

**OFFICE OF SPECIAL MASTERS**

No. 04-1755V

May 30, 2006

For Publication

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JIE BIRDSELL, Parent of \*  
HEATHER BIRDSELL, \*

Petitioner, \*

v. \* Entitlement; hepatitis B vaccine

and idiopathic thrombocytopenic  
purpura with intervening cold

SECRETARY OF THE DEPARTMENT \*  
OF HEALTH AND HUMAN SERVICES, \*

Respondent. \*

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Sylvia Chin-Caplan, Boston, MA, for petitioner.  
Glenn A. MacLeod, Washington, DC, for respondent.

**MILLMAN, Special Master**

**DECISION<sup>1</sup>**

Petitioner filed a petition on December 9, 2004, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine which her daughter Heather Birdsell (hereinafter, “Heather”) received on December 20, 2001 caused her idiopathic

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<sup>1</sup> Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document’s disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

thrombocytopenic purpura (hereinafter, "ITP").<sup>2</sup> ITP is not a Table injury for hepatitis B vaccine. Therefore, this is a causation in fact case.

A hearing was held on April 7, 2006. Testifying for petitioner were Jie Birdsell, who is Heather's mother, and Dr. Richard I. Schiff. Testifying for respondent were Dr. James B. Nachman and Dr. Brian J. Ward.

### **FACTS**

Heather was born on May 16, 2001. She received hepatitis B vaccine and HiB vaccine on December 20, 2001, at the age of seven months. Med. recs. at Ex. 3, p. 1.

On March 13, 2002, she saw Dr. Michael Yuen with a temperature of 101.2° F. She had had fever since March 12<sup>th</sup> and a decrease in appetite. Her mother had noticed petechiae<sup>3</sup> over Heather's face for one month. On examination, Heather had petechiae over her face, trunk, and limbs. Dr. Yuen diagnosed pharyngitis and thrombocytopenia. Med. recs. at Ex. 3, p. 5.

On March 14, 2002, Heather was taken to Sherman Hospital where her doctor Dr. Yuen saw her. Heather's mother stated Heather had petechiae on her face and trunk about six weeks previously, but she had not noticed other symptoms. Heather's platelet count was 3,000. Heather was transferred to Rockford Memorial Hospital. Med. recs. at Ex. 4, p. 14.

Heather was at Rockford Memorial Hospital from March 14-16, 2002. Dr. Mark A. Neumann took the history from Heather's mother that she had had a petechial rash for about six

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<sup>2</sup> Thrombocytopenia is a "decrease in the number of platelets, such as in thrombocytopenia purpura." Dorland's Illustrated Medical Dictionary, 30<sup>th</sup> ed. (2003) at 1906.

<sup>3</sup> Petechiae are the plural of Petechia. Petechia is "a pinpoint, nonraised, perfectly round, purplish red spot caused by intradermal or submucous hemorrhage." Dorland's Illustrated Medical Dictionary, 30<sup>th</sup> ed. (2003) at 1411.

weeks with no recent preceding history of fever. Perhaps Heather had had a cold-type illness in the recent past. Med. recs. at Ex. 5, pp. 1, 5. Dr. Neumann's diagnosis was immune-mediated thrombocytopenia. Med. recs. at Ex. 5, p. 6.

On April 4, 2002, Heather went to see Dr. Jong-Hyo Kwon, a pediatric hematologist at Lutheran General Children's Hospital. Her mother noted Heather to have bruises and petechial rash since about January 20, 2002. Med. recs. at Ex. 6, p. 83. Before her rash, she had a runny nose. Med. recs. at Ex. 6, p. 81. Dr. Kwon stated in the records that Heather had had viral symptoms without fever in January. Med. recs. at Ex. 6, p. 83. Dr. Kwon stated:

The etiology of the ITP is not clear at this time. It could be secondary to the URI symptoms in January of this year or there is a small possibility that it may be related to the immunization that she received in December. However, it is unusual to develop ITP a month after the immunization.

*Id.*

#### **Other Submitted Material**

Both parties submitted medical literature in this case. Petitioner submitted Ex. 14, an article entitled "'Immune Thrombocytopenic Purpura,'" by D.B. Cines and V.S. Blanchette, 346 *New Eng J Med* 13:995-1008 (2002) (this is also respondent's Ex. 4). The authors state:

Immune thrombocytopenic purpura is an autoimmune disorder characterized by a low platelet count and mucocutaneous bleeding. The estimated incidence is 100 cases per 1 million persons per year, and about half of these cases occur in children [footnotes omitted].

*Id.* at 995. The authors also state that children "typically present with the sudden onset of petechiae or purpura a few days or weeks after an infectious illness." *Id.*

Petitioner submitted Ex. 15, an article entitled “Childhood immune thrombocytopenic purpura,” by D.J. Nugent, 16 *Blood Reviews* 27-29 (2002). Dr. Nugent states, “Immune thrombocytopenic purpura (ITP) is one of the most common forms of autoimmune disease in children.” *Id.* at 29. He also states, “It has a seasonal presentation and is often seen more in winter and fall.” *Id.* In explaining the biologic mechanism, Dr. Nugent states:

[W]hen contact to viral and bacterial antigens occurs, high-affinity antibodies with broad specificity are generated, as demonstrated by experiments in syngeneic mice. In addition, the education process of the idiotypic network begun in utero by maternal IgG is not complete in humans until the age of 4 or 5 years, and this education can go awry in the early years with viral infections, generating cross-reactive autoantibodies. [footnotes omitted.]

*Id.*

Respondent filed as Ex. 15 a case report entitled “Thrombocytopenic purpura after hepatitis B vaccine,” by R. Maezono and A.M. de Ulhôa Escobar, 76 *Jornal de Pediatria* 5:395-98 (2000). The authors describe a baby who received hepatitis B vaccine on the 12<sup>th</sup> day of life with facial blotches three days later. She had her second hepatitis B vaccination at one month and 15 days, and the next day, was admitted to the hospital with petechiae on her face, hands, and feet. Her mother did not report any prior infection. *Id.* at 396. The authors state that, generally, ITP occurs after a viral infection episode. *Id.* at 395.

The other medical literature that both parties filed includes articles discussing children with ITP after receiving hepatitis B vaccine, with no discussion of alternative causes, and no distinction between onsets of days to months. The undersigned found these articles unhelpful since, at the very least, one would expect that the presence of an antecedent infection and the association of vaccination with onset months later would occasion some doubt as to the

relationship, if any, of the vaccination to the ITP, although the authors universally state that causation is not proved.

### TESTIMONY

Mrs. Jie Birdsell testified first. Tr. at 4. She went back to work when Heather was four months old and Mrs. Birdsell's mother took care of Heather. Tr. at 6. She does not remember Heather having a cold before she had ITP. Tr. at 10, 11. She does not remember telling Dr. Mark Neumann at Rockford Memorial Hospital on March 14, 2002 that she had a cold-type illness. Tr. at 13. She does not remember telling Dr. Jong-Hyo Kwon on April 4, 2002 that Heather had viral symptoms without a fever in January. Tr. at 14. She admits her memory was better then than it is now. Tr. at 15. Her sole interest was in giving the doctors as complete a picture as she could so Heather would get the best care she could. *Id.* Heather had spots in early or mid-January. Tr. at 8, Her legs were bruising in late January or February. Tr. at 10. Heather is fine right now. Tr. at 16, 17.

Dr. Richard I. Schiff, a clinical immunologist who is medical director of a private company called Baxter BioScience, testified for petitioner. Tr. at 21. He was a pediatric immunologist for 15 years. He has never had a private practice. Tr. at 22. His opinion is that hepatitis B vaccine is the most plausible cause of Heather's ITP based on her history and the medical literature. Tr. at 28. There are some discrepancies on the time of her onset of ITP. It mainly occurred in a six-week range post-vaccination. *Id.* There were some references to a possible runny nose, but no other indication of another plausible cause of ITP. Tr. at 28, 29.

Dr. Schiff stated that he can see how a runny nose can be translated into a viral illness. Tr. at 30. But there was very little evidence to him that Heather had an illness sufficient to cause

ITP. *Id.* The undersigned asked Dr. Schiff if he did not think colds can lead to ITP. *Id.* Dr. Schiff admitted that there is acceptance that viral respiratory illnesses can be an antecedent to ITP. *Id.* But he did not think Heather's runny nose meant she had a viral illness. *Id.* He admitted that viruses cause colds, but all runny noses are not caused by viruses. Tr. at 31. When asked about Mrs. Birdsell's history to Dr. Neumann that Heather had a cold-type illness, Dr. Schiff responded that it did not sound like much of an illness, not enough to generate a systemic response that would lead to ITP. Tr. at 32. When the undersigned queried whether one needed a severe illness to generate an immune reaction, Dr. Schiff agreed that the undersigned was absolutely correct that one does not need a severe illness, but he thought one would need a systemic illness. Tr. at 33.

Dr. Schiff stated that if one goes back in the histories of children with ITP, it is likely that some time in the prior four to six weeks, there is evidence of a cold or viral respiratory illness, but they are not very well characterized. *Id.* But to get a systemic response, one must go beyond just a mucosal reaction. *Id.* There are no studies demonstrating what viruses actually cause ITP. Tr. at 34. The literature indicates the vaccine caused Heather's ITP although the literature just shows an association and not causation. *Id.*

Dr. Schiff does not know when Heather's cold occurred, if it did. Tr. at 36. He stated that the closer the onset of symptoms is to the possible cause, the easier it is to assign causality. Tr. at 38. The literature's discussion of timing varies from days to three months (which Dr. Schiff said was arbitrary). Tr. at 43. The longer you go out from vaccination, the more likely the ITP and vaccination are coincidental. Tr. at 49. Dr. Schiff does not know where the cut-off for onset should be, but does not think three months unreasonable. Tr. at 49, 50.

Dr. Schiff testified that if he accepted that Heather had a cold in January 2002, he would pick the cold as the more proximal cause of her ITP rather than the hepatitis B vaccination she received in December 2001. Tr. at 50, 51.

The literature describes a number of mechanisms underlying ITP, the most popular of which is molecular mimicry. Tr. at 52. An antibody to the virus cross-reacts with platelets, causing ITP. *Id.* Another mechanism is to expose new portions of the glycoprotein on the platelet with epitope spread, which happens more in chronic ITP, which Heather developed. *Id.*

Dr. Schiff admitted that Heather did not have a systemic reaction to her hepatitis B vaccination on December 20, 2001, but he said it was not necessary to cause ITP. Tr. at 55. Since this was her third hepatitis B vaccination, it makes sense that she would react to it because her immune system has been primed and stimulated. Tr. at 56. If Heather had had a significant illness after her vaccination, perhaps he would give it more weight as the cause of her ITP, but the literature does not require a systemic reaction to develop ITP. Tr. at 56, 57.

Dr. James B. Nachman, a pediatric hematologist, testified first for respondent. Tr. at 58. His opinion is that hepatitis B vaccine was not the cause of Heather's ITP. Tr. at 59. In 20-30% of ITP cases, a viral illness precedes the ITP. Tr. at 60. In the rest of the cases, nothing precedes the onset of the ITP. *Id.* The medical records have multiple references to an ill-defined upper respiratory infection in Heather's case. *Id.* Dr. Nachman treats ITP in children. Tr. at 59. A stock question to the parent is to ask if the child had a preceding viral illness. Tr. at 60. He does not think there is any evidence that the severity of an illness is related in any way to whether or not a patient would develop an adverse reaction. Tr. at 60, 61.

Dr. Nachman's opinion is that Heather's viral illness is more likely the cause of her ITP if there is any likely cause. Tr. at 61. In most children with ITP, there is an alloimmune or molecular mimicry process involved rather than an autoimmune process. *Id.* The only recognized clinical association with ITP in the literature is a viral infection. Tr. at 62. Dr. Nachman thought that it was perfectly reasonable to assume that a runny nose (mentioned in Dr. Kwon's notes) signifies a viral illness. Tr. at 64. People readily remember a runny nose. Tr. at 65. There is no evidence to suggest that the severity of an illness predicts what happens after that viral illness. *Id.*

The medical literature has a wide variation in onset of ITP after hepatitis B vaccine: from days to two or three months. Tr. at 68. This is only a temporal association. *Id.* In his 30 years of practice, he has never seen a vaccine associated temporally or otherwise with ITP. *Id.*

Dr. Brian Ward, an infectious disease expert and internist, testified next for respondent. Tr. at 70. He testified that Heather's upper respiratory infection is more likely to be the cause of her ITP than the vaccine. Tr. at 73. An upper respiratory tract infection is a known association with ITP, whereas a vaccination is hypothetical and theoretical. *Id.* In most cases of ITP, we do not know the cause. Tr. at 73, 76. There is no association between the magnitude of the prior infection and the adverse event. Tr. at 80.

Speaking as an infectious disease physician, Dr. Ward stated it does not make sense to say that a runny nose means the infection is limited to the mucosal surface and to say that it is implausible this could cause a systemic reaction. Tr. at 81. To say that just a runny nose is not really much of an infection does not make a whole lot of sense to an infectious disease doctor. *Id.* Even in the absence of direct proof of causation of vaccination to injury, one would want to



see the absence of other causes before concluding there is causation from the vaccine. Tr. at 87. In his experience, questions asked are whether the vaccine is known to cause this event? If yes, is this event known to be associated with other events? Did one of those other events occur? Was there a temporal relationship between the vaccination and this event, or between the other cause and this event? *Id.*

## **DISCUSSION**

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by “reputable medical or scientific explanation[,]” *i.e.*, “evidence in the form of scientific studies or expert medical testimony[.]”

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said “we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...”

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal

association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6<sup>th</sup> Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, Heather would not have had ITP, but also that the vaccine was a substantial factor in bringing about Heather's ITP. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Close calls are to be resolved in favor of petitioners. Capizzano, supra, at 1327; Althen, supra, at 1280. *See generally*, Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994).

In essence, the special master is looking for a medical explanation of a logical sequence of cause and effect (Althen, supra, at 1278; Grant, supra, at 1148), and medical probability rather than certainty (Knudsen, supra, at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen, supra, at 549:

Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.

The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

The Federal Circuit stated in Althen, supra, at 1280, that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."

As the Federal Circuit stated in Knudsen, supra, at 548, “Causation 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.” The undersigned’s task is to determine medical probability based on the evidence before the undersigned in this particular case. Althen, supra, at 1281 (“judging the merits of individual claims on a case-by-case basis”).

As for epidemiological support for causation, the Federal Circuit in Knudsen ruled for petitioners even when epidemiological evidence directly opposed causation from a vaccine. In Knudsen, even though epidemiological evidence supported the opposite conclusion, i.e., that viruses were more likely to cause encephalopathy than vaccinations, the Federal Circuit held that that fact alone was not an impediment to recovery of damages. In Knudsen, supra, at 550, the Federal Circuit stated:

The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine.

The Federal Circuit in Knudsen, supra, at 549, also stated: “The special masters are not ‘diagnosing’ vaccine-related injuries.”

The Federal Circuit in Capizzano emphasized the opinions of petitioner’s four treating doctors in that case in concluding causation of rheumatoid arthritis from hepatitis B vaccination. 440 F.3d at 1326. In the instant action, Dr. Kwon, Heather’s treating pediatric hematologist, evaluated whether her viral symptoms without fever in January (upper respiratory infection) was

the cause of her ITP or the “small possibility” of the vaccination in December 2001, and decided it was unusual for ITP to develop a month after vaccination.

The striking element of petitioner’s expert Dr. Schiff’s testimony is that he initially refused to give credence to the presence of a viral illness or upper respiratory infection in Heather in January before the onset of her ITP. Because there was no definite timing elicited in the records, he just dispensed with it. After initially refusing to evaluate it at all, his second posture was to relegate the viral illness to being just a runny nose. Yet, he admitted that the severity of a preceding illness is not linked to the onset of an adverse reaction, such as ITP. Finally, in his testimony’s third incarnation, Dr. Schiff agreed that if he accepted that Heather had a cold in January 2002 before her onset of ITP, it was more likely that the cold caused the ITP than the vaccination in December 2001.

Respondent’s experts, Dr. Nachman and Dr. Ward, both opined that the cold was the more likely cause of Heather’s ITP. In many cases of ITP, the cause is not known, but in a minority of cases, there is a preceding viral illness.

Based on Mrs. Birdsell’s histories to her daughter’s doctors (Dr. Mark A. Neumann on March 13, 2002 and Dr. Jong-Hyo Kwon on April 4, 2002), the undersigned holds that Heather had a cold-type illness or viral symptoms in January before the onset of her ITP. All three doctors are unanimous that Heather’s preceding cold, rather than the vaccination in December 2001, was the cause of her ITP. Dr. Schiff agreed that, if he accepted Heather had a cold before her ITP, the cold, not the vaccination, was the cause. Dr. Nachman and Dr. Ward reiterated that the cold in January 2002 is more likely the cause of Heather’s ITP than the vaccination a month to six weeks before the onset of her ITP.

Petitioner has failed to prove a prima facie case of causation in fact that hepatitis B vaccine caused her daughter's ITP.

**CONCLUSION**

Petitioner's petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.<sup>4</sup>

**IT IS SO ORDERED.**

\_\_\_\_\_  
DATE

\_\_\_\_\_  
Laura D. Millman  
Special Master

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<sup>4</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.