ in the date that is assumed for the onset of her Crohn's disease. Ms. Locane's primary theory is that her Crohn's disease started after she received the hepatitis B vaccine in August 1997, and that the vaccine caused the disease. Ms. Locane's alternative theory assumes that she was suffering from Crohn's disease when she received the vaccination. In this theory, Ms. Locane maintains that the vaccine significantly aggravated the Crohn's disease.

The preliminary step in adjudicating Ms. Locane's case is to resolve when her Crohn's disease began. This finding will determine whether her causation-in-fact theory is viable or her significant aggravation theory is viable.

A. When Did Ms. Locane's Crohn's Disease Begin?

The first step in deciding Ms. Locane's claim that the hepatitis B vaccine caused her to suffer Crohn's disease is to determine when the Crohn's disease began. Ms. Locane's expert, Dr. Bellanti, indicated that the hepatitis B vaccine caused Ms. Locane's Crohn's disease. Exhibit 22 at 10. When questioned during the hearing, Dr. Bellanti stated that the changes in Ms. Locane's weight before the August 29, 1997 vaccination were not significant. Tr. 88-94. In contrast, Dr. Warner maintained that these changes showed that the Crohn's disease was affecting Ms. Locane before she received the vaccination. Exhibit A at 1. Given such opposing points of view, it is appropriate to resolve this issue first.[5]

A preponderance of the evidence supports a finding that Ms. Locane was already suffering from Crohn's disease before she received the August 29, 1997

[5] Logically, if Ms. Locane suffered from Crohn's disease before she was vaccinated, the vaccination could not have caused the Crohn's disease.

hepatitis B vaccination. The basic reason for this finding is the testimony of Dr. Warner, who has a great amount of experience in Crohn's disease. He expressed this opinion and his opinion is consistent with the published literature about Crohn's disease.

Dr. Warner's qualifications and expertise contribute to the persuasiveness of his opinion that Ms. Locane suffered from Crohn's disease before the vaccination. Dr. Warner is board-certified in gastroenterology. Within the field of gastroenterology, Dr. Warner has specialized in the treatment of Crohn's disease and ulcerative colitis since 1992. Approximately 80 percent of Dr. Warner's professional time is spent on treating patients and Dr. Warner sees between 30 and 50 patients with inflammatory bowel disease per week. Tr. 101-03. Some of these patients are adolescents, although Dr. Warner is not a pediatric gastroenterologist. Tr. 121; tr. 134.

Compared to Dr. Warner, Dr. Bellanti has much less experience with Crohn's disease. Dr. Bellanti does not routinely treat patients with Crohn's disease. Tr. 65. Within the last five years, Dr. Bellanti saw fewer than ten patients with Crohn's disease. Tr. 79.

Differences in experience between experts may be considered by special masters when they weigh the persuasiveness of the experts' testimony. Cedillo v. Sec'y of Health & Human Servs., 89 Fed. Cl. 158, 163, 171, 179-80 (2009) (finding that special master did not act arbitrarily in finding that respondent's experts were more qualified than petitioners' experts), aff'd, 617 F.3d 1238 (Fed. Cir. 2010); Hennessey v. Sec'y of Health & Human Servs., 91 Fed. Cl. 126, 136 (2010) (noting that special master did not err in finding government's expert more qualified to discuss a disease than petitioner's expert); Walersyszak v. Sec'y of Health & Human Servs., 45 Fed. Cl. 573, 578 (1999) (finding special master did not commit an abuse of discretion in finding that respondent's expert was more qualified than petitioner's expert), appeal dismissed, 250 F.3d 753 (Fed. Cir. 2003) (table). Dr. Warner has much greater experience than Dr. Bellanti in treating patients with Crohn's disease. Therefore, his testimony is persuasive.

Dr. Warner explained that a common first symptom of Crohn's disease is a decrease in growth velocity. For example, a child who starts at the 5th percentile and continues to grow at the 5th percentile can be considered a healthy child because his (or her) growth is following the expected pattern. In contrast, a child who starts at the 75th percentile but then falls to the 25th percentile may have a disease. This child may be taller and heavier than the first child, who is in the 5th

percentile, but the change in velocity is significant. Tr. 112-13. The change in growth velocity is a special concern in children because children should be gaining weight as they grow. If a child's weight stays the same, this constant weight will cause the child to fall to a lower percentage compared to his or her peers. Tr. 115-16.[6] Dr. Bellanti agreed that pediatricians track the growth velocity of their patients and recognized, on cross-examination, that a decrease in growth velocity may be the first sign of Crohn's disease. Tr. 65-66.

It is abundantly clear that Ms. Locane's rate of growth dropped before she received the hepatitis B vaccine. Until age 10 or so, Ms. Locane was regularly around the 50th percentile in height and weight. Her status changed by the time she reached age 14 and received the first dose of the hepatitis B vaccine. The growth chart created by Ms. Locane's pediatrician shows that at this age, she had fallen to the 25th percentile in height and the 10th percentile in weight. Exhibit 6 at 15; see also tr. 114 (testimony of Dr. Warner explaining this chart).

In this regard, the decrease in rate of weight gain is more significant than the decrease in rate of height gain. Dr. Warner testified to this point, tr. 109-10, and cited several articles in support. See exhibit C, tab 6 (Crohn's disease in childhood and adolescence, in Crohn's disease (Cosimo Prantera & Burton I. Korelitz eds., 1996)) at 345; exhibit C, tab 8, (Eugene J. Burbibe, et al., Clinical manifestations of Crohn's disease in children and adolescents, 55 Pediatrics 868 (1975)) . Dr. Bellanti's opinion that Crohn's disease affects height more than weight, tr. 92-94, is not in accord with the published literature.[7]

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[6] With regard to changes in weight and height at the beginning of Crohn's disease, adults differ from children. Because adults have stopped growing in height, adults will lose weight. Tr. 115-16.

[7] Given the articles that focus on changes in weight velocity and Dr. Bellanti's testimony that a change in growth velocity may be the first sign of Crohn's disease, tr. 65-66, Dr. Bellanti's testimony that the relevant measure in Ms. Locane's case was her height (not weight) was quite dubious. For purposes of this decision, Dr. Bellanti's testimony is accepted as being offered sincerely. It is found to be unpersuasive because it is not in accord with the prevalent understanding of Crohn's disease. See Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1325-26 (Fed. Cir. 2010) (stating that "[w]eighing 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" and

The facts about Ms. Locane's history allow Dr. Warner to opine that what happened with Ms. Locane was that her weight velocity had decreased before she was actually diagnosed with Crohn's disease. Tr. 111. Against this testimony, Ms. Locane had relatively little response.

Ms. Locane presents essentially two arguments against Dr. Warner's opinion. First, Ms. Locane notes that from the age of 11 and ¼ to age 13, Ms. Locane's weight changed from 83 pounds to 88.25 pounds. From these observances, Ms. Locane implies that her health was normal. Pet'r Reply at 10. This argument, which was not asserted by any doctor in this case, overlooks the rate of change. As discussed above, the relevant measure is the rate of change, not the absolute weight. In addition, Ms. Locane's observations about her weight stop at age 13, when she weighed 88.25 pounds. Ms. Locane actually received the vaccination at age 14, when she weighed 88 pounds. This slight decrease in weight occurred when Ms. Locane should have been gaining weight in her early adolescence. Consequently, Ms. Locane's first attempt to demonstrate that she was gaining weight normally is not consistent with how children develop.

Ms. Locane's second argument is that her treating doctors did not diagnose her as having Crohn's disease until November 1997, which is after she received the hepatitis B vaccine. Pet'r Reply at 10-11. Although this observation is accurate, treating doctors may miss the earliest signs of Crohn's disease. Dr. Warner, who has treated numerous cases of Crohn's disease, explained that it is "subtle medicine" to detect Crohn's disease. Tr. 109. Dr. Warner quoted from one article, saying "The subtlety of these non-gastrointestinal presentations often led to a lag between the onset of symptoms and the arrival of a correct diagnosis. The average delay in diagnosis was 13.7 months, with a range of one month to seven years." Tr. 111 (quoting exhibit C, tab 8 (Burbibe) at 869).

Ms. Locane's presentation fits comfortably within the range of presentations as described by various medical articles. Her growth charts indicate that Ms. Locane's velocity of weight gain and velocity of height gain had decreased by the time she was 13 years old, as measured by her pediatrician in July 1996. See exhibit 12 at 26. Ms. Locane experienced more significant problems of Crohn's disease, such as diarrhea, in November 1997, which is when she was diagnosed as

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"[a]ssessments as to the reliability of expert testimony often turn on credibility determinations, particularly in cases such as this one where there is little supporting evidence for the expert's opinion.").

having Crohn's disease. Between July 1996 and November 1997, 16 months elapsed and this amount of time is close to the average reported delay in diagnosis, which was 13.7 months.

Given the expected presentation of Crohn's disease and Ms. Locane's own history, it is not surprising that no treating doctor diagnosed Ms. Locane as suffering from Crohn's disease during this time. Further, after Ms. Locane had begun to have diarrhea, among other significant problems, and was hospitalized, the doctors focused on treating her Crohn's disease. Although Ms. Locane argues that the failure of any treating doctor to state that her Crohn's disease began before her vaccination means that the disease did not start before the vaccine, Ms. Locane makes too much from the doctor's silence. Ms. Locane does not cite any records in which a treating doctor affirmatively stated that the Crohn's disease started after the vaccination. Pet'r Reply at 11. Thus, in light of all the evidence including the testimony of Dr. Warner, who explained that the onset of Crohn's disease is difficult to detect, Ms. Locane's reliance upon an absence of a diagnosis in the medical records is not persuasive.

These are the two arguments presented in Ms. Locane's reply brief, which focused on when the Crohn's disease began. Ms. Locane's reply generally omits any discussion of Dr. Solny. Although this omission could be construed as a waiver of any argument based upon Dr. Solny, see Vaccine Rule 8(f), Dr. Solny's opinions are taken up as well.

The view of Ms. Locane's expert with a specialty in gastroenterology, Dr. Solny, also does not assist Ms. Locane. After the hearing in which Dr. Warner confirmed his opinion that Ms. Locane's Crohn's disease started before she received the hepatitis B vaccine, Ms. Locane requested permission to obtain a report from another expert. Despite respondent's objection, Ms. Locane's request was granted. Ms. Locane was ordered to have Dr. Solny "address whether petitioner was suffering from Crohn's disease before she received the hepatitis B vaccination. See tr. 105." Order, filed Sept. 14, 2009. Dr. Solny's original report assumed that she received a hepatitis B vaccine in 1994, and asserted that Ms. Locane "fell off the height and weight curves at some point afterward." Exhibit 43 at 2. This statement did not directly address whether Ms. Locane suffered from Crohn's disease before she was vaccinated in 1997. Thus, Ms. Locane was ordered to obtain a supplemental report in which "Dr. Solny should explain when Ms. Locane's Crohn's disease began." Order, filed Nov. 19, 2009. The ensuing report stated that "Ms. Locane first displayed symptoms of her Crohn's disease in early September 1997." Exhibit 45.

Dr. Solny's reports do not assist Ms. Locane because they fail to address the changes in Ms. Locane's growth charts. Ms. Locane was aware that the changes in her growth charts were the basis for Dr. Warner's opinion that she was suffering from Crohn's disease before she received the hepatitis B vaccine in August 1997. Dr. Warner disclosed the basis for his opinion in his report and his testimony. Ms. Locane was given an additional – and unusual -- opportunity to respond to Dr. Warner's opinion with a second expert after the hearing.

Dr. Solny's first report mentions the changes in Ms. Locane's growth curves, suggesting that these changes are significant. Dr. Solny's reference to the changes in the growth occurs in the context of assuming that Ms. Locane received a dose of the hepatitis B vaccine in 1994. Exhibit 41. Dr. Solny's assumption about the alleged 1994 vaccine, however, was in error. Because Ms. Locane did not receive a dose of the hepatitis B vaccine in 1994, any changes in her growth curves before August 1997 could not have been caused by a dose of the hepatitis B vaccine. Dr. Solny corrects this error in his second report because he does not rely upon the alleged 1994 dose. But, in his second report, Dr. Solny omits any discussion of the change in growth curves and instead relies upon Ms. Locane's report of her own symptoms. Exhibit 43 at 2.

Although Ms. Locane was permitted to retain Dr. Solny to respond to Dr. Warner's opinion that she suffered from Crohn's disease before she received the hepatitis B vaccine, Dr. Solny did not state that Dr. Warner erred when he relied upon the changes in Ms. Locane's growth curves to date the onset of Ms. Locane's Crohn's disease. Despite two opportunities and two orders specifically directing Ms. Locane to obtain reports from Dr. Solny on this topic, there was no clear expression of an opinion from Dr. Solny about the relevance of the change on the growth curves. If Dr. Solny had expressed a reasoned disagreement with Dr. Warner's opinion, Dr. Solny's opinion might have been persuasive.[8] However, as

[8] Holding a second hearing to give Dr. Solny an additional opportunity to address this issue is not necessary. The Vaccine Rules authorize special masters to resolve cases "on the basis of written submissions without conducting an evidentiary hearing." Vaccine Rule 8(d). Ms. Locane was given one evidentiary hearing at which time she had the opportunity to address Dr. Warner's opinion, which had been disclosed in his report filed before the hearing. Exhibit A. Ms. Locane was given the unusual opportunity to present a report after the hearing and was instructed to address Dr. Warner's opinion. Dr. Solny's reports could have addressed Dr. Warner's opinion but did not. There is no reason to conduct a

the record stands, Dr. Warner's opinion that Ms. Locane's Crohn's disease began before she received the hepatitis B vaccine is not rebutted by anyone with meaningful experience in treating Crohn's disease. Dr. Warner's opinion is persuasive.

For all these reasons, a preponderance of the evidence supports a finding that Ms. Locane's Crohn's disease began before she received the hepatitis B vaccine. This finding resolves Ms. Locane's claim that the hepatitis B vaccine caused her Crohn's disease. Because Ms. Locane was afflicted with Crohn's disease before she received the hepatitis B vaccine, the vaccine could not have caused the disease. See Shalala v. Whitecotton, 514 U.S. 268, 274 (1995) (stating "There cannot be two first symptoms or onsets of the same injury.").[9]

B. Did the Hepatitis B Vaccine Significantly Aggravate Ms. Locane's Crohn's Disease?

Although Ms. Locane cannot establish that the hepatitis B vaccine caused her Crohn's disease, Ms. Locane would be entitled to compensation if she established that the hepatitis B vaccine significantly aggravated her Crohn's disease. 42 U.S.C. § 300aa-11(c)(ii)(I). Ms. Locane introduced the theory that the hepatitis B vaccine significantly aggravated her Crohn's disease when she asserted in the final paragraph of her first brief filed after the hearing that "[e]ven if the court were to find that changes in Petitioner's growth rate were somehow indicative of a Crohn's Disease that was already somehow underway, then the Hepatitis B vaccines clearly caused a significant aggravation of her condition."

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hearing to elicit oral testimony from Dr. Solny when Dr. Solny could have provided his opinion in writing. Additionally, after Ms. Locane obtained the two reports from Dr. Solny, she did not renew her request for a hearing in her reply brief.

[9] Given that Ms. Locane's Crohn's disease could not have been caused by the hepatitis B vaccine, an analysis of the three-factor test set forth in Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005), is not necessary.

Pet'r Br, filed Aug. 25, 2008, at 11.[10] The significant aggravation theory is not supported by a preponderance of evidence for the reasons that follow.

The Vaccine Act defines "significant aggravation" at 42 U.S.C. § 300aa—33(4). Elements for a claim based upon significant aggravation are set forth in Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (2009). One part of an analysis of a significant aggravation claim is evaluating whether the vaccine made the person worse than the person would have been but for the vaccination. In doing so, the natural course of the disease must be considered. Hennessey v. Sec'y of Health & Human Servs., No. 01-190V, 2009 WL 1709053, at *41-42 (Fed. Cl. Spec. Mstr. May 29, 2009), motion for review denied, 91 Fed. Cl. 126 (2010).

Here, a preponderance of the evidence demonstrates that Ms. Locane's course was consistent with Crohn's disease and was not affected by the hepatitis B vaccinations. Dr. Warner explained that although Crohn's disease does not have one pattern, it is "absolutely typical" for a young person with Crohn's disease to have frequent flares. Tr. 139. Ms. Locane's loss of eight pounds in Novemer 1998 is also a typical experience for people with Crohn's disease. Tr. 138. Ms. Locane points to the nausea, loose stools, and diarrhea that she experienced after the first hepatitis B vaccination as evidence that the hepatitis B vaccine caused her Crohn's disease and relies upon these problems as evidence that Crohn's disease was significantly aggravated by the hepatitis B vaccine. Ms. Locane also notes that after her third dose of the hepatitis B vaccine on February 6, 1998, she had to see her pediatric gastroenterologist on an "urgent basis" on March 16, 1998.

Ms. Locane has failed to present persuasive evidence that separates these problems from an expected course of Crohn's disease. Ms. Locane was ordered to have Dr. Solny discuss the expected course of Crohn's disease. Order, filed Sept. 14, 2009. Dr. Solny's first report omitted this discussion. See exhibit 43. Thereafter, Ms. Locane was ordered to have Dr. Solny, if he believed that the

[10] Ms. Locane's argument about significant aggravation could have been rejected on the procedural ground that it was raised too late. However, Ms. Locane was given the opportunity to develop this theory.

The significant aggravation theory is an alternative theory, ancillary to the theory that the hepatitis B vaccine caused the Crohn's disease. This subordinate status is reflected in Ms. Locane's argument that "there is no reasonable basis upon which the Court may find that she had Crohn's disease prior to her hepatitis b vaccinations." Pet'r Reply at 13.

hepatitis B vaccine significantly aggravated her Crohn's disease, explain "what factors make Ms. Locane's development of Crohn's disease different from the typical development of Crohn's disease in other individuals." Order, filed Nov. 19, 2009. Dr. Solny responded that the August 29, 1997 hepatitis B vaccine caused the Crohn's disease, not that the vaccine significantly aggravated the Crohn's disease. Exhibit 45. Thus, Dr. Solny's reports do not provide any information about how Ms. Locane's pre-existing Crohn's disease was worse because of the hepatitis B vaccinations.

Dr. Bellanti, too, failed to offer any basis for finding that the hepatitis B vaccine made the Crohn's disease worse. In his report filed after the hearing, Dr. Bellanti did not discuss the natural progression of Crohn's disease. Instead, Dr. Bellanti relied upon the sequence of events in which Ms. Locane experienced problems after the first and third doses of the hepatitis B vaccine. Exhibit 42 at 1.[11] Ms. Locane argues that this pattern is evidence of positive rechallenge. Pet'r Br. at 11; Pet'r Reply at 15-16; see also tr. 76-77 (testimony of Dr. Bellanti defining rechallenge). In some circumstances, a positive response to repeated exposures of a substance can be evidence that the substance is affecting the recipient, although establishing rechallenge is not a requirement for petitioners in the Vaccine Program. See Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006); see also Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d 1194, 1199-1200 (11th Cir. 2002).

In this case, the evidence for a pattern of positive rechallenge is not persuasive for two reasons. First, Ms. Locane received a second dose of the hepatitis B vaccine on December 11, 1997. Exhibit 14 at 26. She did not experience any worsening of symptoms following this dose. This counter-example tends to show that the hepatitis B vaccine was not affecting her Crohn's disease.[12]

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[11] Dr. Solny also referenced the third dose of the hepatitis B vaccine, although Dr. Solny erroneously states that Ms. Locane experienced more problems "within one to two weeks." Exhibit 45 at 1.

[12] In his testimony, Dr. Bellanti did not directly address the second dose, although Ms. Locane, herself, offered the opinion that she may not have responded adversely to the second dose of the hepatitis B vaccine because she was taking prednisone. Tr. 17. In Dr. Bellanti's supplemental report, he repeats this suggestion. Exhibit 42 at 1. Trying to determine whether prednisone prevented Ms. Locane from experiencing an adverse reaction to the second dose of the

See Nussman v. Sec'y of Health & Human Servs., 83 Fed. Cl. 111, 119-21 (2008) (holding that special master did not err in rejecting petitioner's rechallenge argument).

Second, since 1998, Ms. Locane has periodically had other flares of Crohn's disease. See exhibit 17 (Ms. Locane's affidavit summarizing her history). These other flares were not preceded by a dose of the hepatitis B vaccine. A reasonable inference is that something other than the hepatitis B vaccine causes Ms. Locane to suffer worse symptoms of Crohn's disease. See Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (stating "that a finding that the administration of a vaccine was not a cause-in-fact of an injury necessarily implies that some other cause resulted in the injury").

For these reasons, there is not preponderant evidence that Ms. Locane's Crohn's disease was significantly worse than it would have been if she had not received the hepatitis B vaccinations. Ms. Locane is not entitled to compensation on the theory of significant aggravation.

IV. Conclusion

Ms. Locane presented two theories for compensation. She primarily asserted that the August 29, 1997 hepatitis B vaccination caused her to develop Crohn's disease. This theory is not sustainable because Ms. Locane actually was suffering from Crohn's disease before she received the hepatitis B vaccine on August 29, 1997.

Ms. Locane's second theory, which was raised for the first time after the hearing, is that the hepatitis B vaccinations significantly aggravated her Crohn's disease. Relatively little evidence was presented on this topic and the evidence that was presented did not persuasively show that Ms. Locane's Crohn's disease was any worse because of the hepatitis B vaccinations.

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.

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hepatitis B vaccine is complicated because Ms. Locane was also taking prednisone in February 1998, when she received the third dose of the hepatitis B vaccine.

s/ Christian J. Moran
Christian J. Moran
Special Master