

cause the aplastic anemia. Rather, a preponderance of the evidence establishes that Breanne's aplastic anemia existed before she received the first dose of the hepatitis B vaccine.

Thus, Breanne is not entitled to receive compensation. Absent a motion for review, the Clerk's Office is ordered to enter judgment in favor of respondent.

I. Factual Background

The facts are straightforward and are reflected in the medical records created contemporaneously with the events they record. Both parties agree to the basic facts as outlined below. The dispute, however, derives from the interpretation of them.

Breanne was born on January 8, 1991. Transcript ("Tr.") 6. Her medical history until she was four years old was routine. Tr. 7.

On October 26, 1995, Breanne saw her pediatrician, Dr. Panitda Toochinda. During this visit, two events with consequence to this case happened. First, Dr. Toochinda obtained a sample of Breanne's blood for routine testing. (As discussed below, the results of these tests were not routine.) Second, Dr. Toochinda gave Breanne several vaccinations, including the first dose of the hepatitis B vaccine. Exhibit 5 at 17.

The October 26, 1995 blood tests showed that Breanne's mean corpuscular volume (MCV) was 90.3 and that her platelet count was 153,000. Exhibit 2 at 5. Dr. Nachman, a pediatric hematologist retained by respondent in this litigation, explained that the mean corpuscular volume was abnormally high and the platelet count was at the low end of normal. Tr. 64.

Approximately one month later, Breanne started to develop many bruises on her body, especially her shins. Initially, Ms. Imlay believed that these bruises were the result of falls and

bumps, typical of a toddler. When the severity of the bruises worsened, Ms. Imlay brought her daughter to the doctor's office. Tr. 9.

On December 29, 1995, Dr. Toochinda saw Breanne again. Dr. Toochinda gave Breanne a second dose of the hepatitis B vaccine. Dr. Toochinda noted the bruises on her body and ordered another blood sample. Exhibit 2 at 1; exhibit 5 at 17, 26.

The blood test from December 29, 1995, contained several abnormal results. The MCV had increased to 94.5 and the mean corpuscular hemoglobin (MCH) was 33.6. Exhibit 2 at 3. Breanne's red blood cell count was 3.07, her hemoglobin count was 10.3, and her platelet count was 49,000. Id.

Dr. Toochinda referred Breanne to a pediatric oncologist, Dr. Clifford Selsky. Following an initial examination, Dr. Selsky stated that Breanne had "macrocytic anemia and thrombocytopenia, etiology of which is unclear at the present time." Exhibit 3 at 8 (report, dated January 3, 1996).

After this initial visit, Breanne continued seeing Dr. Selsky several more times. On January 17, 1996, Breanne had a bone marrow biopsy. Dr. Selsky believed that Breanne could have aplastic anemia. Exhibit 3 at 14-15. This diagnosis was eventually confirmed. Id. at 21.

The progression of Breanne's aplastic anemia is not relevant in determining whether the hepatitis B vaccine caused Breanne's aplastic anemia. It is sufficient to note that Breanne was hospitalized for several weeks at the National Institutes of Health in Bethesda, Maryland, where she was treated by doctors studying aplastic anemia. Afterwards, these doctors continued to care for her, although Breanne also saw her local oncologist, Dr. Selsky. Breanne has undergone several courses of immunosuppressant therapy. Currently, the aplastic anemia is not active.

However, the possibility remains that the disease could return.

II. Procedural History

Ms. Barber filed the petition on July 2, 1999. She filed her first set of medical records on February 12, 2002. Slightly more than two years later, Ms. Barber filed another set of medical records.

Respondent filed its report, pursuant to Vaccine Rule 4, in November 2006. Respondent argued that Breanne was not entitled to compensation because there was no medical evidence showing that the hepatitis B vaccine caused Breanne's aplastic anemia. Resp't Rep't at 9.

Ms. Barber then filed a report from Dr. Eric Gershwin, an immunologist. Exhibit 15. Ms. Barber also submitted several articles on which Dr. Gershwin relied in forming his opinion that the hepatitis B vaccine caused Breanne's aplastic anemia. Exhibits 17-24.

After the parties were given an opportunity to resolve the case, respondent filed the report of Dr. James Nachman, a pediatric hematologist. Exhibit A. Later, respondent filed two supplemental reports from Dr. Nachman and one article on which he relied. Exhibits C-E.

A hearing was held on September 25, 2007. Ms. Imlay testified and presented much of the material set forth in the preceding section. Dr. Gershwin and Dr. Nachman also testified. At the end of the hearing, both parties elected not to file post trial briefs. Thus, the case is ready for adjudication.

III. Analysis

This case largely turns on the persuasiveness of the two experts. Thus, the opinion of Dr. Gershwin and the opinion of Dr. Nachman are summarized initially. Examining these opinions highlights the decisive dispute — whether Breanne was already suffering from an early stage of

aplastic anemia when she received the first dose of the hepatitis B vaccine. On this question, Dr. Nachman is much more persuasive.

Dr. Gershwin believes that the hepatitis B vaccine caused Breanne's aplastic anemia. He notes that Breanne was normal when she received this vaccination. Dr. Gershwin then states that the hepatitis B vaccination stimulated Breanne's immune system to produce T cells that, unfortunately, attacked Breanne's cells that produce blood cells. Tr. 27-29. Dr. Gershwin also believes that the temporal relationship between the introduction of the hepatitis B vaccine and the onset of Breanne's aplastic anemia was appropriate. Tr. 31. Finally, Dr. Gershwin cites to various articles in support of his opinion. Exhibit 15 at 4.

Dr. Nachman holds a much different view. He opines that the hepatitis B vaccine did not cause Breanne's aplastic anemia for two reasons. Primarily, Dr. Nachman contends that the results of the October 1996 blood tests show that although she was not symptomatic at that time, Breanne was already suffering from this disease. Secondarily, Dr. Nachman opines that even if Breanne were healthy when she received the hepatitis B vaccination, the material that Dr. Gershwin presents does not establish a causal relationship between the hepatitis B vaccine and aplastic anemia. Exhibit A; exhibit D.

A foundational question, therefore, is whether Breanne suffered from aplastic anemia at the time she received the hepatitis B vaccination. If she did, then the vaccine could not have caused the aplastic anemia. See Finley ex rel. Finley v. Sec'y of Health & Human Servs., 55 Fed. Cl. 355, 361-62 (2003) (affirming special master's finding that a vaccine did not cause epilepsy when the child had a disposition to developing epilepsy).

By training and experience, Dr. Nachman is much more qualified to opine on the

pathology of aplastic anemia. Dr. Nachman is a hematologist with a specialty in pediatric hematology. Exhibit B; tr. 60 (noting that he is board certified in pediatrics and pediatric hematology/oncology). A hematologist is a doctor who specializes in diseases of the blood and blood-forming organs. In hematology, pediatric patients differ from adult patients. Tr. 63. Thus, his specialization in pediatric hematology adds weight to his opinions.

The October 26, 1995 blood tests are the foundation for Dr. Nachman's conclusion that Breanne was suffering from aplastic anemia when she received the first dose of the hepatitis B vaccine. These tests showed that her mean corpuscular volume was 90.3 femtolitres, which exceeded the normal range of 75.0 to 87.0, and Breanne's platelet count was 153,000 per cubic milliliter. (Breanne's mean corpuscular hemoglobin was also slightly high at 30.9 picograms, compared to a normal result of 24.0 to 30.0. However, Dr. Nachman did not attribute any significance to this test result in his testimony.) Exhibit 2 at 5.

Mean corpuscular volume measures "the average volume, or size, of a single [red blood cell] and is therefore used in classifying anemias." Exhibit 101 (Kathleen Deska Pagana and Timothy J. Pagana, Mosby's Manual of Diagnostic and Laboratory Tests (3d ed.)) at 451. According to Mosby's, the normal findings depend upon a person's age. Id.

Several months before the hearing, when respondent was requested to produce sources discussing mean corpuscular volume, respondent submitted a supplemental report from Dr. Nachman in which Dr. Nachman included an excerpt from the Harriet Lane Handbook. Exhibit C. Without contradiction, Dr. Nachman explained that this is a standard reference source that provides normal test results for a variety of ages. Tr. 66. The Harriet Lane Handbook shows that the mean score for the mean corpuscular volume for children from 2-6 years old is 81, with a

standard deviation of 6, meaning that the high end of normal is 87. Exhibit C at 2. The normal range from the Harriet Lane Handbook matches exactly with the normal range presented on Breanne's test results. Exhibit 2 at 5.

Dr. Gershwin attempted to argue that Breanne's mean corpuscular volume was within the normal limits. These attempts were not persuasive. First, Dr. Gershwin sought to use normal values from a different source, a Medline Plus reference. Exhibit 26 at 2. However, Dr. Nachman explained that this source did not set forth normal scores for Breanne, but instead, listed normal scores for adults. Tr. 75. Second, Dr. Gershwin suggested that the values in the Harriet Lane Handbook were out of date, derived from tests done in the 1950's. Tr. 44. However, when Dr. Gershwin was presented with the data sources cited in the Harriet Lane Handbook, he retreated. Tr. 95; see also tr. 44 (testimony of Dr. Nachman about sources of information in the Harriet Lane Handbook). Therefore, a preponderance of the evidence establishes that Breanne's mean corpuscular volume was abnormally high.

Dr. Nachman explained, credibly, why a high mean corpuscular volume indicates an underlying problem with a child's production of blood cells.

The first sign of aplastic anemia in children is generally an elevation in MCV because when marrow damage begins, the first thing that happens before any cell line becomes decreases. So there's no hemoglobin drop, no platelet drop, no white cell drop. The first thing that happens is the MCV becomes elevated because the marrow is reverting back to this fetal pattern of red blood cell production, which it does when it is damaged.

Tr. 64-65. Given that the medical records demonstrate an elevated MCV level before Breanne received the first vaccine, it reasonably follows that her aplastic anemia existed prior to receipt of the hepatitis B vaccination.

Given that a preponderance of the evidence demonstrates that Breanne was suffering from aplastic anemia before she received the hepatitis B vaccination, further discussion is not necessary. Breanne has not alleged, nor does any evidence support a theory, that the hepatitis B vaccination significantly aggravated her pre-existing aplastic anemia. Even if Ms. Imlay had established a theoretical link between the hepatitis B vaccine and aplastic anemia, a finding which is not being made here, this proof would be insufficient in Breanne's case because the aplastic anemia began prior to the vaccination. Therefore, the cause of Breanne's aplastic anemia was something other than the vaccine.

IV. Conclusion

There is no doubt that Breanne and her family have suffered. However, it is also clear that the aplastic anemia, which unfortunately afflicted Breanne, was caused by something other than the vaccine. Thus, Breanne is not entitled to compensation through this program. In the absence of a timely motion for review, the Clerk's Office is ordered to enter judgment in favor of respondent.

IT IS SO ORDERED.

Christian J. Moran
Special Master